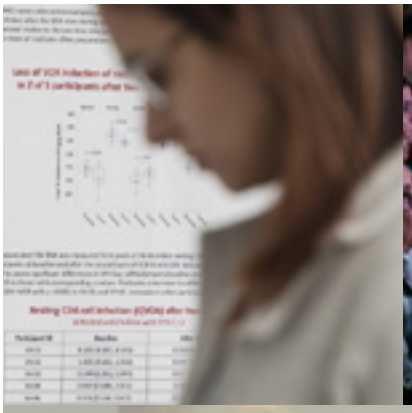
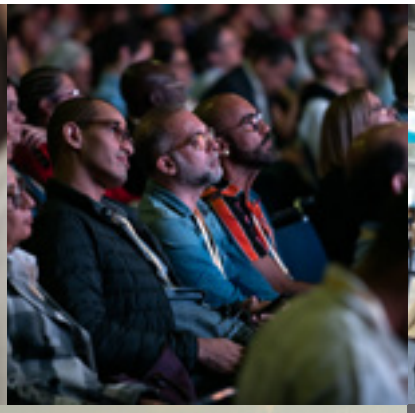
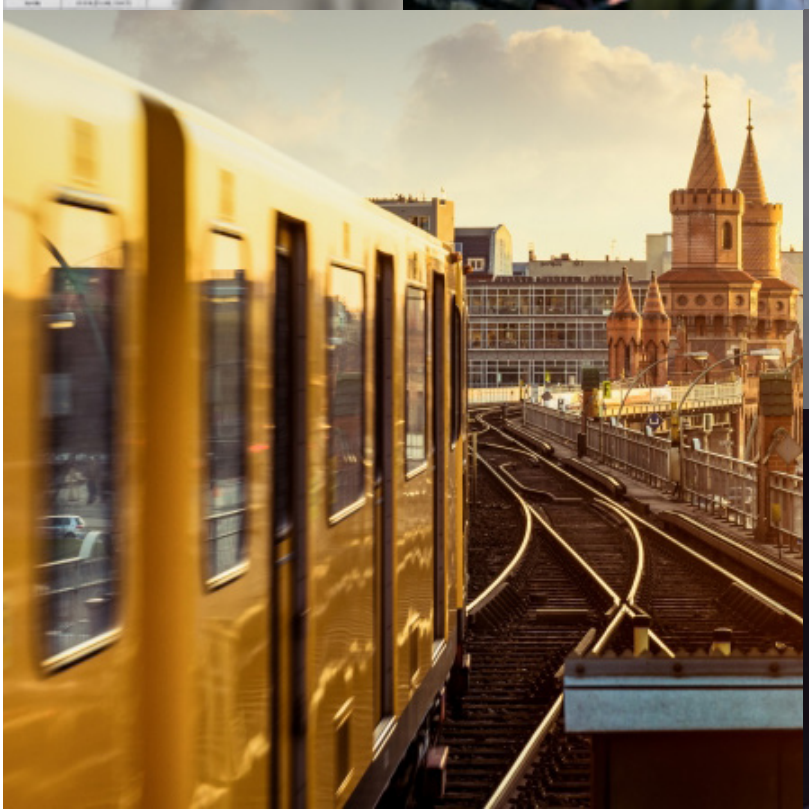
IAS 2021

IAS 2021
Abstract Book



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Abstract Mentor Programme

The Abstract Mentor Programme (AMP) was introduced at the 15th International AIDS Conference (AIDS 2004), with the objective to help young or less experienced researchers improve their abstracts before submitting them, in order to increase the chance of their work being presented at conferences.

Over the years, the AMP has proven to increase the motivation of early career researchers, as well as the number of abstract submissions received from resource-limited countries. This year, 122 mentors were enlisted and helped review 54 abstracts from 39 authors. 82% of the reviewed abstracts were submitted to IAS 2021 and the following were selected:

- 1 On-demand oral abstract session
- 15 E-Posters

We would like to thank all volunteer abstract mentors, listed below, who supported early-career HIV researchers improve the quality of their abstracts:

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Abstract Submission

Over 1,800 abstracts were submitted to IAS 2021 – the 11th IAS Conference on HIV Science. All abstracts went through a blind peer-review process done by over 600 abstract reviewers. These reviewers are international experts in the field of HIV, including members of SPC and track members. Each abstract was reviewed by three to four reviewers.

The abstracts were reviewed for the quality and originality of the work. Late-breaking abstract reviews included an additional assessment of the late-breaking nature of the research. All reviewers were instructed to abstain from scoring any abstract on which they are an author or co-author, have a financial or personal conflict of interest, or do not have the appropriate expertise to evaluate. Each abstract was scored numerically against five pre-determined criteria, which were equally weighted to get a final score. The final score ranged from one (the lowest) to six (the highest). Any abstracts that received less than three reviews or where there was a scoring discrepancy between reviewers were additionally reviewed by the SPC.

Statistics for Abstracts

Regular abstracts submitted	1827
Regular abstracts accepted	826
Oral abstracts	131
Poster exhibition abstracts	695
Late-breaking abstracts submitted	214
Late-breaking abstracts accepted	54
Late-breaking oral abstracts	16
Late-breaking poster abstracts	38
Total abstracts submitted	2041
Total abstract accepted	880

Region and gender breakdown of presenting authors of all accepted abstracts

Gender

Female:	55%
Male:	43%
Transgender female:	0.5%
Transgender male:	0.5%
Non-binary or gender non-conforming:	1%

Region

Africa:	26%
Asia & the Pacific Islands:	11.5%
Europe:	16%
Latin America & Caribbean:	6.5%
USA & Canada:	40%

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Xu Yu, United States
Evy Yunihastuti, Indonesia
Alessia Zamborlini, France
Michael Zwick, United States

TABLE OF CONTENTS

Oral Abstract Sessions

Oral Abstract Sessions with Live Q&A

E-Posters

Track A – Basic science

Track B – Clinical science

Track C – Prevention science

Track D – Social, behavioural and implementation science

Late Breakers

Late-breaker abstracts

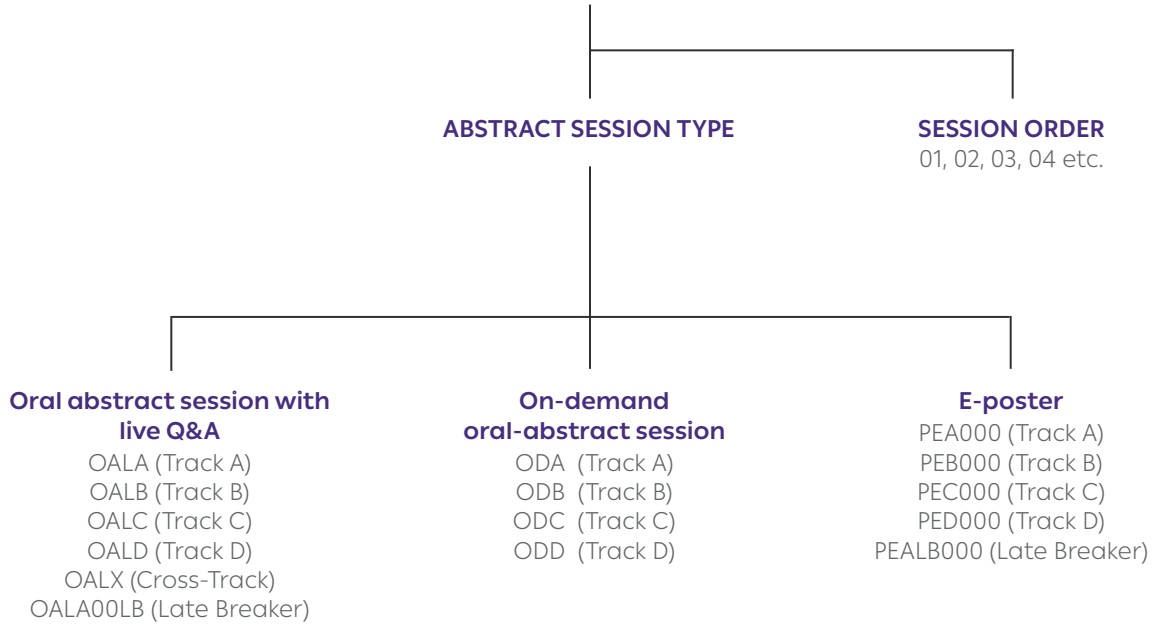
Late-breaker posters

Author Index

IAS 2021 Abstract Coding

Example 1: **OALA01** = **OAL** (Session type) – **A** (Track) – **01** (Session order)

Example 2: **PEA0001** = **PE** (presentation type) – **A** (track) – **0001** (abstract order)



ORAL ABSTRACT SESSIONS

OAA01 Living with HIV: Confronting the challenges of comorbidites and inflammation

OAA0101

Defining an adipose tissue single cell atlas to understand metabolic disease in HIV

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Background: Adipose tissue (AT) is a critical regulator of metabolic health and is emerging as important in HIV. Despite this, data on the complex cellular milieu and immune regulation is lacking. We sought to assess the AT microenvironment in persons with HIV (PWH).
Methods: We performed subcutaneous abdominal liposuction and isolated the stromal vascular fraction (SVF) from 16 HIV-negative diabetics, 16 HIV-positive non-diabetics and 16 HIV-positive diabetics on long-term ART. Cells were stained with a panel of 5' DNA-sequence tagged antibodies (TotalSeq-C) that represented standard lineages, activation and regulatory markers (45 antibodies). For the analysis, CellRanger (version 3.0.0) was used to demultiplex the raw sequencing data, extract filter and correct barcodes and unique molecular identifiers, remove cDNA PCR duplicates and align reads to the human transcriptome (GRCh38). The resulting BAM files and filtered count matrices were used in analyses. We assessed the AT cell types and their association of these subsets with the pre-adipocytes (Spearman rank correlation).
Results: Agnostic to metabolic disease, PWH had lower proportions of pre-adipocytes (median 20.4% in non-diabetic and 36.4% in diabetic) compared with HIV-negative diabetic participants (62.7%) (Figure 1).

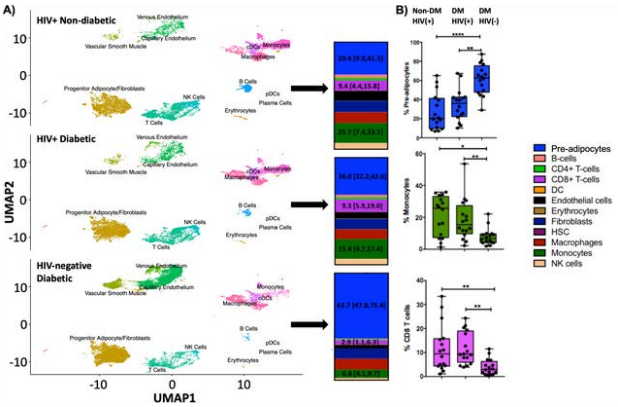

Figure 1. Differences in the cells that make up the SVF atlas from of PWH and HIV-negative controls. Uniform Manifold Approximation and Projection (UMAP) plots that were generated using the Seurat package (R) and corresponding bar plots on the right show the proportions of the different cell types - Highlighting pre-adipocytes, monocytes and CD8 T cells) (A). Dot plots indicate each participant (16 per group for a total of 48 samples) (B). Bar and box plots were generated with Prism 7.0.
Abbreviations, DC - denditric cell, HSC - hematopoietic stem cell, NK - natural killer cell. Statistical Analysis, Kruskal Wallis Test * p<0.05, ** p<0.01, *** p<0.001, **** p<0.0001.

The proportion of CD8 T-cells, monocytes and NK cells were significantly higher in PWH compared with HIV-negative participants, irrespective of metabolic disease. Pre-adipocyte and NK cells were inversely related in non-diabetic PWH (r=-0.68, *p*=0.005), diabetic PWH (r=-0.70, *p*=0.004) and HIV-negative diabetics (r=-0.51, *p*=0.05). A similar trend was observed between CD8 T cells and pre-adipocytes.
Conclusions: We have generated a detailed atlas of AT SVF by HIV and diabetes-status and show that PWH have higher proportions of NK and T cells compared with diabetic HIV-negative. We hypothesize that this may correlate with the HIV-reservoir. Future studies will pair this data with measurements of the HIV reservoir quantification and ART drug levels to understand how AT contributes to viral persistence.

OAA0102

Mechanisms of residual immune activation in HIV-1 infected human lymphoid tissue ex vivo

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Background: HIV-1 infection triggers immune activation, as reflected by the upregulation of various cytokines. This immune activation remains elevated despite efficient suppression of virus by antiretroviral therapy (ART) and leads to early age-related diseases. Mechanisms of this residual immune activation remain unknown. Here, we addressed these mechanisms in HIV-1–infected human lymphoid tissues *ex vivo* subjected to ART.
Methods: Human lymphoid tissues *ex vivo* were infected with HIV-1 and viral replication was suppressed by ART. Tissue immune activation was evaluated from measurements of 29 cytokines in culture medium using multiplexed immunoassays.
Results: We investigated several potential causes of the residual immune activation, including:
(i) a proinflammatory effect of ART drugs themselves;
(ii) an early HIV-1–triggered "cytokine storm", which could in turn trigger a sustained cytokine dysregulation;
(iii) herpesvirus reactivation;
(iv) HIV-1 protein release; and
(v) production of defective virions and extracellular vesicles (EVs).
Neither ART itself, nor simulated cytokine storms, nor exogenously added HIV-1 proteins triggered a sustained cytokine upregulation. In contrast, defective (replicative-incompetent) virions and EVs induced sustained cytokine upregulation, as did infectious virus. Tissue immune activation was accompanied by reactivation of CMV.
Conclusions: Immune activation in HIV-1 infected *ex vivo* human lymphoid tissue after HIV-1 suppression is mediated by the EVs and/or defective viral particles.

OAA0103

The association of cardiovascular risk factors and disease in people living with HIV in the UK: a retrospective matched cohort study

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Background: Heightened risk of cardiovascular disease (CVD) and associated risk factors in people living with HIV (PLWH) have been reported in various settings; however, results are limited and differ geographically. We aimed to identify the association of CV risk factors and disease in PLWH compared to those without HIV in the UK.

Methods: A matched cohort was derived from The Health Improvement Network (THIN) database from January 2000 to January 2020. Adult (≥18y) people with an HIV diagnosis (exposed) were eligible and matched for gender and age with up to four people without HIV (unexposed).

Outcomes included CVD (stroke, myocardial infarction (MI), peripheral vascular disease (PVD), ischaemic heart disease (IHD) and heart failure (HF)), hypertension, diabetes, chronic kidney disease (CKD), lipid-lowering drug use and all-cause mortality. Cox proportional hazard regression models were used to compare the risk of each outcome between the exposed and unexposed group.

Results: The cohort comprised 9233 exposed and 35721 unexposed individuals; 34% were females and the mean age was 41. Across all models, the exposed group was at a higher risk for CVD (HR 1.54, 95% CI 1.30, 1.83), specifically stroke (HR 1.49, 95% CI 1.11, 2.00), hypertension (HR 1.37, 95% CI 1.22, 1.55), lipid-lowering drug use (HR 1.96, 95% CI 1.78, 2.16), CKD (HR 2.40, 95% CI 1.93, 2.98) and all-cause mortality (HR 2.68, 95% CI 2.32, 3.10). CVD risk remained significant across sub-groups of gender, age, smoking status and index year. Younger patients (≤40y) had the highest risk of CVD (HR 2.01, 95% CI 1.29, 3.13) and all-cause mortality (HR 6.09, 95% CI 4.36, 8.51).

Females had double the risk for MI (HR 2.67, 95% CI 1.02, 6.95) and IHD (HR 2.34, 95% CI 1.17, 4.71) whereas males had a slightly increased risk for stroke (HR 1.55, 95% CI 1.11, 2.15) and IHD (HR 1.47, 95% 1.14, 1.91).

Conclusions: PLWH, particularly of younger age, are at a heightened risk for mortality, cardiovascular risk factors and disease. Therefore, screening for CV risk factors and disease in PLWH should be routine. Further research is needed to ascertain the drivers of these risks to inform prevention strategies.

OAA0104

Higher comorbidity and comedication burden in women and young people living with HIV

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Background: Advancements in antiretroviral therapies (ART) have led to longer life expectancies for people living with HIV (PLWH). An understanding of comorbidity and comedication prevalence in HIV subpopulations is important for personalized care.

Methods: A retrospective study was conducted using an administrative claims database. Adults (≥18 years) with ≥1 pharmacy claim for an ART or HIV/AIDS diagnosis code in medical claims during 2018 (index date: earliest ART/HIV claim) were identified (PLWH). Adults without HIV (PLWoH) were matched 2:1 with PLWH on age, gender, race, region, and insurance type. Continuous health plan enrollment of 12 months prior to (baseline), and 30 days after index date was required. Differences in baseline comorbidities and comedications between PLWH and PLWoH across age, gender and race were assessed using descriptive statistics.

Results: At total of 20,256 PLWH were matched to 40,512 PLWoH. The mean age was 52 years, 20% were women and 28% were Black. Multimorbidity (≥2 comorbidities) and polypharmacy (≥5 non-ART drugs) prevalence was higher in PLWH than PLWoH, and increased with age, in women, and in Black populations, with the largest differences in prevalence observed in the 18-39 age group (Table 1). The prevalence of most comorbidities was higher in PLWH vs PLWoH in 18-39 age group, but differences varied in older groups. Comorbidities such as hypertension, cardiovascular disease (CVD), diabetes mellitus, and chronic kidney disease (CKD) were more prevalent in women than men among PLWH, but differences between PLWH vs PLWoH by gender were inconsistent (Table 1). Neuropsychiatric conditions were more prevalent in PLWH than PLWoH in all strata (p<0.05).

Conclusions: Comorbidity and polypharmacy burden were higher in PLWH than PLWoH with notable differences in specific comorbidities in younger age groups and women. An individualized approach to care including ART can minimize drug-drug interactions and adverse events and thereby improve patient outcomes.

	PLWH							PLWoH						
	18-39	40-49	50-59	60-69	70+	Women	Men	18-39	40-49	50-59	60-69	70+	Women	Men
Multimorbidity	**24.1**	**38.9**	**53.0**	**69.0**	**80.0**	**59.4**	**48.5**	11.1	28.6	46.7	60.2	75.4	52.9	39.3
CVD	**3.2**	5.5	11.4	19.5	32.9	**14.3**	**12.0**	1.2	4.6	10.9	19.2	32.0	12.6	11.3
Hypertension	**8.2**	**20.5**	35.3	**52.0**	68.3	**44.6**	31.2	4.5	18.0	35.2	50.0	66.7	38.8	30.5
Diabetes mellitus	**2.3**	7.6	**13.7**	**23.1**	30.4	**21.0**	**12.1**	1.6	8.6	17.8	25.3	31.5	19.5	14.9
CKD	**3.5**	**7.0**	**12.7**	**20.9**	**33.7**	**18.0**	**12.5**	1.3	5.1	9.7	14.1	22.5	11.0	9.0
Neuropsychiatric	**18.8**	**22.8**	**26.9**	**29.6**	**28.5**	**29.0**	**24.4**	10.2	16.8	21.4	19.6	20.9	25.6	16.1
Polypharmacy	**56.6**	**70.5**	**79.5**	**87.6**	**92.4**	**81.5**	**75.0**	31.0	50.3	65.8	78.6	86.5	74.9	57.3
All values presented are percents; **BOLD** font indicates where p<0.05 for differences between PLWH and PLWoH; Ages in years														

OAA0104 Table 1.

OAA02 Reinforcing host immunity against HIV

OAA0201

STAT modulation as strategy to improve NK cell cytotoxicity against HIV and cancer

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Background: NK cells are important effectors of the innate immune response to a variety of viral infections and malignant cells. HIV infection, even after initiation of antiretroviral therapy, results in significant defective NK cells function. Thus, strategies that improve NK cell activity are urgently needed. The janus kinase (JAK)–signal transducer and activator of transcription (STAT) pathway is critical for NK cell development, survival, proliferation, and cytotoxic function. In this work we tested whether the previously characterized HIV latency-reversing agent (LRA) 3-Hydroxy-1,2,3-benzotriazin-4(3H)-one (HODHBt), a modulator of STAT pathway activity could also enhance NK cell function.
Methods: NK cells from HIV negative donors were isolated from PBMCs and incubated in the presence of IL-15, HODHBt or a combination of both. We performed RNASeq and a set of diverse assays to evaluate NK cell phenotype and cytotoxic function against HIV-infected CD4T and cancer cells. We also evaluated the ability of HODHBt to improve cytokine-induced memory-like NK cell responses upon cytokine recall.
Results: We observed that NK cells treated with HODHBt plus IL-15 increased their cytotoxic profile phenotype compared to those treated with IL-15 alone. This was demonstrated by an increased expression of activation markers (CD25 and CD69), components of the cytotoxic cell granules (Granzyme A, Granzyme B, perforin, granulysin), death receptor ligands (APO2L/TRAIL and CD95L/FasL) and enhance pro-inflammatory cytokine production (IFN-g and CXCL-10). Moreover, HODHBt enhanced killing of different tumor cells and favored killing of HIV-infected CD4T cells. Finally, HODHBt improved memory-like NK cell responses upon cytokine recall.
Conclusions: Overall, our data suggest that enhancing the magnitude of JAK-STAT signaling pathway with HODHBt may favor NK cell cytotoxicity phenotype and function, and this pathway could be explored for novel cell adoptive immunotherapeutic approaches using NK cells against HIV and associated malignances.

OAA0202

Defining CTL immunotherapy candidates against replication-competent and defective HIV

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Background: An effective HIV-specific CD8+ T-cell (CTL) response that targets cells expressing vulnerable regions of the genetically diverse proviruses will be required to control human immunodeficiency virus (HIV) during antiretroviral therapy (ART) interruption. To contribute to this effort, we defined immunogenic CTL epitopes within genetically intact and defective proviruses which are effective for multiple human leukocyte antigen class I (HLA-I) alleles.
Methods: A repertoire of 8-14 mer peptides was generated from the *gag, pol, vif, nef, vpr* and *env* genomic regions extracted from 350 proviral sequences derived from six participants with known HLA-I alleles. We then employed the Protein BLAST and NetMHCIpan-4.0 algorithms to select the peptides that are HIV-specific and binders to participant HLA-I alleles. Next, we applied protein network analysis to select the peptides derived from evolutionarily constrained regions that are crucial for structural maintenance of HIV proteins. We also performed an interaction network analysis to delineate the peptides that can form a stable complex with both HLA-I molecules and T-cell receptor alpha/beta chains (TCRαβ).
Results: From the proviruses of long-term treated individuals, we obtained a repertoire of 17.6 million peptides derived from *gag, pol, vif, nef, vpr* and *env* genomic regions. Only a fraction of these peptides (0.03%) were binders to the participant HLA-I alleles. Of the six regions examined, *vpr* contained the highest density of HIV-specific peptides that were binders to participant HLA-I alleles. Of these, only four Vpr peptides (9-10 mer) can form a stable complex with TCRαβ and canonical forms of HLA-I molecules. These four Vpr peptides were predicted to bind to multiple HLA-I alleles/supertypes, including those associated with protection against HIV, with a global population coverage of 74%. Importantly, these peptides are identified from both genetically intact and defective proviruses suggesting CTL response to these peptides has the potential to target HIV-infected cells containing diverse HIV genomes.
Conclusions: Employing our immunoinformatics analysis pipeline, we defined several peptides within topologically important regions of the Vpr protein. Future therapeutic vaccines and other immunotherapies should consider including these peptides as they are predicted to enhance CD8+ T-cell response against HIV-infected cells containing diverse proviruses.

OAA0203

Immunogens based on VLPs presenting epitopes of the HIV-1 fusion peptide

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Background: The characterization of bnAbs epitopes allows the identification of vulnerable sites on the HIV-1 Env, which are the basis for the development of HIV B-cell immunogens. One of the relatively conserved targets of bnAbs is the fusion peptide (FP), which includes a linear epitope recognized by the antibody VRC34.01. One of the approaches to the development of immunogens is the construction of chimeric virus-like particles exposing linear epitopes. A promising system for the presentation of foreign epitopes is HBcAg, which forms particles with a size of about 36 nm, consisting of 240 HBcAg monomers.
This study aims to develop an HBcAg-based immunogen aimed at the induction of neutralizing antibodies to FP HIV-1.
Methods: Targets were represented by amino acid sequences corresponding to positions env 512-519 amino acid residues of the fusion peptide of HIV-1 isolates - AIGLGAAF (subtype A6), VVGLGAVF (recombinant form CRF63_02A), and AVGIGAVF (consensus sequence). Further, we designed and synthesized oligonucleotide duplexes encoding the

selected epitopes and cloned them as part of the pET21-HBcAg plasmid vector. After that, the plasmid constructs were used to transform E. coli BL21 cells. Recombinant proteins were purified using chromatography. The size and morphology of the obtained chimeric HBcAg particles were determined using electron microscopy. The antigenicity of chimeric particles was analyzed by dot blot and ELISA using the neutralizing antibody VRC34.01.

Results: Three recombinant plasmids encoding HBcAg variants containing fragments of FP HIV-1 in the region of the main antigenic determinant were obtained. Producer strains of HBcAg-FP variants were obtained. Purified and soluble HBcAg-FP preparations were obtained. It was found that the obtained proteins form particles of a characteristic spherical shape with a size of 40 to 50 nm. Moreover, it was shown that the antibody VRC34.01 interacts with FP in the HBcAg.

Conclusions: As a result of the work, HBcAg particles were obtained with FP HIV-1 fragments on their surface. These particles are currently being tested for the ability to induce HIV-neutralizing antibodies in laboratory animals.

The study was supported by the grant of the President of the Russian Federation MK-583.2020.4.

OAA0204

Plasma IL-21 associates with HIV-1 Neutralising potency of polyclonal IgG in the periphery

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Background: Although the development of HIV-1 potent and broadly Neutralising Antibodies (bNAbs) is strongly associated with viral load, host immune factors may play an additional role. IL-21 contributes to antibody avidity and affinity maturation but it remains unclear whether IL-21 associates with bNAb elicitation in HIV-1 infection. We therefore investigated the correlates of IL-21 in bNAb elicitation in patients infected with HIV-1 non-B subtypes.

Methods: A total of 417 HIV-1-infected treatment naïve and treated but failure individuals were recruited in Tanzania. For preliminary screening, neutralising activity was assessed against subtype B, Tier 2 Envelope (strain JRFL), followed by secondary screening using a Global panel of 12 Envelopes spanning various HIV-1 subtypes. Murine Leukaemia Virus Envelope was used as a specificity control and drug resistance mutations were inserted in pseudoviruses to prevent the effect of residual antiretroviral drugs in plasma. IgG fraction was purified from plasma as needed and used in neutralisation assays. IgG neutralising breadth was defined as the percentage of neutralised Envelopes on the panel while potency was the mean of IC_{50} values across the panel. Cytokines (such as IL-21 and IL-6) were quantified using Cytometric Bead Array.

Results: In a total of 417 plasma samples screened, 32 (7.7%) exhibited neutralising potency against JRFL Envelope and therefore qualified for IgG purification. Among them, 3 (0.72%) could be Elite Neutralisers since they exhibited neutralising potency against ≥80% of the global Envelope panel. As expected, neutralising breadth correlated with viral load within the neutralisers subset ($p<0.02$), but not with sex or age. IL-21 levels correlated with the Neutralising potency of IgG fractions ($p=0.04$) of the 32 neutralisers. Plasma IL-6 and IL-5 did not correlate with either IgG neutralising potency or breadth.

Conclusions: Plasma IL-21 level could be a surrogate marker for potent neutralizing antibodies in viremic patients with HIV-1 non-B subtype infection.

OAA03 New technologies and targets in the HIV landscape

OAA0301

Novel multiplex analyses reveal disparate natural killer cell signaling pathway activation during lentivirus infection

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Background: Natural killer (NK) cells are critical effector cells for modulating Human Immunodeficiency Virus (HIV)-1 and Simian Immunodeficiency Virus (SIV) transmission and subsequent opportunistic disease. Unfortunately, NK cell responses are also often highly dysregulated in HIV-1 and SIV infection, but the mechanisms remain unclear. Although perturbation of surface receptor expression and function of NK cells in infection has been widely reported, elucidation on impact of downstream signaling events remains unclear. This is further complicated by the fact that most cell signaling assays can only assess at most three phosphorylation events at a time. In order to fill this knowledge gap we decided to investigate the NK cell signalome in humans and macaques in greater detail during lentiviral infection.

Methods: We developed an NK cell multiplex signaling assay on the Luminex platform to assess the simultaneous phosphorylation (p) events of 10 major signaling molecules critical to NK cell function: p-Syk, p-Ick, p-LAT, p-ZAP70, pJNK, p-NFkB, p-p70S6K, p-Akt, p-STAT3, and p-STAT5). Analyses were performed on enriched human NK cells and NK cells from control and chronically SIVmac251-infected rhesus macaques following stimulation by cross-linking several classes of receptors including CD16, NKp46 (natural cytotoxicity receptor), NKG2D (NKG2 family receptor), and CD2 (co-receptor).

Results: All stimulations tested activated Immunoreceptor Tyrosine-based Activating Motif (ITAM)-based signaling (Syk, lck, LAT, ZAP70), MAP kinase (JNK), and STAT5 pathways in human NK cells. As expected, CD16-based activation was the most robust for all analytes, although CD2 stimulation induced additional STAT3 activation. Importantly, activation profiles regardless of stimulus were similar between uninfected human and macaque NK cells. Compared to controls, NK cell signaling in SIV-infected animals was globally reduced in magnitude following CD16 stimulation, but signaling in response to CD2 stimulation was increased, specifically within the STAT5 pathway. These data were consistent with an upregulation of CD2 on NK cells during SIV infection.

Conclusions: We were able to establish a multiplex platform to evaluate complex cell signaling in NK cells, and demonstrated clear changes in CD16 versus CD2 signaling during SIV infection. Application of this technology will offer new insights into how HIV-1 dysregulates the NK cell response and open up new avenues for immunotherapeutics.

OAA0302

HIV modifies the m⁶A and m⁵C epitranscriptomic landscape of the host cell

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Background: The study of RNA modifications, today known as epitranscriptomics, is of growing interest. The N6-methyladenosine (m⁶A) and 5-methylcytosine (m⁵C) RNA modifications are abundantly present on mRNA molecules, and impact RNA interactions with other proteins or molecules, thereby affecting cellular processes, such as RNA splicing, export, stability and translation. Recently, these epitranscriptomic marks were found to be present on HIV transcripts and affect viral replication. However, no study has been performed to date to investigate the impact of HIV replication on the transcript methylation level in the infected cell.

Methods: We used a productive HIV infection model to explore the landscape of m⁶A and m⁵C marks on the transcriptome of HIV-infected cells. For this, the SupT1 T cell line was mock-treated or infected with a high dose of VSV-G pseudotyped HIVeGFP-based vector to ensure ~80% infection efficiency. Cells were collected at 12, 24 and 36h post-infection for mRNA extraction and FACS analysis. M⁶A RNA modifications were investigated by methylated RNA immunoprecipitation followed by sequencing (MeRIP-Seq). M⁵C RNA modifications were investigated using a bisulfite conversion approach followed by sequencing (BS-Seq). Untouched mRNAs were used as input controls. Libraries were prepared using TruSeq stranded mRNA protocols (Illumina) and sequenced on Illumina HiSeq2500.

Results: Our data suggest that HIV Infection impacted the methylation landscape of HIV-infected cells, inducing mostly increased methylation of cellular transcripts upon infection. Indeed, differential methylation analysis identified 59 m⁶A hypermethylated and only 2 hypomethylated transcripts and 14 m⁵C hypermethylated transcripts and 7 hypomethylated ones. Furthermore, both m⁶A and m⁵C methylations were detected on viral transcripts and viral particle RNA genomes.

Conclusions: Our results provide a valuable resource for m⁶A and m⁵C transcripts in the non-infected and HIV-infected cell and highlight differentially methylated transcripts that may modulate HIV expression and thus HIV replication. Thus, epitranscriptomic analyses may uncover novel players in the HIV-host interplay, thereby offering a novel array of opportunities to inhibit HIV replication.

OAA0303

GS-9822, a preclinical LEDGIN, displays a block-and-lock phenotype in cell culture

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Background: The ability of HIV to integrate into the host genome and establish latent reservoirs is the main hurdle towards an HIV cure. LEDGINs are small-molecule integrase that target the binding pocket of LEDGF/p75, a cellular cofactor that substantially contributes to HIV integration site selection. They are potent antivirals that inhibit HIV integration and maturation. In addition, they retarget residual integrants away from transcription units towards a more repressive chromatin environment. A previous study also demonstrated that after CX14442 treatment, residually integrated proviruses are more latent and refractory to reactivation, supporting the use of LEDGINs in a functional cure strategy.

Methods: In this study we compared GS-9822, a potent, pre-clinical lead compound, with the research compound CX14442 with respect to antiviral potency, integration site selection, latency and reactivation. Using AlphaScreen and multiple round HIV-1 replication in MT-4 cells we compared the activities of CX14442 and GS-9822. In addition, integration sites after LEDGIN treatment were sequenced (Illumina Miseq) and the surrounding chromatin environments were compared using the INSPIRED platform. Using established double reporter viruses we studied both latency and reactivation after treatment with either LEDGINs or the integrase inhibitor raltegravir as a control.

Results: GS-9822, a pre-clinical LEDGIN, is a potent antiviral with nanomolar activity against wild type HIV-1. GS-9822 inhibits the LEDGF/p75-integrase interaction and reduces HIV-1 integration. Much like CX14442, GS-9822 was able to retarget integration of residual proviruses away from active genes and gene dense regions, resulting in a more repressive epigenetic landscape.

Finally, when using a double reporter construct, CX14442 and GS-9822 were shown to reduce HIV-1 infectivity, increase immediate latency and decrease the reactivation potential of residual integrants. Remarkably, GS-9822 induced these effects at 200-300-fold lower concentrations than CX14442.

Conclusions: The ability to retarget integration sites and induce a deep latent state (block-and-lock) is not specific for a single LEDGIN, CX14442, but a class-effect related to the inhibition of the LEDGF/p75-integrase interaction. Highly potent LEDGIN compounds that inhibit this interaction can induce these effects at doses achievable in the clinic, making LEDGINs an interesting candidate for functional HIV cure research.

OAA0304

Proteomic evidence of vesatolimod-induced enhancement of "cross-talk" between innate and adaptive immune cells in HIV controllers on ART

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Background: Vesatolimod (VES), an oral TLR7 agonist, induces interferon-stimulated genes and circulating cytokines in a dose-dependent manner in healthy volunteers and PWH on ART. In a Phase 1b trial of VES in HIV controllers, we observed modest but significant delay in viral rebound and decrease in viral set-point, following ART interruption. We investigate mechanisms associated with these outcomes by assessing proteomic changes following VES.

Methods: We enrolled 25 HIV controllers (pre-ART viral load 50-5000c/mL) on ART for ≥6mo. Seventeen participants received 10 biweekly doses of VES and 8 received placebo, followed by analytical treatment

interruption. Immune cell activation after VES was evaluated using flow cytometry. Plasma samples were used for high-throughput proteomic analysis with Proximity Extension Assay (PEA) technology. Data were analyzed with Ingenuity Pathway Analysis.

Results: Compared to placebo, VES cumulatively induced innate and adaptive immune cell activation. Geometric mean fluorescent intensity of CD40 on pDC, and frequency of $CD69^{+}CD56^{dim}$, $CD69^{+}CD56^{bright}$ NK cells, and $Ki67^{+}CD4^{+}$ T cells were significantly increased 1-day after VES dose-10 (p=0.0007, p=0.0115, p=0.0311, p=0.0033). Frequency of activated monocytes ($CD14^{+}CD16^{+}$) and $CD8^{+}$ T cells ($CD38^{+}CD8^{+}$) were increased by day-3 after VES dose-10 (p=0.0056; p<0.0001). Among 92 proteins evaluated by PEA, 21 proteins were significantly upregulated 1-day after VES dose-1 and 10 (p-value <0.05). Pathway analysis of shifts revealed significant increase in immune responses following VES treatment, including pathways involved in T-cell differentiation, recruitment, and migration (z-score ≥1.96) and in crosstalk between dendritic cells and NK cells, NK-cell signaling, Th1 pathways, and antiviral responses (z-score≥1.96; Fig).

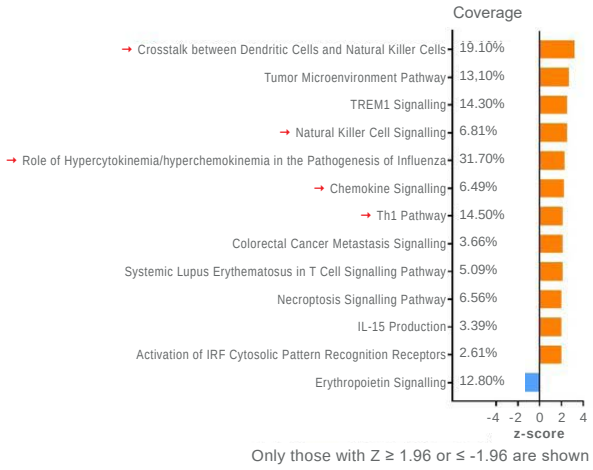

Figure. Inferred pathways changes following VES treatment

Conclusions: We utilized novel high-throughput proteomic analysis approach to explore mechanisms associated with VES outcomes. An unbiased model revealed extensive shifts in immune function after administration of VES, with evidence of "cross-talk" between innate and adaptive immune response. Findings support the hypothesis that achievement of post-ART control requires combination of increased cellular immune responses coupled with balanced inflammatory response.

OAA04 Finding our way: Examining new approaches for cure

OAA0401

The circadian clock machinery regulates HIV transcription in CD4+ T cells

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Background: $CD4^{+}$ T cells are key HIV-1 infection targets and are highly enriched in viral reservoirs in people living with HIV (PLWH) receiving viral-suppressive antiretroviral therapy (ART). Current antiretroviral drugs block different steps of the viral replication cycle but not the transcription, a process under the control of host-cell transcription factors. Residual HIV transcription during ART is a major cause of chronic immune activation and non-AIDS co-morbidities. In previous studies, we demonstrated that the transcriptional signature associated with HIV permissiveness in Th17 cells includes the circadian clock components/regulators BMAL1 and REV-ERBs. Of note, REV-ERBs act as transcriptional repressors of BMAL1 (a transcriptional activator binding to E-boxes in the HIV promoter) and RORC2 (the master regulator of Th17 polarization). Thus, we hypothesized that REV-ERBs regulate both BMAL1-mediated HIV replication and RORC2-mediated effector functions in Th17 cells.

Methods: To test this hypothesis, we used the REV-ERB agonists SR9009 and SR9011, reported to be efficient in decreasing Th17-mediated autoimmune pathology in mice. Memory $CD4^{+}$ T cells from uninfected individuals were stimulated with CD3/CD28 antibodies and exposed to HIV *in vitro*. A viral outgrowth assay (VOA) was performed with memory $CD4^{+}$ T cells of ART-treated PLWH activated *via* CD3/CD28 in the presence/absence of the REV-ERB agonists. Lentiviral vectors were used to over express BMAL1 in primary CD4+ T cells. Cytokines and HIV-p24 levels were measured by ELISA. HIV-DNA integration was quantified by PCR.

Results: CD3/CD28 triggering resulted in a significant downregulation of REV-ERBα and REV-ERBβ, and the up-regulation on BMAL1 mRNA expression. The REV-ERB agonists potently inhibited HIV replication *in vitro* and viral outgrowth in VOA. The antiviral effects coincided with decreased IL-17A and IFN-γ production. Single-round infection with a VSV-G-pseudotyped HIV showed decreased HIV-p24 expression/production but no differences in HIV-DNA integration in presence of REV-ERB agonists, indicative of an inhibitory effect post-integration, likely during transcription. Finally, we confirmed that BMAL1 overexpression increases HIV replication.

Conclusions: These results provide a strong rationale for further evaluating the possibility to therapeutically target REV-ERBs as a way to limit BMAL1-dependent HIV transcription and subsequently diminish chronic immune activation and non-AIDS co-morbidities during ART.

OAA0402

RNA-directed gene therapy protects CD4+ T cells during HIV challenge and delays virus rebound post-ART in humanized mice

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Background: The HIV-1 latent reservoir is a major barrier to developing an HIV cure. Gene therapy is a promising treatment, highlighted by the success of the Berlin and London patients. Using RNA-directed gene-modified stem cells to induce and enforce super-latency, we aim to mimic natural virus latency in an HIV-1 functional cure "block and lock" approach, combined with conventional CCR5 mRNA targeting. We have previously shown novel siRNAs induce potent HIV-1 silencing in various cell lines *in vitro* and provide protection from virus challenge in a humanized mouse model of **acute** HIV-1 infection. We now investigate their potential for gene therapy using shRNA-transduced CD34+ haematopoietic stem cells in a humanized mouse model of **chronic** HIV-1 infection with ART.

Methods: Human CD34+ stem cells were transduced using GFP-labelled lentivirus expressing promoter-targeted shRNA, shPromA or dual construct shPromA/shCCR5 or controls; mock- or empty(-shRNA+loop)-transduced, and transplanted into irradiated NSG mice. At 18 wks post-engraftment mice were challenged with CCR5-tropic HIV-1_{JR-FL}. Mice were bled at wks 3, 5, 7 and 10 post-infection (p.i.), received ART for 8 wks, following which ART was interrupted. Virus rebound was measured for 4 wks prior to/at sacrifice by flow cytometry analysis of CD4+ T cells/GFP expression, RT-qPCR analysis of viral load and RNAscope in lymph nodes and spleen tissue.

Results: Transduction efficiencies ranged between 40-70%. At sacrifice transduced mice expressing shPromA or dual shPromA/shCCR5 showed up to 100% CD4+ GFP expression, with means of ~70%. This correlated with a stable CD4 T cell count in dual shPromA/shCCR5 transduced mice, over 40 wks of challenge, ART and ART interruption, compared to mock and empty-transduced mice, which were 1.5 and 2 logs lower, respectively. Virus rebound was delayed 7 days in dual transduced mice, which showed a 1 log decrease in viraemia at 4 wks post-ART interruption compared to controls. Quantification of RNAscope and immunostaining of lymph nodes and spleen will determine the level of virus silencing in tissue.

Conclusions: This study demonstrates RNA-directed *ex vivo* gene therapy targeting shPromA/shCCR5 has the potential to protect against HIV-1, following ART interruption in a humanized mouse model.

OAA0403

The balance of mucosal CD4 T cells prior to infection is associated with control of virus replication after therapeutic vaccination in SIV-infected rhesus macaques

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Background: A therapeutic vaccine that induces lasting control of HIV infection could eliminate the need for lifelong antiretroviral therapy (ART). However, barriers to an effective therapeutic vaccine include insufficient vaccine immunogenicity in the periphery and gut-associated lymphoid tissue (GALT), and an incomplete understanding of what host parameters affect ART efficacy, vaccine immunogenicity, and viral control. Here, we investigated a therapeutic SIV DNA vaccine and a novel combination of adjuvants, and characterized immune parameters associated with viral control post-ART.

Methods: Adult male rhesus macaques were infected with SIVΔB670 and initiated ART 6 weeks post-infection (wpi). Beginning at 32wpi, animals received 5 therapeutic immunizations spaced 4 weeks apart. ART was suspended at 55wpi to evaluate efficacy. One group received a DNA vaccine (MAG) expressing SIV Gag, Pol, Env and Nef, with *E. coli* heat-labile enterotoxin, LT, via Gene Gun (MAG+LT; N=5). Another group received MAG and a genetic adjuvant combination expressing soluble CD80, soluble PD-1, IL-12, IL-33, RALDH2, and the catalytic subunit of LT via intradermal electroporation (MAG+AC; N=5). Controls received empty plasmid DNA via Gene Gun (Controls; N=4). T-cell responses and immunophenotyping in PBMC and GALT were determined by flow cytometry, while viremia was measured by RT-qPCR.

Results: Every animal exhibited robust acute viremia (median 10^7 RNA copies/mL plasma), but ART did not fully suppress viral replication in all animals. Post-ART, 3/5 MAG+AC animals controlled viremia (median viral loads ≤10^3 RNA copies/mL plasma), compared to 1/5 MAG+LT and 1/4 control animals (controllers). Nine animals, among all groups, exhibited immediate viral rebound (median viral loads >10^3 RNA copies/mL, non-controllers). Although was no significant difference between groups in protection from viral rebound, lower post-ART viral burden correlated with increased ART responsiveness and polyfunctional SIV-specific $CD8^+$ T-cells in mesenteric lymph nodes prior to and during ART interruption. Notably, improved responses to ART and control of viral rebound correlated with elevated frequencies of colonic $CD4^+$ T-cells and lower Th17/Treg ratios pre-infection.

Conclusions: These results indicate that mucosal immunity prior to infection can influence ART efficacy and the outcome of immunotherapeutic vaccination, suggesting that therapies capable of modulating host mucosal immunity may be needed to achieve an HIV functional cure.

OAA0404

Early antiretroviral therapy favors post-treatment SIV control, which is associated with enhanced CD8+ T-cell antiviral activity against rebounding virus – the pVISCONTI study

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Background: The VISCONTI study proposed that post-treatment control (PTC) might be favored by early antiretroviral treatment (cART) initiation. However, a formal demonstration has not been established and the underlying mechanisms leading to PTC remain elusive. We used a non-human primate model to assess, in standardized conditions, the impact of early *versus* late cART initiation on immune responses and the outcome after analytical treatment interruption (ATI).

Methods: SIVmac251-infected cynomolgus macaques (CyMs) remained untreated (n=17) or initiated cART at primary (day 28 post-infection [*p.i.*], n=12) or at chronic (6 months *p.i.*, n=12) infection. cART was maintained for 24 months. The animals were then monitored for 12 months after ATI. Plasma viral loads (pVL), CD4+ T-cells, and CD8+ T-cell responses (phenotype and viral inhibition assay) were analyzed throughout the study.

Results: pVL levels were similar at cART initiation for both groups of CyMs receiving cART (D28 and M6). After ATI, all CyMs experienced viral rebound (>1000 copies/mL), except one animal in the D28 group. Viral rebound occurred earlier in the M6 group (17.5 days) when compared with D28 group (28 days) (p=0.0009). Early treatment significantly impaired definitive loss of viral control (p=0.012). Moreover, 82% of CyMs in the D28 group were defined as PTC (<400 copies/mL) at the end of the study, which was higher than in the M6 group (25%) or among non-treated (12%) CyMs (p=0.0003). The anti-SIV activity of CD8+ T-cells, as measured in the viral inhibition assay, was weak in all animals at primary SIV-infection, but strongly increased after ATI, in particular in D28 CyMs (6.6x fold [3.5-9.8] post-ATI vs primary infection). The CD8-antiviral activity that emerged following viral rebound was stronger in PTCs (p= 0.016) early after ATI and at the end of the study in blood and lymphoid tissues (spleen, peripheral and mesenteric lymph nodes). A negative correlation was found between the anti-SIV activity of CD8+ T-cells and cumulated pVLs post-ATI (r=-0.41, p=0.05).

Conclusions: Early cART initiation favored PTC in SIVmac251-infected CyMs. This was associated with the promotion of a robust secondary SIV-specific CD8+ T-cell response, which might contribute to efficiently counteract viral rebound after ATI in PTCs.

OAA0405

Evaluation of HIV-1 reservoir size and broadly neutralizing antibody (bNAb) susceptibility in individuals who initiated ART during acute and chronic infection

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Background: Persistence of the viral reservoir is the main barrier to curing HIV. Initiation of ART during primary HIV infection can limit the size and diversity of the viral reservoir. Characterization of the differences between individuals who initiate ART during primary and chronic infection will be critical for clinical trial design and HIV cure strategies.

Methods: A cross-sectional, non-interventional study was performed to characterize the viral reservoir in people living with HIV. Four cohorts were enrolled with participants that initiated ART during Fiebig I-II, Fiebig III-IV, early (<=3 months of infection) or chronic (>=6 months of infection) infection. Participants underwent leukapheresis and viral reservoir in PBMCs was evaluated by the Intact Proviral DNA Assay (IPDA), the Total HIV DNA Assay (THDA), and the Quantitative Viral Outgrowth Assay (QVOA). Viral diversity and susceptibility to the bNAb elipovimab were determined by genotyping of the viral envelope gene.

Results: An increase in reservoir size was observed with increased time to ART initiation (Fiebig stages through chronic infection) when measured by IPDA and THDA whereas no difference was observed by QVOA. Viral diversity was lower in participants initiating ART during acute infection than chronic infection, and acute ART-treated individuals also showed higher susceptibility to elipovimab as 71% of cohort 1 participants, 78% of cohort 2 participants, 53% of cohort 3 participants, and 44% of cohort 4 participants were sensitive.

	Cohort 1 Fiebig I-II (n=16)	Cohort 2 Fiebig III-IV (n=17)	Cohort 3 Early infection (n=14)	Cohort 4 Chronic infection (n=17)
Time on ART (years, median (Q1, Q3))	4.1 (1.3, 7.8)	5.0 (3.0, 7.0)	2.9 (2.0, 5.2)	5.1 (2.9, 6.6)
Pre-ART HIV-1 RNA (log10 copies/mL, median (Q1, Q3))	5.95 (5.40, 6.73)	5.88 (5.47, 6.69)	5.43 (4.67, 6.33)	4.44 (4.10, 4.75)
CD4+ cell count at screening (cells/µL, median (Q1, Q3))	784 (636, 1109)	716 (675, 848)	913 (860, 1134)	824 (688, 968)
Intact HIV DNA, IPDA (copies/10^6 CD4+ cells, median (Q1, Q3))	28.86 (3.53, 58.09)	28.63 (24.67, 125.90)	82.28 (14.07, 206.10)	57.72 (20.42, 185.00)
Cell-associated HIV DNA, IPDA (copies/10^6 CD4+ cells, median (Q1, Q3))	163.30 (50.47, 319.00)	79.92 (27.01, 465.40)	308.50 (164.10, 641.30)	359.50 (184.10, 1583.00)
Cell-associated HIV DNA, THDA (copies/10^6 CD4+ cells, median (Q1, Q3))	32.40 (9.00, 249.15)	37.12 (19.18, 129.08)	50.77 (29.95, 304.60)	138.27 (54.31, 499.81)
Replication competent HIV, QVOA (copies/10^6 CD4+ cells, median (Q1, Q3))	0.060 (0.014, 0.286)	0.069 (0.014, 0.315)	0.105 (0.014, 0.286)	0.070 (0.014, 0.257)

Table 1. Characteristic and HIV reservoir

Conclusions: Early treated individuals had lower reservoir size, lower viral diversity and higher susceptibility to bNAbs (exemplified by elipovimab) supporting that individuals who initiate ART during Fiebig stages, and in particular during Fiebig I to IV, would be an attractive population for early proof of concept bNAb cure-related trials. The IPDA provides both intact and total HIV DNA measurements and was able to differentiate between early and late cohorts and should therefore be given priority as a reservoir measurement in HIV cure trials.

OAB01 Hepatitis, STI and COVID-19

OAB0101

Robust SARS-CoV-2-specific serological and functional t-cell immunity in PLWHIV

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Background: While description of protective humoral and T-cell immune responses has been reported among immunocompetent (IC) individuals, its characterization among PLWHIV remains uncertain.
Methods: SARS-CoV-2-specific serological and functional T-cell immune responses against main immunogenic antigens were assessed in 11 HIV-positive patients at three (T1) and six months (T2) following confirmed-SARS-CoV-2-infection, and compared to a cohort of 34 immunocompetent (IC) individuals developing mild (outpatient, n=21) and severe (inpatient, n=13) disease. Also, SARS-CoV-2 (Spike)-specific memory B cells responses were investigated A healthy non-infected group of 16 patients whose PBMC (peripheral blood mononuclear cells) had been bio-banked before COVID-19 pandemic (2018) were also analyzed.
Results: Median (range) age was 51 (33-67); nadir and current T-CD4 cell count was 219 cells/ml (28-600) and 633 cells/ml (284-1000) respectively. Only 5/11 patients needed hospital admission and one of them required ICU. Patients displayed similar IFN-γ, IL2 and polyfunctional IFN-γ/IL2 producing T-cell frequencies than IC with mild symptoms at three and six months after infection. IC patients with more severe COVID-19 infection exhibited the highest T-cell immune responses (Figure 1). However, all (14/14) severe, 7/11 (63%) HIV and 3/18 (16.7%) mild IC patients showed IgG seropositivity at 6 months (p<0.005) (Figure 2). Interestingly, a broad range of SARS-CoV-2 (Spike)-specific memory B-cell responses in the majority of HIV patients, despite the absence of SARS-CoV-2-specific IgG antibodies at three (4/4) and six (2/4) months (Figure 3).

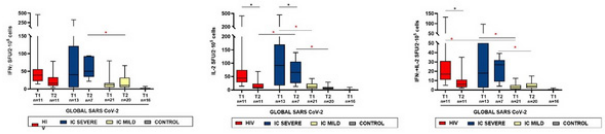

Figure 1. Global T-cell responses specific to SARS-CoV-2 at different time-points
* Intra-group statistically significant differences (p<0.05)
* Inter-group statistically significant differences (p<0.05)

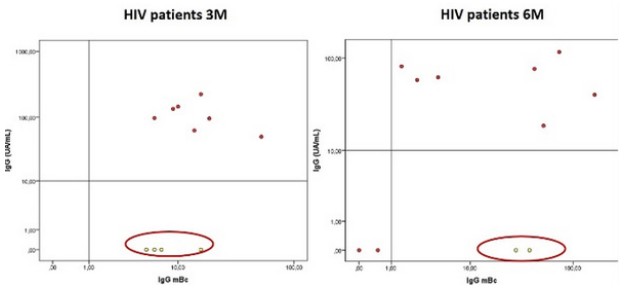

Figure 3: SARS-CoV-2 (S1/S2) antibodies and Anti-Spike IgG B cell ELISPOT correlation among HIV patients at 3 and 6 months after infection.
[+] Horizontal line defines the antibody detection cut-off
[†] Vertical line defines the B-cell ELISPOT cut-off

Conclusions: Our data suggest a comparable natural immunization among chronic HIV, similar to that of IC convalescent patients developing similar COVID-19 disease severity. Notably, functional B and T-cell assessment may more reliably detect immunized patients with robust immune memory responses as compared to serological memory assessment during mid-term convalescence.

OAB0102

Rising substance use linked to STI and HCV in Thai MSM after acute HIV infection

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Background: We report longitudinal trends in alcohol and recreational drug use and their associations with clinical outcomes in a Thai cohort of people living with HIV who are men who have sex with men (MSM).
Methods: From 2017-2019, participants in the RV254/SEARCH010 cohort of acute HIV infection completed a questionnaire every 24 weeks about drug, alcohol use and group sex. Positive use was defined as ≥1 self-reports of substance use during a calendar year. Risky alcohol use was defined as AUDIT-C score ≥4. Logistic regression with generalized estimating equations estimated odds ratios (ORs) and 95% confidence intervals (CIs) for factors associated with recreational drug and risky alcohol use.
Results: Among 604 participants with substance use data, median age was 26 years and 93.5% were MSM. Alcohol consumption was reported in 83.3% and risky alcohol use in 38.1%. Recreational drug use was reported in 46.9%. From 2017 to 2019, rising trends were observed for risky alcohol use, any recreational drug use, poppers, and methamphetamine injection (Table).
New recruits to the cohort in 2017-2019 (n=137) were more likely than those enrolled between 2009 and 2016 to report methamphetamine use (30% vs. 19%, p=0.01) and injection of methamphetamine (20% vs. 3.9%, p<0.01). Participants who used recreational drugs were more likely to have hepatitis C coinfection (OR 3.42, 95%CI 1.88-6.21), syphilis coinfection (OR 2.69, 1.75-4.13), gonorrhea (OR 7.74, 5.04-11.89), chla-

mydia (OR 1.61, 1.12-2.31), and group sex (OR 7.74, 5.04-11.89). Methamphetamine injection was highly associated with group sex (OR 28.40, 10.99-73.41).

Substance	All n=604	2017 n=328	2018 n=548	2019 n=594	P-value test for trend
Alcohol	503 (83.3)	218 (66.5)	412 (75.2)	456 (76.8)	0.001
AUDIT-C score ≥4	230 (38.1)	49 (14.9)	131 (23.9)	192 (32.3)	<0.001
Erectile dysfunction drugs	172 (28.5)	50 (15.2)	119 (21.7)	118 (19.9)	0.170
Recreational drug use (includes all below)	283 (46.9)	68 (20.7)	191 (34.9)	210 (35.4)	<0.001
Poppers	242 (40.1)	69 (21.0)	153 (27.9)	173 (29.1)	0.013
Ecstasy	33 (5.5)	5 (1.5)	24 (4.4)	19 (3.2)	0.312
Oral amphetamines	22 (3.6)	2 (0.6)	15 (2.7)	13 (2.2)	0.183
Methamphetamine	129 (21.4)	33 (10.1)	87 (15.9)	85 (14.3)	0.146
Injection of methamphetamine	46 (7.6)	6 (1.8)	24 (4.4)	27 (4.5)	0.061

Table. Proportion of participants reporting substance use by calendar year

Conclusions: Substance use has increased in Thai MSM living with HIV. Recreational drugs are strongly associated with the acquisition of sexually transmitted infections, including hepatitis C. Substance use screening at diagnosis and at every routine visit should be integrated into clinical practice for MSM with HIV in Thailand.

OAB0103

High HCV cure rates in C-FREE, first community-based study offering testing and treatment of viral hepatitis and HIV among people who use drugs and their partners in Thailand

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Background: Among people who inject drugs (PWID) in Thailand, HIV and hepatitis C (HCV) antibody prevalence is estimated at 25% and 70%, respectively. C-Free is a cohort study of community-based testing and treatment of HCV, hepatitis B virus (HBV), and HIV for people who use drugs (PWUD), implemented at six drop-in-centres (DICs) offering harm reduction services in Thailand.

Methods: Individuals who currently/previously used drug(s), aged at least 18, were screened for HCV, HBV, and HIV. Those with negative hepatitis B surface antigen (HBsAg) and antibody receive HBV vaccination. GeneXpert was utilized to measure HIV RNA, HCV RNA, and HBV DNA on-site, for those with reactive rapid tests. Those with confirmed HIV and HBV infection were referred to existing national programs. Participants with HCV infection without evidence of decompensated cirrhosis, hepatocellular carcinoma, or end stage renal disease, were offered a twelve-week course of sofosbuvir/velpatasvir. Those with negative HIV and/or HCV were offered repeat testing at three-month intervals

Results: Between June 2019 and January 2021, 1,118 participants enrolled, 949 (84.9%) were male, median age was 43 years (range 18-73), and 841 (75.2%) reported a lifetime history of injecting drugs. HCV antibody was detected in 809 (72.4%), HIV antibody in 460 (41.1%), and HbsAg in 54 (4.8%). 72.6% of those with HIV were coinfected with HCV. Among 809 with reactive HCV Ab, 667 (82.45%) had detectable HCV RNA, 226 (39.4%) reported actively injecting drugs, and 60 (9%) had evidence of cirrhosis using an AST to Platelet Ratio (APRI) of 2.0.

Of 652 participants who met HCV treatment eligibility criteria, 573(87.9%) have started sofosbuvir/velpatasvir, 420 (73.3%) have completed treatment, and 353 (61.6%) have reached the sustained virological response (SVR) timepoint. SVR was achieved by 326 participants; 92.4% (95%CI 89-95%) in the intent-to-treat analysis and 95.3% (95%CI 93-97%) of 342 in the per-protocol analysis. No treatment-related serious adverse events were observed.

Conclusions: Community-based HCV treatment with sofosbuvir/velpatasvir for PWUD in Thailand, within harm reduction settings, is safe and highly effective. National programs should urgently integrate community-based HIV and HBV/HCV test and treat services as standard of care for drug-using populations to decrease morbidity and onward transmission of these infections.

OAB0104

Reaching HCV micro-elimination in HIV/HCV co-infected individuals in the Netherlands: exploring remaining barriers to HCV treatment

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Background: With universal access to direct-acting antivirals (DAA) since November 2015, the Netherlands is progressing towards micro-elimination of hepatitis C virus (HCV) in people living with HIV (PLWH). However, some HCV-viremic PLWH have yet to receive DAA-treatment. We described the barriers for DAA-uptake in these individuals.

Methods: We included HCV-viremic individuals from a nationwide cohort of PLWH in the Netherlands with ≥1 visit during universal DAA-access (database lock=31 December 2019). Based on their last visit, these individuals were grouped as DAA-treated or -untreated. We identified variables associated with being DAA-untreated using multivariable

logistic regression. In December 2020, physicians of DAA-untreated PLWH were asked to complete an in-depth questionnaire on barriers to DAA-uptake and risk of onward HCV-transmission.

Results: Of the 25,196 PLWH ever screened for HCV, roughly 5% were HCV-viremic between 2003-2014, decreasing to 1.6% in 2016 and 0.7% in 2019. 983 PLWH were HCV-viremic during the universal DAA-access era; 76/983 remained DAA-untreated at the time of database lock. Being DAA-untreated was associated with belonging to a key population other than men who have sex with men (OR=10.6, 95%CI=5.5-22.0), older age (OR/10 years=1.6, 95%CI=1.3-1.9), infrequent follow-up (OR=17.1, 95%CI=8.3-36.6) and excessive alcohol use (OR=1.7, 95%CI=1.4-5.3). Of the 76 persons known to be DAA-untreated at database lock, 41 were no longer in care (deceased, n=23; lost to follow up, n=12; moved abroad, n=6), while six initiated DAA since database lock. The remaining 29 were still DAA-untreated and in care in December 2020 (29/983, 3%), in whom the most common barriers to DAA-uptake were patient-related concerns (Table 1).

Physician-reported barriers to DAA-treatment and risk of onward transmission in HCV-viremic persons living with HIV in the Netherlands (n=29)	
Barrier to DAA-treatment uptake*	
Patient refusal	9 (31%)
No liver fibrosis	7 (24%)
Infrequent visit attendance	6 (21%)
Severe comorbidity	5 (17%)
Insufficient adherence expected	3 (10%)
Physician-reported risk of onward HCV transmission#	1 (3%)
Additional data collection form not returned	9 (31%)

Data obtained via questionnaire by the treating physician (December 2020).
*Five most frequent barriers mentioned. Multiple barriers per individual are possible. #Risk of onward sexual transmission and/or onward transmission through drug use.
Abbreviations: DAA: direct-acting antivirals. HCV: hepatitis C virus

Conclusions: The current prevalence of HCV-viremic PLWH in care is low in the Netherlands, coinciding with widespread DAA-uptake since 2016. Patient refusal is the main barrier to DAA-uptake in the remaining DAA-untreated. Few of these individuals appear to engage in activities associated with risk of onward HCV-transmission.

OAB0105

Evaluation of the HCV cascade of care among people with HIV/hepatitis C co-infection in New South Wales, Australia: a data linkage study

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Background: Evaluating the hepatitis C virus (HCV) care cascade can provide a benchmark to track the effectiveness of interventions and identify service gaps at the population level. This study evaluated HCV RNA testing and treatment uptake pre- and post-direct-acting antiviral (DAA) availability and assessed factors associated with non-treatment in the DAA era among people living with HIV/HCV co-infection in NSW, Australia.

Methods: Records of individuals with HCV positive serology in NSW (1993-2017) were linked to HIV notification, perinatal data collection, hospitalization, births, deaths, and marriages, opioid agonist therapy (OAT), incarceration, and cancer registry datasets. These were then linked to national datasets of HCV RNA testing and HCV therapy dispensing from 2010. Factors associated with non-treatment uptake in the DAA era were assessed using logistic regression.

Results: Among 988 people living with HIV with an HCV notification between 1993 and 2017 in NSW, 751 ever received RNA testing, and 419 ever initiated treatment. The proportion receiving HCV RNA testing remained stable from pre-DAA era (2010-2015; 77% [260/336]) to post-DAA era (2016-2018; 72% [89/123]). However, HCV treatment initiation dramatically increased from 7% (16/225) in the pre-DAA era to 73% (194/267) in the post-DAA era. Median time from HCV notification to RNA testing decreased from 13 weeks in 2010 to zero weeks in 2012-2017. Median time from HCV diagnosis to treatment decreased from 311 weeks in 2010 to less than five weeks in 2017. The unadjusted logistic regression model indicated no association between available demographic characteristics (i.e., year of birth, aboriginal ethnicity, country of birth, local health district of residence at the time of HCV) as well as drug and alcohol use (i.e., drug dependence and history of alcohol-use disorder) and non-treatment in DAA-era.

Conclusions: A dramatic increase in HCV treatment uptake was seen in DAA era compared with pre-DAA era among people living with HIV in Australia. These findings indicate that in settings of unrestricted DAA access, such as Australia, very high treatment uptake is possible in people living with HIV/HCV co-infection that can lead to HCV elimination among this population.

OAB02 HIV with and without TB

OAB0201

Outcomes and incidence of TB among people living with HIV who received TB preventive therapy in Uganda

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Background: TB preventive therapy (TPT) among people living with HIV (PLHIV) reduces the risk of developing TB disease. In Fort Portal region, data on TPT outcomes among PLHIV are scarce. We determined TPT outcomes and probability of TB occurrence among PLHIV who initiated TPT.

Methods: We retrospectively pooled electronic medical records data of a cohort of PLHIV aged 1 year and older who received TPT (isoniazid) from August 2016 through June 2020 at Fort Portal Regional Referral Hospital, Kilembe Mines and Kabarole hospitals in Fort Portal region, Uganda. TPT outcomes included: completed TPT, defaulted, transferred out, died, stopped TPT, or developed TB. TPT outcomes were measured six months after TPT initiation and were reported as frequencies. Clients were followed up for 24 months from date of TPT initiation to estimate risk of TB occurrence. TB diagnosis was based on either clinical diagnosis or bacteriologic detection by GeneXpert MTB/Rif or sputum smear microscopy. We compared the incidence of TB among patients who completed TPT and those who defaulted.

Results: A total of 10,085 PLHIV on ART [65% female, mean age 39 years (SD=12.7)] initiated TPT during the study period. Overall, 96% (9,661/10,085) completed TPT, 0.4% (38/10,085) died, 0.13% (13/10,085) de-

veloped TB, 1.5% (152/10,085) defaulted, while 2% (219/10,085) transferred and 0.02% (2/10,085) stopped treatment due to side effects. In 114,993 person months of follow-up, 0.1% (13/10,085) PLHIV developed TB, 69% (9/13) being male and above 35 years; 46% (6/13) developed TB within the first six months of TPT. During a mean of 11.4 months follow up, the TB incidence was 0.011% (95%CI: 0.007-0.019) with those who completed TPT having a lower incidence rate (IR=0.006%, 95%CI: 0.003 - 0.013) compared with those who had defaulted TPT (IR=1.23%, 95%CI: 0.55 - 2.74). Thirteen percent (11/8,243) of individuals who developed TB were on a dolutegravir-based antiretroviral treatment regimen.

Conclusions: Although most of the PLHIV who initiated on TPT completed six months of treatment, a small proportion of TB disease and deaths still occurred. We recommend that clinicians emphasize screening for active TB before initiating TPT among PLHIV through clinical group sessions for challenging cases.

OAB0202

The clinical effects of durably low CD4 counts while virologically suppressed among ART-initiating persons with HIV in Latin America

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Background: People with HIV (PWH) with insufficient immune responses after initiating antiretroviral therapy (ART) have higher risks of comorbidities and death. Cumulative time with low CD4+ counts (CD4), even with successful virologic suppression (VS), has been associated with poor outcomes. In the Caribbean, Central and South America network for HIV epidemiology (CCASAnet), a high proportion of deaths are attributed to late ART initiation, with approximately half of patients initiating ART with CD4<200 cells/μL. We estimated the effect of cumulative time with CD4<200 cells/μL on mortality and comorbidities among ART-initiators with VS during 2000-2017.

Methods: We followed PWH in CCASAnet initiating ART with CD4 and HIV RNA measures from initial VS (HIV RNA <200 copies/mL) until death or loss to follow-up. Individuals were censored when HIV RNA was first ≥200 copies/mL. We fit Cox models to estimate risk of death and/or AIDS- and non-AIDS-related severe comorbidities (SCM; including cancers and cardiovascular, liver, and renal diseases) by time-updated percentage of follow-up time with CD4<200 cells/μL (%$t_{CD4<200}$), adjusting for sex, age, HIV transmission route, education, calendar year, clinic site, and in secondary analyses, time-updated CD4 count.

Results: Among 9,123 patients with VS contributing a median of 51.5 (IQR: 26.1, 91.5) months, 78% were men, median age was 34 years, 4,668 (51%) started ART with CD4<200 cells/μL, and median %$t_{CD4<200}$ was 0% (IQR: 0, 15%). For those starting ART with CD4<200 cells/μL, median %$t_{CD4<200}$ at 12 months was 36% (IQR: 0, 100%) and at 24 months was 18% (IQR: 0, 58%). A total of 283 (3%) deaths and 774 (8.4%) patients with SCM were identified. Comparing %$t_{CD4<200}$ of 15% vs. 0%, the adjusted relative hazard (aHR) of death was 1.27 (95% confidence interval [CI]: 1.20-1.34), of SCM was 1.13 (95% CI: 1.09-1.17), and of either was 1.15 (95% CI: 1.12-1.19). Estimates were similar when also adjusting for time-updated CD4 count: aHR=1.11, (95%CI: 1.05-1.18); aHR=1.08, (95%CI: 1.04-1.12); and aHR=1.10, (95%CI: 1.07-1.13), respectively.

Conclusions: Virologically suppressed PWH spending more time with CD4<200 cells/μL had an increased risk of death and severe comorbidities in this Latin American cohort. Vigilant screening for comorbidities is needed in these populations.

OAB0203

Correlates associated with mortality among HIV-TB co-infected patients in Mumbai, India

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Background: Tuberculosis (TB) is the commonest opportunistic infection and cause of death in patients with Human Immunodeficiency Virus (HIV) in developing countries. Successful TB treatment outcomes are lower among HIV infected compared with non-infected patients. We studied the factors associated with mortality in patients co-infected with HIV and TB in Mumbai, India.

Methods: We studied association of demographic data (age, gender, migrant), clinical history (history of TB, type of TB), treatment history (ART and Anti TB Treatment [ATT], CD4 and weight at TB diagnosis) with mortality in 1571 co-infected patients registered for care in 2018. Logistic regression models were used to estimate the odds ratios (OR) and 95% confidence intervals (CI) for multivariate analysis.

Results: Of 1571 co-infected patients, 950 (60%) were men, 610 (39%) were women, and 11 (1%) were male-to-female transgenders/Hijras. The mean age (standard deviation) was 39.1 (12.1) years. There was an equal proportion of pulmonary (790) and extra pulmonary TB (781). The median (interquartile range) CD4 count at the time of diagnosis was 226 (106, 386). About 859 (55%) patients were taking ART at time of TB diagnosis and 712 (45%) patients were treatment naïve for both the diseases at the time of diagnosis. Nineteen percent of co-infected patients (295) had died during the follow-up period. Mortality was significantly associated with age (>= 60 years) and CD4 count at the time of diagnosis (< 200 CD4 cells). Higher weight at the time of diagnosis and individuals who were not from Mumbai were less likely to die. Detailed ORs and their CIs are presented in Table 1.

Death	Odds Ratio	[95% confidence Interval]		P>z
19-29 yrs	2.16	0.84	5.52	0.109
30-59 yrs	3.31	1.40	7.83	0.006
>= 60 yrs	4.57	1.57	13.31	0.005
Treatment Naïve	1.91	1.40	2.62	0.001
Pulmonary TB	0.91	0.66	1.24	0.535
Weight	0.96	0.95	0.98	0.001
CD4 (201-500)	1.00	0.58	1.75	0.992
CD4 (< 200)	2.53	1.51	4.25	0.001
Past History of TB	1.20	0.88	1.65	0.242

Conclusions: Patient centric counselling and early diagnosis of both the diseases can help improve TB treatment outcomes. Screening tests of urine LAM among patients with advanced HIV disease can help in early detection and management of TB, thereby reducing mortality.

OAB0204

Long-term survival and predictors of mortality in HIV/TB patients in Uganda

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Background: HIV/TB co-infected patients may have reduced survival even after successful completion of TB treatment; however, the data on long-term survival of these patients in sub-Saharan Africa is limited. This 5-year retrospective cohort set out to determine the long-term survival and predictors of mortality after completing TB treatment in antiretroviral therapy (ART) experienced HIV/TB co-infected patients in Uganda.

Methods: This was a 5-year retrospective cohort analysis of all ART experienced HIV/TB co-infected patients who completed TB treatment in a specialist HIV clinic between 2009 and 2014. The characteristics of patients were described using frequencies and medians. The survival and factors associated with all-cause mortality were determined using Kaplan-Meier methods and Cox proportional hazard models, respectively.

Results: 1128 patients completed TB treatment between 2009 and 2014, of which 573 (50. 8%) were males. The median age was 36 years (IQR: 31-43), the median BMI was 21.93 kgm^2 (IQR: 20.05-24.22), the median CD4 cell count was 233 cells/ul (IQR: 138-365). The person time at risk during the five years of follow-up was 4410.60 person-years. 67(5.9%) patients died during the study period and mortality occurred at 15.19 per 1000 person-years (95% CI: 11.96- 19.30). The probability of death was 0.0251 (95% CI: 0.0173-0.0364), 0.0575 (95% CI: 0.0447-0.0738), and 0.0684 (95% CI: 0.0541-0.0862), at 1, 3 and 5 years respectively. CD4 count <200 cells/ul, BMI < 18 kgm^2 and TB relapse were associated with mortality: unadjusted Hazard Ratio (uHR)= 3.73, (95% CI: 2.01- 6.94, p-value <0.001), uHR =2.06 (95% CI: 1.21-3.49, p-value= 0.008), and uHR= 1.95, (95% CI: 1.11- 3.41, p-value 0.020), respectively. However, in the multivariate analysis, only BMI <18 kgm^2 was associated with mortality, adjusted HR= 3.78, (95% CI: 1.93- 7.40, p-value <0.001).

Conclusions: In this clinic, ART experienced HIV patients that were co-infected with TB seemed to have a reasonably good 5-year survival probability (93.16%) after completing TB treatment. This could be attributed to the increased access to ART in Uganda. Notably, being malnourished is the single most important predictor of mortality in this cohort, and thus the continuous close monitoring of at-risk patients could avert mortality.

OAB0205

Incidence and co-factors of Mtb infection in first 2 years of life: observational follow-up of a randomized controlled trial of INH to prevent primary Mtb infection among HIV-exposed uninfected children

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Background: In the infant TB Infection Prevention Study there was a trend for decreased TST-positivity after 12-months INH among Kenyan HIV-exposed uninfected (HEU) infants. We present 24-month observational follow-up.

Methods: Infants age 6 weeks without known TB exposure were randomized to 12-months INH vs. no INH**.** Mtb infection was measured at 12 months by interferon gamma release assay (IGRA, QFT-Plus), with tuberculin skin test (TST, positive ≥10 mm) added 6 months after first study exit due to low accrued endpoints. Follow-up was extended with repeat TST placed at 24 months. Observational outcome was cumulative Mtb infection by 24 months with any positive Mtb infection test considered 'ever positive'. Correlates of Mtb infection were evaluated by generalized linear models and risk of conversions/reversions by multinomial regression.

Results: As previously reported, among 300 HEU infants enrolled (150/arm), 28/265 (11%) with 12-month Mtb infection endpoints were positive, with a trend for lower 12-month Mtb infection among infants randomized to INH (HR 0.53 [95%CI 0.24-1.14], p=0.11]) driven by TST-positivity (RR 0.48 [95%CI 0.22-1.05], p=0.07). Among 228 children completing 24-month follow-up, 25 (13.3%) were TST-positive.

Overall, 39/275 (14%) infants with Mtb infection outcome at 12 or 24 months were positive; cumulative Mtb infection incidence was 9.8/100 PY (INH 7.5 vs no INH 9.8/100 PY, HR 0.75 [95%CI 0.40-1.42], p=0.37] and associated with lack of flush toilet or running water (p<0.001 and p=0.02, respectively). Among 162 infants with TST at 12 and 24 months, 68% (17/25) with 12-month TST-positivity reverted; 5.4% (7/137) TST-negative converted. While post-trial TST conversions were similar among no INH and INH (2/83 [2.4%] vs 5/79 [6.3%], RR 0.4 [95% CI 0.08-2.2], p=0.30), children not receiving INH were more likely to have TST reversions (No INH [13/83, 15.7%] vs. INH [4/79, 5.1%], RR 3.4 [95% CI 1.03-10.8], p=0.04).

Conclusions: In post-RCT follow-up, 24-month cumulative Mtb infection incidence measured primarily by TST was high and associated with poorer household conditions in this cohort of HEU children. Trend for decreased TST-positivity after 12 months of INH was not sustained. TST reversions occurred frequently; fewer reversions among INH recipients may reflect INH potential to delay the timing of primary infection.

OAB03 ART

OAB0301

Comparison of viral replication for the 2-drug regimen (2DR) of dolutegravir/lamivudine (DTG/3TC) versus a 3/4-drug tenofovir alafenamide–based regimen (TBR) in the TANGO study through week 96

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Background: TANGO demonstrated non-inferior virologic efficacy (HIV-1 RNA ≥50 c/mL, Snapshot) of switching to DTG/3TC vs continuing TBR in HIV-1-infected, virologically suppressed adults at 96 weeks. Abbott RealTime HIV-1 assay measures viral load (VL) from 40 to 10,000,000 c/mL, and provides qualitative target detected (TD) or target not detected (TND) outcomes for VL <40 c/mL. Clinical significance of low-level VL <50 c/mL remains unclear. We assessed proportion of participants with TD/TND and elevated VL through Week 96 (Wk96).

Methods: Proportions of participants with VL <40 c/mL and TND were analysed by visit (Snapshot) through Wk96. Participants' TD/TND status over time, overall and by Baseline VL classifications, was assessed. Frequency of elevated VL categories including "blips" was determined.

Results: At Wk96, similar proportions of participants had TND with 2DR and 3DR (73% [271/369] vs 69% [255/372], respectively; adjusted difference, 4.9%; 95% CI, −1.7, 11.4; Snapshot). Across Baseline VL categories, proportions with TND at all visits through Wk96 were higher at 37% (137/369) with 2DR vs 31% (114/372) with 3DR (Table 1). Occurrence of elevated VL (Table 2) was low and similar across arms through Wk96, and most frequently observed VL rebounds were "blips." Zero and 3 confirmed virologic withdrawals were observed with 2DR and 3DR, respectively.

	Baseline	DTG/3TC (N=369)			TBR (N=372)		
		TND	TD	≥40 c/mL	TND	TD	≥40 c/mL
		n[1]=302 (82%)	n[1]=51 (14%)	n[1]=11 (3%)	n[1]=303 (81%)	n[1]=59 (16%)	n[1]=9 (2%)
Post-Baseline	At least one VL ≥50 c/mL[2]	14 (5%)	7 (14%)	2 (18%)	26 (9%)	9 (15%)	1 (11%)
	At least one 40≤ VL <50 c/mL[2]	5 (2%)	5 (10%)	1 (9%)	10 (3%)	3 (5%)	1 (11%)
	At least one VL <40 c/mL & TD[2]	152 (50%)	33 (65%)	8 (73%)	160 (53%)	41 (69%)	6 (67%)
	All VLs <40 c/mL & TND[2]	131 (43%)	6 (12%)	0 (0%)	107 (35%)	6 (10%)	1 (11%)

Post-baseline categories are mutually exclusive and determined by highest VL observed. Five participants with Baseline VL <40 c/mL in DTG/3TC arm and one participant with Baseline VL ≥50 c/mL in TBR arm not presented due to no post-baseline VL data. 1. n: Participants with post-baseline VL data (percentages based on N). 2. Percentages based on n.

Table 1. Changes in quantifiable and non-quantifiable VL levels by baseline VL category through week 96

Elevated Viral Load Categories for Participants in ITT-E Population	DTG/3TC (N=369) n (%)	TBR (N=372) n (%)
1. Participants with VLs between 50-200 c/mL and no VL ≥200 c/mL	21	33
1a. VLs between 50-200 c/mL with adjacent values <50 c/mL (defined as "blips")	18 (5%)	28 (8%)
1b. ≥2 consecutive VLs between 50-200 c/mL	3 (<1%)	5 (1%)
2. Participants with at least one VL ≥200 c/mL	4	8
2a. A single VL ≥200 c/mL and no 2 consecutive VLs ≥50 c/mL	4(1%)	5 (1%)
2b. ≥2 consecutive VLs ≥50 c/mL with at least one VL ≥200 c/mL	0	3* (<1%)
Total (all categories)	23 (6%)	36 (10%)

*Three participants met confirmed virologic withdrawal (CVW) criteria by Week 96. CVW was defined as 2 consecutive on-treatment VL measurements of ≥50 c/mL with the second VL ≥200 c/mL.

Table 2. Summary of participants with elevated VL categories through week 96

Conclusions: Similar proportions of participants had TND at all visits through Wk96 in both treatment arms. Regardless of Baseline VL, incidence of intermittent viremia was low and similar between arms. These "deep dive" virology findings further support the potency and durability of 2DR vs 3DR in maintaining viral suppression.

OAB0302

Week 124 results of the randomized, open-label, Phase 3 FLAIR study evaluating long-acting cabotegravir + rilpivirine for treatment in adults with HIV-1 infection (ITT-E population)

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Background: Long-acting (LA) intramuscular injections of cabotegravir (CAB) and rilpivirine (RPV) have been developed as an alternative to daily oral dosing for HIV-1. The Phase 3 FLAIR study (NCT02938520) demonstrated noninferiority of switching virologically suppressed participants from daily oral dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) to monthly CAB+RPV LA through Week (W) 48 and W96. Results for participants who received CAB+RPV for 124 weeks are presented.

Methods: In the Maintenance Phase (W0–100), participants were randomized (1:1) to continue DTG/ABC/3TC or switch to monthly CAB+RPV LA after initially receiving a ≥4-week oral lead-in of CAB+RPV. At W100, participants receiving DTG/ABC/3TC could switch to CAB+RPV LA or withdraw.

The primary endpoint was the proportion of participants with plasma HIV-1 RNA ≥50 copies/mL at W48 (FDA Snapshot algorithm). W124 endpoints included proportion of participants with HIV-1 RNA ≥50 and <50 copies/mL, confirmed virologic failure (CVF; two consecutive viral loads ≥200 copies/mL), and safety and tolerability.

Results: Overall, 283 participants received ≥1 dose of CAB+RPV; median (range) age was 34.0 (19–68) years, 22% were female (sex at birth), and 76% were white. At W124, 14 (4.9%) participants had HIV-1 RNA ≥50 copies/mL, with 227 (80.2%) maintaining suppression (HIV-1 RNA <50 copies/mL). Through W124, 5 (1.8%) participants met CVF, one additional participant since W96 (**Table**).

Injection site reactions (ISRs) were the most common drug-related adverse event (AE); most were Grade 1 or 2 (99.5%). The proportion of participants with ISRs decreased over time (W4: 72%; W48: 23%; W96: 19%; W124: 18%). Serious AEs and AEs leading to withdrawal occurred in 12% (one drug related) and 5% of participants, respectively, through 124 weeks.

Conclusions: At W124, monthly CAB+RPV LA maintained virologic suppression in most participants; the safety and tolerability profile was consistent with prior W48/W96 results. These results demonstrate the durability of CAB+RPV LA as a well-tolerated, effective maintenance therapy.

Outcome, n (%) ITT-E Population	CAB+RPV LA n=283
HIV-1 RNA <50 copies/mL	227 (80.2)
HIV-1 RNA ≥50 copies/mL	14 (4.9)
Data in window not below threshold	5 (1.8)
Discontinued for lack of efficacy	8 (2.8)
Discontinued for other reason while not below threshold	1 (0.4)
No virologic data	42 (14.8)
Discontinued due to AE	15 (5.3)
Discontinued study for other reason*	26 (9.2)
On study but missing data in window	1 (0.4)
Participants with CVF†	5 (1.8)
Safety	
Number of injections‡	17,392
Number of ISR events‡	3732
Pain, n (% of injections)‡§	3131 (18)
Nodule, n (% of injections)‡	162 (1)
Induration, n (% of injections)‡	158 (1)
≥Grade 3 ISR events‡	18
Participants who withdrew due to ISR or injection tolerability	7 (2)
Any Grade 3 or 4 AE	49 (17)
Excluding ISRs	38 (13)
Drug-related AEs	17 (6)
Drug-related AEs excluding ISRs	5 (2)
AEs leading to withdrawal	15 (5)
Any SAE	33 (12)
Drug-related SAEs	1 (<1)¶

AE, adverse event; CAB, cabotegravir; CVF, confirmed virologic failure; INSTI, integrase strand transfer inhibitor; ISR, injection site reaction; ITT-E, intention-to-treat exposed; LA, long-acting; NNRTI, non-nucleoside reverse transcriptase inhibitor; RAM, resistance-associated mutation; RPV, rilpivirine; SAE, serious adverse event.
*Other reasons included: relocation, frequency of visits, intolerability of injections, pregnancy, frequency of injections, burden of travel, incarceration, lost to follow-up, and other.
†One additional participant met the CVF criterion since Week 96 (Week 108); there were no INSTI or NNRTI RAMs at baseline, but L74I integrase polymorphisms were present. NNRTI RAMs V106V/A, V108V/I, E138G, and M230L and INSTI RAMs N155H and R263K were found at suspected virologic failure.
‡Event-level data.
§Only ISRs with an incidence ≥1% are listed.
¶Right knee monoarthritis was reported in the Week 48 analysis.

Table. Efficacy (FDA Snapshot) and safety data at week 124

OAB0303

Prevalence of baseline virological risk factors of increased virological failure to CAB+RPV among ARV-naïve patients

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Background: Multivariable baseline factor analysis across CAB+RPV phase 3 studies recently showed that HIV-1 subtypes A6/A1, characterized by the L74I integrase (IN) polymorphism, and presence of RPV resistance-associated mutations (RAM), as well as body mass index, were associated with an increased risk of virological failure of this dual-therapy. The aim of this study was to describe the prevalence of CAB and RPV RAM among ARV-naive patients depending on the subtype.

Methods: From 2010 to 2020, 4212 sequences from ARV-naïve patients with both RT and IN available sequences were collected from three large Parisian Academic Hospitals genotypic databases. CAB and RPV RAM were defined according to the ANRS algorithm (www.hivfrenchresistance.org).

Results: Among 4212 sequences, 38.6% belonged to B subtype and the most prevalent non-B subtype was CRF02_AG (32.4%). Subtype A represented 5.1% of the sequences within 85.5% was of subtype A6/A1 (n=183/214). Overall, the presence of at least one CAB or RPV RAM was 16.2% and 14.3%, respectively. The overall prevalence of L74I in IN and E138A in RT was 13.0% and 3.2%, respectively, and stable over the decade. The frequency of L74I was significantly higher in non-B than in B subtypes (17.4% vs 6.0%, p<0.0001) with the highest prevalence observed in subtype A (49.5%). The frequency of E138A was significantly higher in non-B than in B subtypes (3.8% vs 2.2%, p=0.0003) and was 7.9% in subtype A (n=17/214). Sixteen patients (0.4%) displayed virus harboring both E138A and L74I polymorphisms.

Considering genotypic resistance interpretation, using ANRS algorithm, 0.74% (n=31), 7.3% (n=306) and 0.09% (n=4) of sequences were resistant to cabotegravir, rilpivirine or both, respectively. Thus, 183 sequences were subtype A6/A1 and 244 were interpreted as resistant to RPV (after excluding those of subtype A6/A1) leading to 427 (10.1%) of sequences combining both baseline virological risk factors of CAB+RPV dual-therapy failure.

Conclusions: Among large sequences databases, when combining RPV RAMs and HIV-1 subtype A6/A1 prevalence, 10.1% of ARV-naive patients would not be eligible for CAB+RPV dual-therapy. These data re-emphasize the need of a pre-therapeutic genotypic resistance test to detect polymorphisms, transmitted drug resistance and to define HIV-1 subtype.

OAB0304

Islatravir safety analysis through week 96 from a phase 2 trial in treatment naïve adults with HIV-1 infection

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Background: Islatravir (ISL, MK-8591) is a nucleoside reverse transcriptase translocation inhibitor (NRTTI) in development for treatment and prevention of HIV-1 infection. We previously showed that ISL + doravirine (DOR) was effective in maintaining viral suppression through week 96 and was well-tolerated. Here we present a detailed safety analysis of those results.

Methods: In this Phase 2b trial, treatment-naïve adults with HIV-1 were randomized to receive ISL (0.25, 0.75, or 2.25mg) + DOR (100mg) and lamivudine (3TC, 300mg) QD, or a fixed-dose combination of DOR (100mg), 3TC (300mg), and tenofovir disoproxil fumarate (300mg) (DOR/3TC/TDF) QD. In the ISL groups, participants who achieved HIV-1 RNA <50 copies/mL at Week 20 or later, stopped 3TC at the next study visit. All participants receiving ISL were switched to ISL (0.75mg) between weeks 60 and 84. For the current analysis, we conducted a detailed review of adverse events (AEs) and examined these AEs for study periods at weeks 0-48, 48-96 and 0-96.

Results: 121 participants received drug and were included in the analyses. Similar AE rates between treatment arms were observed across all arms of the trial for each time period. No dose-dependent difference in the safety profile of ISL was observed. AEs were more frequent in the first 48 weeks of the trial, as compared to the second 48-week period, for all treatment arms (see table).

During the 96 week-period overall, diarrhea, mostly mild and transient, was more frequently reported for DOR/3TC/TDF (19.4%) as compared to ISL groups (combined 7.9%), while headache was more common in ISL groups (combined 11.1%) as compared to the DOR/3TC/TDF group (6.5%).

	Weeks 0-48		Weeks 48-96		Weeks 0-96	
	Combined ISL	DOR/3TC/TDF QD	Combined ISL	DOR/3TC/TDF QD	Combined ISL	DOR/3TC/TDF QD
Number of participants, N	90	31	80	27	90	31
≥1 AE, n (%)	66 (73.3)	24 (77.4)	52 (65.0)	18 (66.7)	74 (82.2)	27 (87.1)
AEs of moderate or severe intensity, n (%)	32 (35.6)	15 (48.4)	28 (35.0)	9 (33.3)	43 (47.8)	16 (51.6)
Drug-related AEs, n (%)	7 (7.8)	6 (19.4)	0 (0.0)	3 (11.1)	7 (7.8)	7 (22.6)
Serious AEs, n (%)	4 (4.4)	2 (6.5)	1 (1.3)	1 (3.7)	5 (5.6)	3 (9.7)
Drug-related serious AEs, n (%)	0 (0.0)	1 (3.2)	0 (0.0)	0 (0.)	0 (0.0	0 (0.0)
Discontinued due to AEs, n (%)	2 (2.2)	1 (3.2)	1 (1.3)	0 (0.0)	3 (3.3)	1 (3.2)
Deaths, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhea, n (%)	6 (6.7)	5 (16.1)	2 (2.5)	1 (3.7)	7 (7.8)	6 (19.4)
Headache, n (%)	10 (11.1)	2 (6.5)	0 (0.0)	0 (0.0)	10 (11.1)	2 (6.5)

Table.

Conclusions: ISL was well-tolerated, regardless of dose, through 96 weeks of treatment, with most AEs reported as mild and transient. No participants had drug-related AEs or discontinued the study due to a drug-related AE between weeks 48-96.

OAB0305

New generation of HYBRID CAR-T cells efficiently kill HIV infected cells and neutralize cell-free virus

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Background: The current gold standard in HIV treatment fails to provide a definitive cure. Infected patients must adhere to a lifelong therapy burden, which on its own can impose side effects. High economic costs and patient stigmatization further contribute to the social impact of the HIV epidemic. Cell and gene therapies for HIV are increasingly gaining ground, especially over the last decade.
However, most of them suffer from important practical limitations. Here we propose an innovative approach, Hybrid CAR, which combines the cytotoxic function mediated by Chimeric Antigen Receptor (CAR) with antiviral properties of broadly neutralizing antibodies (bNAbs) secreted from the same engineered cell. This will address both the cellular and viral components of HIV pathogenesis.
Methods: Primary CD8+ cells (derived from healthy donors) were lentivirally transduced to express anti-HIV CAR and bNAb from the same bicistronic construct. CAR expression was validated by flow cytometry and RT-qPCR, while the secreted antibody was detected by ELISA. Co-culture of Hybrid CAR-T cells with autologous, HIV-infected CD4+ T cells was performed to evaluate the direct cytotoxic effects. Supernatants collected from Hybrid CAR T-cell monocultures were used to evaluate neutralization potential of T cell secreted antibodies in a TZM-bl assay.
Results: Hybrid CAR-T cells demonstrated efficient killing of HIV-infected, autologous CD4+ T cells with complete inhibition of viral replication. Secreted antibodies alone were able to reduce infectivity of HIV, demonstrating dual, synergistic functionality of the Hybrid CAR.
Conclusions: This data provides proof of concept for the Hybrid CAR platform and shows successful secretion of anti-HIV antibodies from primary T cells, as well as retained killing function mediated by simultaneously expressed CAR. Ongoing experiments are being performed to provide evidence of Antibody Dependent Cytotoxicity (ADCC) and Antibody Dependent Phagocytosis (ADCP) exerted by the CAR-T cell secreted bNAbs.

OAB04 Monitoring

OAB0401

Is systematic Xpert MTB/RIF improved the detection of tuberculosis in HIV-infected patients in a low tuberculosis incidence setting in West Africa?

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Background: Tuberculosis is a leading cause of death in HIV-patients, but its diagnosis is challenging. We assessed the performance of Xpert MTB/RIF (Xpert) in a low tuberculosis incidence setting in Lomé (Togo) and Bamako (Mali), regardless of the presence of tuberculosis presumptive symptoms.
Methods: We included all consenting HIV-infected patient aged ≥15 years, not initiated on antiretroviral therapy (ART) or on ART ≤ 1 month. Participants were screened for tuberculosis with 4-symptom screening (fever, cough, night sweats, and weight loss) as recommended by World Health Organization (WHO), and with Xpert performed on a sputum sample. In addition, sputum was tested using mycobacterial culture. We compared the sensitivity and specificity of a WHO 4-symptom screening strategy plus Xpert for those who reported any one of the symptoms, to Xpert for all HIV-infected patients regardless of tuberculosis presumptive symptoms, with mycobacterial culture as a gold standard.
Results: Patients were recruited between January 1 and December 31, 2020. 545 patients were enrolled, of whom 85% (467/545) who completed the diagnostic algorithm were included in this study (82% in Lomé; median age 37.4 years (interquartile range: 30.4-46.3); 65% female; WHO HIV stage I, 55%). Fever was reported in 15%, whereas cough, weight loss, and night sweats were reported in 26%, 39% and 14%, respectively. Overall, 46 (10%) tuberculosis cases were identified by Xpert or mycobacterial culture. Of these, four tuberculosis patients reported none of the four clinical symptoms. The Rifampicin resistance was rare (2%, 1/46). Compare to mycobacterial culture, the WHO 4-symptom screening strategy plus Xpert sensitivity was 53% (95% confidence interval [95%CI] 38–68%). While, the sensitivity of the systematic use of Xpert was 63% (95%CI 0.47–0.77). The specificity was 99% (95%CI 98–100%) for both strategies.
Conclusions: In this operational research supported and funded by WHO-TDR, the prevalence of tuberculosis among HIV-positive patients starting ART or on ART for less than one month was 10%. The use of the WHO 4-symptom screening strategy plus Xpert will missed 9% of the tuberculosis cases. The systematic screening for tuberculosis using Xpert at ART initiation regardless of tuberculosis presumptive symptoms could improve its early diagnosis and treatment.

OAB0402

The point of care device needed for confirming active hepatitis C infection in the prison population

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Background: Hepatitis C virus (HCV) RNA screening is a critical step for HCV treatment and care. A rapid HCV RNA test or point-of-care (POC) test would be extremely helpful in diagnosing active HCV infection. GeneDrive is a novel POC HCV RNA assay, permits identification of active HCV infection for all HCV genotype with lower limit of detection of 1406-3203 IU/ml. We therefore, validated a GeneDrive POC assay to detect HCV RNA in the high-risk population with limited access to HCV RNA testing.

Methods: A pilot "Test and Treat HCV in prison" was conducted in a Central Prison in Bangkok, Thailand between 2019-2020. The Study addresses hepatitis C high risk population (prison group) and is to be tested on the GeneDrive HCV RNA assay. We validated the GeneDrive HCV assay of the pre-treatment samples comparing results with those obtained from the Abbott RealTi*m*e HCV assay as a reference test with limit of detection 12 IU/ml.

Results: A total of 158 samples from prisoners with positive anti HCV were included in this validation, 126 samples were HCV detection from Abbott RealT*i*me HCV test (HCV RNA (log10) ranged1.8-7.4 IU/ml) and another 36 samples with HCV RNA undetectable (HCV RNA < 12 IU/ml). The GeneDrive HCV assay showed 100% sensitivity (95% CI 97%-100%) and 97.2% specificity (95% CI 85.5-99.9%) to detect HCV. The sensitivity (100%) and specificity (97.2%) for the GeneDrive HCV RNA assay were the same as the gold standard test. Agreement between Abbott Real time PCR and GeneDrive is 99.4%. The performance of evaluation is shown in table 1.

	n/N	% (95% confidence interval)
Sensitivity	122/122	100 (97-100)
Specificity	35/36	97.2 (85.5-99.9)
Positive predictive value	122/123	99.2 (95.6-100)
Negative predictive value	35/35	100 (90-100)
AUC	-	0.99 (0.96-1)

Table 1. Performance of GeneDrive evaluation

Conclusions: GeneDrive, a novel POC HCV RNA assay yielded a high performance to confirm active HCV infection. To ending hepatitis C in resource limited settings (RLS), this portable POC device is a good alternative to facilitate "Test and treat HCV" in a real clinical setting in many RLS.

OAB0403

Plasma separation cards are suitable for HIV-1 genotypic drug resistance testing

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Background: Plasma specimens are considered the gold standard for HIV drug resistance testing. However, the collection, preparation, storage and transport of plasma remain a challenge in resource-limited settings. To mitigate these challenges, Roche Molecular Diagnostics developed a sample collection device, the plasma separation card (PSC), to separate and stabilize plasma from whole blood using a proprietary membrane and stabilizing fleece. PSCs have been successfully used for HIV viral load testing. This study aimed to assess the feasibility of the PSC as an alternative collection matrix for HIV-1 genotypic drug resistance testing.

Methods: The study was conducted at Charlotte Maxeke Johannesburg Academic Hospital from December 2019 to April 2020. Plasma, dried blood spot (DBS) and PSC samples were prepared from thirty-five routine specimens. Spotted cards were lysed using two-hour and overnight lysis methods. Specimens from all collection matrices were extracted (Nuclisens EasyMag, Biomerieux) and sequenced using an in-house developed Sanger-based assay. Results were compared, using plasma as the gold standard, to determine amplification and sequencing success rates and drug resistance mutation concordance.

Results: The median plasma viral load was 4.4 $\log_{10}$ copies/ml (IQR: 3.68 – 4.99 $\log_{10}$ copies/ml). Amplification success rates for PSC lysed using the two-hour or overnight lysis method (97%, n=34 each), and DBS two-hour lysis (97%, n=34) or overnight lysis (86%, n=30), were achieved. These were comparable to plasma samples (97%, n=34). Sequencing success rates were higher using the two-hour lysis method, 100% and 88% for PSC and DBS respectively compared to 91% and 82% using overnight lysis. A percentage similarity of >98% at drug resistance mutation sites was achieved for all specimens, except for one DBS 2h-lysis sample and one DBS overnight lysis sample. Of the detected drug resistance mutation discordances between plasma and spotting samples, most had no or limited impact on the clinical management of patients and <1% resulted in clinically significant changes.

Conclusions: These findings indicate the PSC, lysed using a two-hour method, is a suitable alternative to plasma for HIV-1 drug resistance testing. Plasma Separation Cards may increase access to HIV drug resistance testing in settings experiencing challenges using plasma.

OAB0404

Evaluation of new high-throughput platforms for the quantification of HIV-1 RNA in plasma to support scale-up of viral load testing in low- and middle-income countries

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Background: Roche announced that the conventional COBAS AmpliPrep/COBAS TaqMan (CAP/CTM) system will be phased out by early 2024 and replaced with new high-throughput systems, such as the Roche cobas 4800 (c4800) and the cobas 6800/8800 (c6800/c8800). We sought to independently evaluate the analytical and clinical performance of the c4800 and the c6800/c8800 for HIV-1 viral load testing using plasma for the World Health Organization Prequalification (WHO-PQ) and for use in President's Emergency Plan for AIDS Relief (PEPFAR)-supported countries.

Methods: Analytical performance, including the limit of detection (LOD), precision, linear reportable range, subtype detection, and cross-contamination, were evaluated at the Centers for Disease Control and Prevention using the third WHO HIV-1 RNA Standard and virus culture covering HIV-1 subtypes A, B, C, D, and CRF02-AG. Remnant clinical specimens (n=1,349) were tested in South Africa to assess the assays' accuracy and agreement with the reference assay on CAP/CTM. LOD was calculated using PROBIT analysis. Bland-Altman and correlation analysis were used to analyze the bias and measurement agreement.

Results: LOD was estimated to be 20.6 copies/mL (95% confidence interval [CI]: 14.9-40.5) for the c4800 and 12.5 copies/mL (95% CI: 8.9-43.5) for the c6800/c8800. Within-laboratory standard deviations were less than 0.2 $\log_{10}$ copies/mL on both platforms. A high degree of linearity was seen on all tested subtypes for the both platforms with R^2 values greater than 0.98. No cross-contamination was observed for either platform. When compared to the reference assay, the c4800 had a demonstrated sensitivity of 96.8% (95% CI 93.8-98.4) and a specificity of 98.8% (93.6-99.8) in detecting virologic failure (viral load ≥1,000 copies/mL), whereas the c6800/c8800 had a sensitivity of 98.0% (95.3-99.1) and a specificity of 94.9% (89.9-97.5). The average bias between the new assay and the reference assay was less than 0.12 $\log_{10}$ copies/mL for both platforms.

Conclusions: The c4800 and c6800/c8800 demonstrate comparable accuracy and precision to the reference method. The improved chemistry of c6800/c8800 makes it more sensitive and supports use as the new reference standard for plasma viral load testing. These findings contributed to WHO-PQ and PEPFAR approval for their use in scale-up of viral load testing in low-and middle-income countries.

OAB0405

APOBEC editing in HIV DNA proviral *vif* and *pol* long-reads issued from virologically-suppressed patients included in the ANRS LAMIDOL trial

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Background: In HIV-1, hypermutated viruses induced by APOBEC3F/3G cytidine-deaminase activity represent a part of defective viruses. Few data are available with long-reads UDS technology regarding the linkage of APOBEC3F/3G editing. The objective of this study was to assess the proportion of APOBEC3F/3G defective viruses in PBMC from ARV-treated patients with prolonged virological suppression.

Methods: UDS of *vif* (579pb) and *pol* (3012pb) regions was performed on HIV-DNA from PBMC collected at baseline from virologically-suppressed patients since a median of 4.5 years, switched to DTG+3TC in the ANRS167-LAMIDOL trial. Long-reads were obtained using PacBio-Sequel system, alignments were performed with Geneious. In-house Python programs were designed to identify defective sequences and APOBEC-related resistance mutations (APOMut). All hypermutated sequences and those containing at least one stop codon were considered defective.

Results: Among the 110 patients assessed, HIV vif and pol sequencing was available for 79 and 19, respectively. The median number of reads was 2,200 (IQR=1,460-2,931) and 5,978 (IQR=5,357-8,023) for vif and pol, respectively. At least one proviral defective read was detected in 15 patients (19%, IC95%=11.0-29.4) in vif and 9 (47%, IC95=24.4-71.1) in pol. When present, the median percentage of reads with at least 1 stop codon was 36.2% (IQR=28.7-100) and 4.2% (IQR=1.8-37.1), in vif and pol,respectively. Hypermutated reads were detected in proviruses of 3 (3.8%, IC95=0.8-10.7) and 4 (21.1%, IC95=6.1-45.6) patients, in vif and pol,respectively. 11 APOMut were detected in HIV-DNA of 5 patients (26%): D30N, M46I and G73S in protease (all in a single patient); E138K (n=1), M184I (n=3) and M230I (n=3) in RT; E138K (n=1) in integrase. Eight of the 11 APOMut were present in minority proportions (range=1.1-14.7%). Overall, APOMut and stop codons were present on the same reads in 98% of cases.

Conclusions: In these ART-treated patients with prolonged virological suppression, 19% of *vif* and 47% of *pol* sequences harbored at least one defective provirus. Long-read UDS showed that stop codons and APOMut were linked on the same read in almost all cases. In addition, we showed that virological suppression was maintained on DTG+3TC despite baseline minority APOMut in 26% of cases.

OAB05 Pregnancy, children & adolescents

OAB0501

HIV immune reconstitution inflammatory response syndrome and the risk of adverse pregnancy-fetal outcomes among ART naïve women aged 20-49 years in selected public hospitals, Nairobi, Kenya

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Background: This study described the incidence of adverse pregnancy-fetal outcomes (APFOs) in Kenyan HIV-infected ART-naive pregnant women and examined the relationship between maternal HIV-immune reconstitution inflammatory response syndrome (IRIS) /related risk factors and APFOs. This prospective cohort study was carried out among 102 HIV-IRIS-exposed and 102 HIV-IRIS non-exposed pregnant women after initiating ART.

Methods: Both groups were enrolled from two hospitals in Nairobi County, Kenya in July 2019. Data were collected in a standard structured form, including maternal and demographic characteristics, HIV-IRIS status, HIV-IRIS related factors, and their pregnancy outcomes. APFOs were assessed by maternal HIV-IRIS status and HIV-IRIS related factors using logistic regression analysis.

Results: The incidence of APFOs, over the entire period, in IRIS versus non-IRIS, was 26.47% and 10.78% and the rates were 0.012 and 0.0045 per person's week, respectively. The RRs of APFOs was double-fold among IRIS cases compared to non-IRIS cases RR (2, 2.69, and 2) respectively. IRIS cases were three times more likely to experience an APFO compared to non-IRIS cases [OR=3; 95% CI: 1.4-6.4; P=.004]. At specific visit times, APFOs were associated with IRIS mostly at delivery (P=0.006) as compared to other times; [OR=2.1; 95%CI: 0.502-8.482; P=.0.16]; [OR=2.5; 95%CI: 1.295-8.121; P=.0.006] and [OR=2.4; 95%CI: 0.216-27.286; P=0.71]. APFOs with higher frequencies at specific points among IRIS and non-IRIS cases were; at the end of the second trimester; miscarriage, 3 (2.9%), 2 (2.0%), at delivery; LBW 11 (10.8%), 3 (2.9%) and within two weeks after delivery; newborn intensive care admission (newborn jaundice) 2 (2.0%), 1 (1.0%), respectively all with p> .05 about HIV-IRIS. LBW showed the highest incidence/significance relative to IRIS [OR=3.8; 95%CI: 1.079, 14.754; P=0.0019]. Multiple logistic regression for the entire follow-up period dropped maternal HIV-IRIS and revealed HIV-RNA viral load at baseline of above 50 copies/ml [AOR=2.7; 95%CI: 1.2-6.3; P=.017], closely, maternal placental syndrome (MPS) characterized by hypertensive events [AOR=0.1; 95%CI:0.0-1.0; P = .052] and mother's general health during delivery [AOR= 4; 95%CI: 4.0:1.8-9.1;P=.001] as independent predictors of APFOs.

Conclusions: Maternal HIV-IRIS was associated with significantly increased risks of APFOs. Modifiable risk factors should be monitored and controlled in clinical practice more so towards delivery.

OAB0502

Factors associated with severity of Edinburgh Postnatal Depression Screen (EPDS) and optimal cut-off of EPDS for diagnosis of depression and anxiety among postpartum HIV- positive women in Lusaka, Zambia

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Background: Postnatal depression (PND) may affect adherence to HIV treatment and thus postnatal HIV transmission. The Edinburgh Postnatal Depression Screen (EPDS), widely used to screen for PND, has not been previously validated in HIV-infected, perinatal women in LMICs. Additionally, factors associated with severity of depression are unknown.

Methods: As part of PND treatment study, we screened HIV-infected women with the EPDS between 6-10 weeks postpartum. To identify women at the lower symptom threshold, those scoring ≥6 of 30 were referred for a Mini International Neuropsychiatric Interview (MINI). The optimal EPDS threshold for diagnosis of depression was determined using receiver operating characteristic (ROC) curve analysis. Multiple imputation was used to characterize those with EPDS<6. Based on the literature, mild depression was defined as an EPDS 7-13 and moderate to severe as an EPDS ≥14. Differences between groups and factors associated with severity of depression were calculated using Chi square and t-tests.

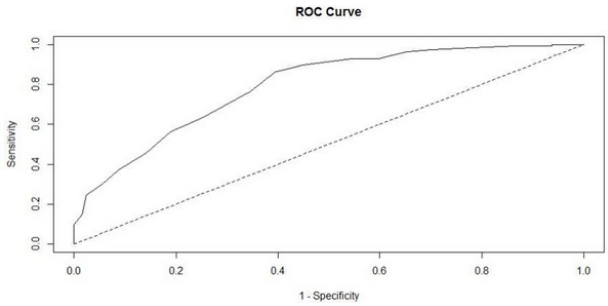

Figure 1: Receiver Operating Characteristic (ROC) curve for optimal EPDS threshold defining depression

Results: 192/240 (80%) women screened had an EPDS ≥6 , of whom 120 (63%) agreed to undergo MINI evaluation. Using the MINI diagnostic tool, an EPDS score of 10 performed best at discriminating depression with sensitivity of 86% and specificity of 61%. The area under the curve was 0.79 after imputation. 59 MINI-evaluated women (49%) scored ≥14, indicating moderate/severe depression. Factors associated with an EPDS ≤ 13 were living with partner (RR=0.63; 95% CI 0.44, 0.90; p=0.01), living in poverty (RR=0.68; 95% CI 0.47, 0.98; p=0.04) and having fewer life stressors (mean difference -1.0 (-1.8, -0.2) p=0.01).

Conclusions: An EPDS ≥ 10 is the optimal threshold for determining depression in HIV- infected postpartum women. Among women evaluated with a MINI, women with moderate to severe depression were more likely to not live with a partner and have a greater number of life stressors.

OAB0503

Longitudinal study on insulin resistance and metabolic syndrome in children with perinatal HIV infection and HIV exposed uninfected children in South Africa

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Background: HIV is associated with insulin resistance and Metabolic Syndrome, driven by HIV-associated immune dysregulation and by antiretroviral therapy (ART). However, few longitudinal studies have been conducted in children living with perinatally-acquired HIV (CLpHIV). We evaluated the trajectory of insulin resistance and Metabolic Syndrome in CLpHIV compared to children who are HIV-unexposed and uninfected (CHUU), and children who are HIV-exposed and uninfected (CHEU).

Methods: The study included children previously part of the Children with HIV Early antiRetroviral (CHER) trial and P1060 trial followed at Tygerberg Children's Hospital in South Africa between 2014 and 2020, along with CHEU and CHUU from the same communities. The cohort comprised 485 children, with 141 CLpHIV, 169 CHEU and 175 CHUU, with a median age at baseline of 9 years. The main outcome was the Homeostatic Model Assessment of Insulin Resistance (HOMA-IR), and secondary outcomes included LDL cholesterol, triglyceride-to-HDL ratio, android fat mass and systolic blood pressure. We used a mixed effects model to model the progression of metabolic indicators over time in each HIV group. Directed Acyclic Graph analysis was used to identify covariates, whereafter the following were considered as confounders: gender, height, age group, Tanner puberty stage and ethnicity.

Results: Adjusted mean HOMA-IR was 15% (95%CI:2%–29%) greater in CLpHIV than CHUU. Adjusted mean triglyceride-to-HDL ratio was 48%(95%CI:35%–62%) greater in CLpHIV than CHUU, and the adjusted mean LDL was 0.25 mmol/L greater in CLpHIV than CHUU (95%CI:0.11–0.40). In all analyses, no significant difference was found between CHEU and CHUU.

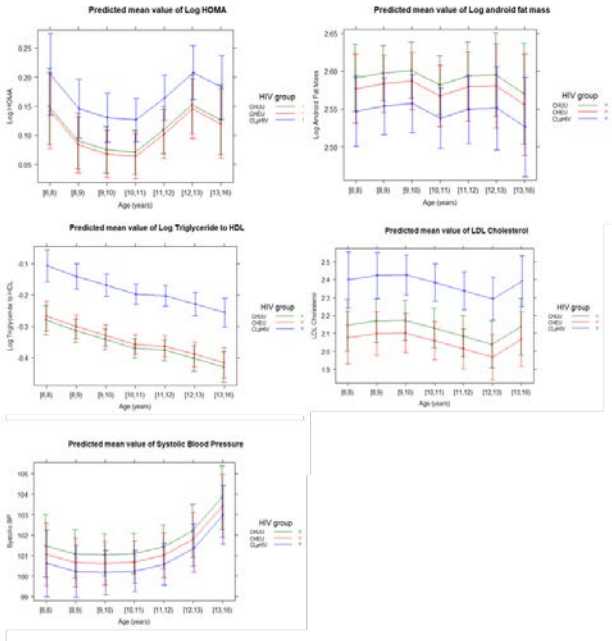

Figure 1: Predicted values for each metabolic indicator over time, by HIV group

Conclusions: CLpHIV have persistently elevated insulin resistance, triglyceride-to-HDL ratio and LDL cholesterol into puberty, and therefore should be monitored carefully for subclinical cardiovascular disease and receive appropriate preventative interventions, as CLpHIV will have a lifelong exposure to HIV-associated immune dysregulation and ART.

OAB0504

The road to success is paved with dolutegravir: Dolutegravir treatment success among in children and adolescents living with HIV (CALHIV) at the Baylor Tanzania Centres of Excellence

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Background: Efficacy and safety data of novel antiretrovirals, such as dolutegravir (DTG), in children and adolescents often lags behind adult data, and can lead to hesitation and slow uptake by HIV clinicians. Beginning in 2019, the Baylor Tanzania program began an enthusiastic rollout of DTG among CALHIV. We describe outcomes and safety data of this DTG rollout among CALHIV enrolled at the Baylor Tanzania clinics in Mbeya and Mwanza, Tanzania.

Methods: Retrospective chart review was conducted to describe outcomes and safety data of CALHIV who received DTG as part of their ART at the Baylor College of Medicine Children's Foundation – Tanzania Centres of Excellence (COEs) in Mbeya and Mwanza, Tanzania between 1 March 2019 (when DTG became available) and 30 November 2020. HIV viral load(VL) suppression was defined as VL<1000 copies/mL.

Results: A total of 1703 CALHIV received DTG, representing 62.4% (1703/2727) of all CALHIV on ART and 78.1% (1703/2180) of CALHIV eligible for DTG by weight (>20kg) at the COE. TLD was used in 57.0% (970/1703), followed by 39.2% (667/1703) on ABC-3TC-DTG and 3.9% (66/170-3) on AZT-3TC-DTG. Among the DTG cohort, 13.6% (231/1703) were new ART initiations, 63.2% (1077/1703) were shifted from a NNRTI regimen, and 23.2% (395/1703) were shifted from a PI regimen.

Outcomes revealed no severe drug toxicity and no discontinuations of DTG, with 98.3% (1674/1703) remaining active in COE care and 1.7% (29/1703) transferred out. Multi-month prescriptions were used in 73.6% (1254/1703) of DTG patients. At the end of the study period, 92.4% (1002/1084) of patients on DTG with documented VL were suppressed, compared to 86.4% (1257/1455) of those with VLs prior to DTG. Among those with pre- and post-DTG VLs (n=908), 85.6% (149/174) of previously unsuppressed became suppressed, and 94.6% (694/734) of previously suppressed remained suppressed.

Conclusions: DTG was well tolerated and highly effective in our clinically diverse cohort of CALHIV, and it use resulted viral suppression for many previously unsuppressed CALHIV. These results encourage widespread use of DTG among eligible CALHIV, especially those who remain unsuppressed on their current regimens.

OAB0505

Neuropsychiatric manifestations and sleep disturbances in children and adolescents randomised to dolutegravir-based ART vs standard-of-care in the ODYSSEY trial

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Background: Dolutegravir is associated with neuropsychiatric adverse events (NPAEs) in adults. We present first randomised data in children and adolescents.

Methods: ODYSSEY is an open-label, multi-centre, randomised trial, comparing efficacy and safety of dolutegravir-based ART(DTG) with standard of care (SOC) in children initiating first- or second-line therapy. We compared NPAEs, including serious adverse events (SAEs), grade ≥3 events, ART-modifying events and suicidality-related events, and patient/carer mood-and-sleep questionnaire responses in DTG versus SOC.

Results: 707 children ≥14kg were randomised (sub-Saharan Africa 88%, Thailand 9%, Europe 4%); 311 children started first-line (92% efavirenz-based in SOC); 396 second-line(98% PI-based). Median(IQR) age was 12.2 (9.1,14.9); 362 (51%) were male; median follow-up 142 (124,159) weeks. There were 31 NPAEs (in 23 children): 18 (15) in DTG vs 13 (8) in SOC (Table). Median (IQR) age and time from enrolment at first event were 15.9 (10.4,17.5) years and 72 (47,124) weeks respectively. Most NPAEs (23) were in children starting first-line; and most (22) occurred in males. Ten participants (5 DTG;5 SOC) had 13 SAEs: 7 DTG (3 epilepsy/convulsions, 1 headache/hypertension, 1 depression, 1 parasuicide, 1 psychosis) vs 6 SOC (3 epilepsy/convulsions, 1 dizziness, 2 parasuicide). 12 children (8 DTG;4 SOC) experienced 15 suicidality events: 10 suicidality ideation (6 DTG;4 SOC) and 5 parasuicide (2 DTG;3 SOC). ART-modifying NPAE(s) included 3 DTG (2 depression, 1 psychosis) and 2 SOC (1 parasuicide, 1 dizziness).

Small number of participants/carers reported symptoms of self-harm (8 DTG;1 SOC, p=0.04), "life was not worth living" (17 DTG; 5 SOC, p=0.009) or suicidal thoughts (13 DTG; 0 SOC, p<0.001) in mood-and-sleep questionnaires; the reported symptoms were transient and did not lead to treatment change. There were no differences between treatment groups in low mood/feeling sad, problems concentrating, feeling worried or feeling angry/aggressive, time to fall asleep, nightmares/vivid dreams or sleep quality.

Conclusions: Numbers of NPAEs and reported neuropsychiatric symptoms were low. More participants reported neuropsychiatric symptoms in the DTG arm vs SOC, however this difference should be interpreted with caution in an open-label trial.

	DTG, N=350		SOC, N=357		Total, N=707		P-value
All neuropsychiatric adverse events, N [N participants]	18	[15]	13	[8]	31	[23]	0.125*
-Neurological adverse events	6	[6]	6	[5]	12	[11]	0.736*
-Psychiatric adverse events	12	[10]	7	[4]	19	[14]	0.112*
Serious adverse events	7	[5]	6	[5]	13	[10]	
Grade ≥3 adverse events	12	[9]	8	[7]	20	[16]	
ART-modifying events	3	[3]	2	[2]	5	[5]	
Hazard Ratio for time to first NPAE[§] (95% CI)	1.87 (0.79, 4.41)		1(ref)				0.154

NPAE= neuropsychiatric adverse events. *Comparing number of participants with at least 1 event. [§]Adjusted for ODYSSEY A and B.

Table. Summary of neuropsychiatric adverse events in ODYSSEY

OAC01 Proof in the pudding: PrEP outcomes in diverse settings

OAC0101

Global adoption of guidelines on and use of oral pre-exposure prophylaxis (PrEP): current situation and future projections

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Background: With the 2020 global target of three million oral pre-exposure prophylaxis (PrEP) users set during the UN General Assembly in 2016 at an end, we assessed global trends in the adoption of World Health Organization (WHO) PrEP recommendations into national guidelines and numbers of PrEP users, and estimated future trajectories of PrEP users.

Methods: Data obtained through the Global AIDS Monitoring (GAM) and WHO regional offices was collated to report numbers of PrEP users and WHO PrEP recommendations adoption by country for 2016-2019. To forecast PrEP user numbers until 2023, model countries were selected in each region. PrEP use growth rates observed in these model countries were applied to countries in corresponding regions under different scenarios, including a COVID-19 disruption scenario with static global PrEP use in 2020.

Results: In 2019, there were 630,000 PrEP users across 76 countries (41% in Americas region and 36% in African region), a 70% increase from 2018. 124 countries had adopted the WHO PrEP recommendations in

national guidelines: 35 countries in 2018 and 24 in 2019. Without COVID-19 disruptions, 1.0-1.1 million global PrEP users by the end of 2020 and 2.4-5.2 million by 2023 were projected (see figure).

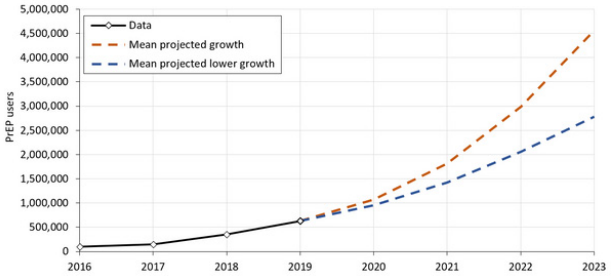

Figure. Global numbers of PrEP users (2016-2019) and mean projected PrEP user growth (2020-2023) under growth rates observed in model countries and lower growth scenarios.

Conclusions: Widespread adoption of WHO PrEP recommendations coincided with a global increase in PrEP use. While the 2020 global PrEP target will be missed, we estimated future growth in PrEP use. In many countries, PrEP user numbers are small relative to numbers of new HIV infections and PrEP recommendations are not implemented at scale, limiting current impact of PrEP on reducing HIV incidence. New PrEP products could expand the PrEP user base and, together with greater oral PrEP use through simplified delivery, PrEP could make a significant contribution to ending AIDS by 2030.

OAC0102

Early predictors of seroconversion among enrolees in a PrEP program in Brazil, Mexico and Peru – the IMPREP Demonstration study

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Background: ImPrEP, a PrEP Demonstration Project for men who have sex with men (MSM) and transwomen in public health facilities in Brazil, Mexico and Peru, started enrolling mid-2018 and as of December 2020 included 3842, 3005 and 2265 participants, respectively. Since PrEP effectiveness requires personal commitment, PrEP programs should offer additional support to people more likely to seroconvert. In this analysis we assessed seroconversion in the cohort and modeled its early predictors.

Methods: ImPrEP enrolled consenting, HIV negative MSM and transwomen 18+ y.o. reporting recent (within 6 months): condomless anal sex; HIV positive/unknown status sex partner; STI diagnosis or signs/symptoms; or transactional sex. Enrolled participants received 30-days of PrEP and returned at 1-month for a safety visit; subsequent prescriptions and visits were quarterly, all visits included HIV testing and behavioral assessments. Adherence was measured using the medication possession ratio (MPR): the number of pills prescribed divided by the days between visits. Anyone who tested HIV-positive post-enrollment were withdrawn from the cohort and linked to HIV care. Cox regression was used to identify early predictors of seroconversion, including baseline socio-demographics and behaviors, plus MPR at the 1-month visit; the multivariate Cox model included all variables with p values <0.1, controlling by gender and country.

Results: Seroconversions by country, population and age group are shown in Table 1 below. In the multivariate Cox model, risk of seroconversion was associated with being 18-24 y.o. (aHR 4.8, 95%CI 2.3-10.1), condomless receptive anal sex (aHR 2.0, 95%CI 1.1-3.6), MPR of 0.53-1 (aHR 2.8, 95%CI 1.5-4.9); MPR<0.53 (aHR 3.7, 95%CI 1.8-7.6), and being from Peru (aHR 4.0, 95%CI 2.0-7.9), controlling for gender, transactional sex, and initial intention to use PrEP.

Country	MSM 18-24 n [rate (95% CI)]	TW 18-24 n [rate (95% CI)]	MSM 25+ n [rate (95% CI)]	TW 25+ n [rate (95% CI)]	TOTAL n [rate (95% CI)]
Brazil	10 [0.87 (0.42-1.61)]	1 [1.94 (0.05-10.81)]	4 [0.1 (0.03-0.26)]	0 [0.00 (0.00-2.82)]	15 [0.28 (0.16-0.47)]
Mexico	4 [1.16 (0.32-2.97)]	0 [0.00 (0.00-49.92)]	7 [0.4 (0.16-0.82)]	0 [0.00 (0.00-18.01)]	11 [0.52 (0.26-0.92)]
Peru	22 [4.05 (2.54-6.13)]	4 [9.47 (2.58-24.24)]	17 [1.71 (0.99-2.73)]	3 [1.71 (0.35-5.00)]	46 [2.62 (1.92-3.49)]
TOTAL	36 [1.77 (1.24-2.45)]	5 [4.94 (1.60-11.53)]	28 [0.42 (0.28-0.6)]	3 [0.92 (0.19-2.68)]	72 [0.79 (0.62-0.99)]

Table 1. Seroconversions by Country, Population and Age Group.

Conclusions: The risk for seroconversion in ImPrEP was associated with younger age (18-24), being from Peru, reporting condomless receptive anal sex, and early signs of non-adherence (low MPR). Strategies are needed to support enrollees with these criteria to remain adherent and prevent seroconversion.

OAC0103

Comparing adherence to HIV Pre-Exposure Prophylaxis (PrEP) among new, male PrEP users initiating F/TAF vs. F/TDF

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Background: Pre-exposure prophylaxis (PrEP) with emtricitabine/tenofovir disoproxil fumarate or tenofovir alafenamide (F/TDF or F/TAF) is effective at preventing HIV when used consistently. There are limited real-world data that compare adherence and seroconversion rates for F/TAF and F/TDF over concurrent timeframes. This study compared adherence measures and HIV incidence in new PrEP users initiating either F/TAF or F/TDF using a real-world database.

Methods: This retrospective longitudinal analysis used PurpleLab, a nationally representative medical and pharmacy claims database (all U.S. payer types). Eligible users were (recorded as) male adults (≥18 years) with no history of PrEP (variable baseline from 10/1/2015), initiating F/TAF or F/TDF 10/1/2019-1/31/2020 (index date) with ≥1 medical claim 30 days prior (for improved linkage to clinical records). Users with evidence of HIV/HepB treatment or ≥1 HIV/HepB diagnosis (-12 months to +30 days of index date) were excluded. Included users were followed for ≥240 days.

Outcomes included: proportion of days covered (PDC), adherence (PDC ≥0.8), and seroconversion (≥1 claim with HIV diagnosis). Differences in outcomes were assessed using Chi-square and T-tests. Multivariable logistic regression estimated the effect of PrEP regimen on adherence, controlling for age group, geography and type of insurance.

Results: A total of 1,113 F/TAF and 1,961 F/TDF users met study criteria. Adherence dropped over time for both regimens; F/TAF users had significantly higher mean PDC and adherence (PDC ≥0.8) at all time points (Table).

In multivariable analyses, F/TAF users had 1.67 higher odds of adherence (PDC ≥0.8) relative to F/TDF (180 days; P<0.0001); adherence odds also increased with older age, private insurance. Differences between seroconversion rates (F/TAF: 1.24/100 person-years; F/TDF: 1.80/100 person-years) were not significant (p>0.05).

Regimen	Mean PDC (180d)	Mean PDC (210d)	Mean PDC (240d)	Adherence (180d)	Adherence (210d)	Adherence (240d)
F/TAF (n=1,113)	0.65**	0.62**	0.58**	47%**	44%**	36%**
F/TDF (n=1,961)	0.57	0.53	0.50	34%	31%	23%
PDC: proportion of days covered; Adherence: proportion of users with PDC ≥0.8; d = days of follow up ** differences significant at p<0.0001 comparing F/TAF to F/TDF over follow up period						

Table: Adherence Measures Over Time, by PrEP regimen

Conclusions: These results are the first to compare adherence to F/TDF and F/TAF over concurrent timeframes, using real-world data. F/TAF users had higher levels of adherence, compared to F/TDF users over the same period. Overall seroconversion rates were low for both F/TDF and F/TAF; the study did not have sufficient power to detect differences between the two cohorts.

OAC0104

Variation in preferences for long-acting injectable PrEP among US men who have sex with men: a latent class analysis

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Background: Cabotegravir long-acting injectable HIV pre-exposure prophylaxis (LAI-PrEP) is shown to be safe and efficacious. Understanding variations in potential user preferences for LAI-PrEP may be useful to inform segmented implementation strategies, and subsequently improve uptake and thus community-level effectiveness.

Methods: HIV-negative, sexually active men who have sex with men (MSM) aged ≥15 living in the US were recruited online for the 2019 American Men's Internet Survey. They completed a discrete-choice experiment with nine paired profiles with hypothetical LAI-PrEP attributes: out-of-pocket cost, perceived side effects, injection frequency, perceived stigma, and service location. Latent class analysis was used to segment respondents into groups based on their preferences for the hypothetical attributes presented, and relative importance of preference weights and willingness-to-pay were calculated. Finally, associations with group membership based on sociodemographic characteristics and sexual risk behavior were tested using logistic regression.

Results: Two latent classes emerged from 2,206 respondents. "Value-conscious" respondents (30%) exhibited strong dislike for higher out-of-pocket cost. Cost was 2.5 times more important than frequency and perceived side effects. "Outcomes-conscious" respondents (70%) exhibited a strong dislike for perceived severe side effects. Their dislike for severe side effects was 3.2 times more important than cost.

Neither group ascribed importance to service location nor stigma. Value-conscious respondents were significantly younger (mean [IQR]: 29.1 [21-33] vs. 31.3 [22-37] years, chi-2 p<0.000), more likely to be racial/ethnic minorities, less educated, live in rural areas, and have public or no insurance.

Outcome-conscious respondents were marginally more likely to have ever used oral PrEP and were significantly less likely to have had condomless anal sex with an HIV-serodiscordant partner in the past year or to have only casual partners. Willingness-to-pay analysis demonstrated that the outcomes-conscious class would pay $354 to avoid side effects (vs. $32 in the value-conscious class).

Conclusions: Perceived side effects emerged as an important barrier for uptake of hypothetical LAI-PrEP for a large proportion of potential MSM users. Minimizing out-of-pocket costs is likely to increase uptake, especially among younger racial minority groups, and is important to equitable access. Tailored communication strategies are recommended for the two different groups of potential LAI-PrEP users.

OAC0105

Estimated long-acting PrEP effectiveness in the HPTN 084 cohort using a model-based HIV incidence in the absence of PrEP

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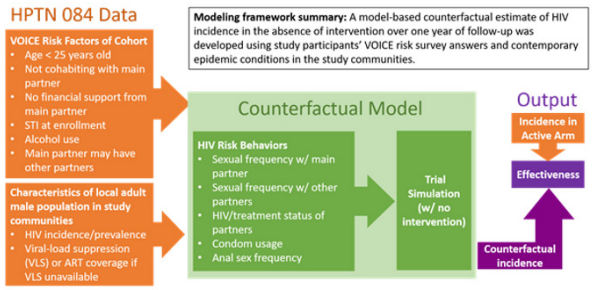
Background: HPTN 084 is a randomized double-blind controlled-superiority study assessing the safety and efficacy of long-acting injectable cabotegravir for pre-exposure prophylaxis (CAB-LA) for preventing HIV in African women aged 18-45 years. Daily oral tenofovir disoproxil fumarate and emtricitabine (TDF/FTC) was an active comparator; there was no placebo control. We estimate the incidence in a hypothetical placebo control arm and project the effectiveness of CAB-LA compared to placebo.

Methods: Our model-based counterfactual predicts HIV risk in cohorts of sub-Saharan Africa (SSA) women based on individual VOICE risk scores and HIV incidence, prevalence, and viral load suppression among adult males in the communities of each trial site. HIV risk is used to predict cumulative HIV incidence over one year of follow-up. This model was calibrated to data from the VOICE trial and previously validated by comparing predicted HIV incidence to that observed in HPTN 035, FEM-PrEP, ASPIRE, and ECHO.



Results: Overall, we project a counterfactual placebo incidence of 2.2% (95% cred. int. 1.7% - 2.8%) in the HPTN 084 study cohort compared to 0.2% (95% conf. int. 0.06-0.52%) in the CAB-LA arm and 1.86% (95% conf. int. 1.3-2.57) in the TDF/FTC arm, suggesting an effectiveness against HIV acquisition of 91% (95% cred. int. 76%-97%) and 15% (95% cred. int. -26%-44%), respectively, compared to placebo.

Conclusions: For ethical reasons effectiveness of new HIV prevention products, such as CAB-LA, must be compared to an approved PrEP product such as TDF/FTC, whose effectiveness depends on adherence. Counterfactual estimates of incidence allow for comparison of such products against a hypothetical placebo control. This model-based counterfactual, using contemporary epidemic data and participant risk factors, provides additional assurance that CAB-LA reduced HIV acquisition risk by 90% among women in SSA. This effectiveness estimate can be further refined and validated with additional counterfactuals using other data and methodologies.

OAC02 COVID-19 and HIV: Reaching key populations

OAC0201

SARS CoV-2 seroprevalence among HIV-negative participants using tenofovir/emtricitabine- based PrEP in 2020 – a sub-study of PREVENIR-ANRS and SAPRIS-Sero

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Background: Tenofovir (TDF) has shown activity on the SARS-CoV-2 RdR polymerase *in vitro* and in ferrets. There is controversy regarding the potential benefit of TDF to reduce SARS-CoV-2 infection or COVID-19-related morbidity. Our objective was to compare the seroprevalence rates of SARS CoV-2 IgG among male participants using TDF/FTC-based PrEP and matched controls.

Methods: Male participants from the PREVENIR study conducted in Ile de France, who are receiving on demand or daily PrEP and with an available sample between May and October 2020 were included in this study. The Sapris-Sero study was a sub-study of the national Sapris cohort, with several wave of sampling from May 2020 after the end of the March-May lockdown. Male participants of the SAPRIS-Sero study living in Ile de France were matched to each PREVENIR participant on age (± 5 years), socio-occupational category and date of sampling (± 1 month). Odd Ratios (OR) of the comparison between the 2 studies was calculated using stratified logistic regression. SARS-CoV2 IgG anti S was measured using the Abbott SARS-CoV-2 IgG II Quant antibody test in PREVENIR and the Euroimmuns Anti-SARS-CoV-2 ELISA IgG test in SAPRIS-Sero.

Results: In PREVENIR, 844 participants with a median (IQR) age of 38 (31 – 45) years were matched to 844 participants of SAPRIS-Sero cohort, aged of 41 (35 – 48) years. Matching was possible on the 3 variables for 729 participants. PrEP was on demand in 420 (49.8%) and daily in 424 (50.2%) individuals. For PREVENIR and SAPRIS-Sero cohorts, SARS CoV-2 IgG was negative in 753 (89.2%) and 738 (87.4%) subjects, low positive/undetermined in 4 (0.5%) and 28 (3.3%) and positive in 87 (10.3%) and 78 (9.2%), respectively. Considering low positive /undetermined as negative, OR was estimated as 1.13 (0.82-1.53). Sensitivity analyses (restricted to full matched samples and/or considering undetermined as positive) led to similar results.

Conclusions: Prevalence of SARS-CoV-2 IgG was similar in PrEP users and in a matched cohort in the Paris region after the COVID lockdown suggesting that TDF/FTC has no role in reducing SARS-CoV-2 acquisition.

OAC0202

Demand creation and HIV self-testing delivery during COVID-19 contingency measures of physical distancing among adolescents' key population enrolled in PrEP in Brazil

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Background: HIV self-testing (HIVST) helps to prevent disruptions in the HIV testing services during COVID-19 pandemic especially among adolescent's key population (AKP) of men who have sex with men and transgender women. We aimed to analyze HIVST distribution to AKP in PrEP1519 cohort as part of the COVID-19 contingency plan.

Description: Data is from the first PrEP demonstration cohort study among AKP aged 15-19 years old ongoing in three large Brazilian cities (PrEP1519). During physical distancing measures (PDM), started in March 2019 in Brazil, demand creation via social media was intensified and an HIVST delivery strategy was adopted in PrEP1519 clinics. A package with an HIVST and guidance was made available for AKP to be pick-up at the clinics or by delivery services/mail to their preferred addresses. Video guidance was developed and publicized in PrEP1519 Instagram and YouTube. This analysis reports findings comparing the pre-pandemic (March 2019-March15th 2020) and pandemic (March 16th-December 2020) periods. Bivariate analysis and chi-square test were used to test differences in the HIVST distribution.

Lessons learned: 1,597 HIVST were delivered, 39.8% and 60.2% during the pre-pandemic and pandemic periods, respectively. The number of requests increased 86% during the pandemic, and 16% of these were delivered to home addresses. Among AKP who requested an HIVST before March 15th 2020, 27.1% reported private use, 24.0% gave to a sexual partner and 48.9% gave to a friend. COVID-19 pandemic changed these patterns: 78.7% reported private use, 8.9% gave to a sexual partner and 12.3% gave to a friend (p-value<0.001). Before the pandemic, most AKP used an HIVST because of condomless sex (34.0%) or as a checkup (34.0%). During PDM, condomless sex was reported by 49.6% as the main reason for self-testing.

Conclusions/Next steps: HIVST requests among Brazilians AKP in PrEP1519 cohort increased significantly. Demand creation via social media made it possible to reach more AKP and will be sustained even after PDM restrictions are lifted. These experiences offer important lessons for other middle-income countries, as well as other countries scaling up PrEP.

OAC0203

Real-world utilization of F/TDF and F/TAF for HIV Pre-exposure Prophylaxis during the COVID-19 pandemic in the US, December 2019 – June 2020

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Background: Extensive impact of the COVID-19 pandemic on health-care delivery has been reported, including impacts on the use of daily F/TDF and F/TAF for HIV pre-exposure prophylaxis (PrEP). Using a real-world claims database, we evaluated the utilization of PrEP in the United States (US) from December 2019 to June 2020.

Methods: HIV-1 negative individuals in the US who used F/TDF and F/TAF for PrEP between December 1, 2019 and June 31, 2020 were identified from a prescription claims database. We conducted a retrospective descriptive trend analysis.

Results: Over 46,000 individuals initiated F/TAF (median age 36 years, interquartile range, [IQR] 29–48) and 29,000 initiated F/TDF for PrEP (median age 31 years, IQR 25–40) between December 2019 and June 2020. Progressive drops in PrEP initiation were observed in February, March and April 2020, coinciding with the start of COVID-19 spread in the US and the resulting restrictions (Figure 1A). The overall number of PrEP users showed only a slight decrease after March 2020, mostly attributable to the attenuated increasing trend of F/TAF users after April (Figure 1B). PrEP initiation started to increase again after April, with more new PrEP prescriptions coming from family physicians and nurse practitioners/physician assistants and less from infectious disease physicians. Decreases in new PrEP use were seen in in multiple geographic areas and across race/ethnicity groups, with decreases most pronounced in white individuals living in the Southern US states (Figure 1C).

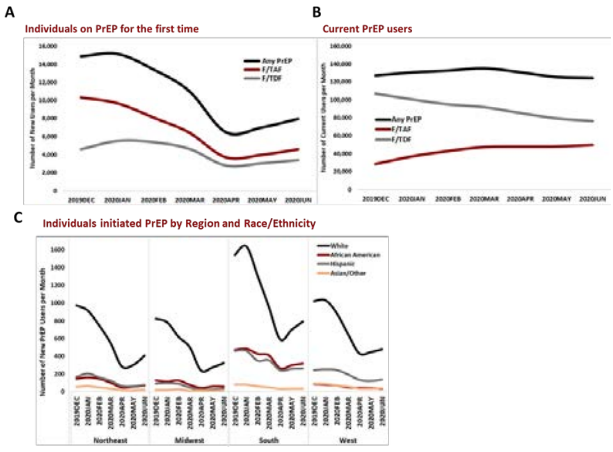

Figure 1

Conclusions: This real-world analysis demonstrates how prescription claims data can be utilized to track PrEP use amidst the significant impact of the COVID-19 pandemic. Our findings suggest that COVID-19 has had a substantial impact on PrEP initiations, while having a lesser impact on overall use. These findings suggest that targeted efforts will be needed to provide PrEP to new users during and after the pandemic.

OAC0204

Going online to ensure uninterrupted HIV services during COVID-19 in Nepal

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Background: In Nepal, the COVID-19 pandemic placed substantial pressure on HIV programs to adapt to new physical distancing policies and restrictions in movement that limited people from accessing HIV services in person. Building upon five years of online HIV service delivery, the PEPFAR- and USAID-supported LINKAGES and EpiC programs in Nepal amplified the government and community partners' online efforts to ensure safe and sustained HIV service access during the COVID-19 pandemic.

Description: From March to October 2020, EpiC Nepal supported a dramatic shift toward virtual client support and online HIV service access. New devices and mobile data packages were procured for outreach workers and community-based supporters to maintain contact with key populations and people living with HIV (PLHIV). Virtual and online support was also facilitated by the development and dissemination of new key messages on HIV and COVID-19 prevention, care, and treatment. EpiC upgraded the project's online reservation application,available at www.merosathi.net, with additional services available for booking and a new program-facing case management system. Several popular social media influencers were mobilized as "virtual peer champions" to promote benefits of HIV treatment and care, including through the newly available virtual or online channels.

Lessons learned: From March to October 2020, 40,230 individuals received information on HIV and COVID-19 prevention virtually—a rate five times higher than in the July 2019 to February 2020 period.A total of 11,744 PLHIV were reached virtually for treatment adherence support, monitoring, and education,which was not done before the COVID-19 pandemic; 906 individuals tested for HIV and 141 were diagnosed with HIV from online approaches. Among all the individuals (906) who were linked through online engagement to off-line HIV testing services, 16 percent received positive results—a rate three times higher than in the July 2019 to February 2020 period, when 612 individuals were tested and 31 individuals were diagnosed with HIV.

Conclusions/Next steps: Our findings suggest that online approaches provided continued service access for key populations and PLHIV. Institutionalizing virtual solutions in Nepal helped safeguard gains made in the HIV response from the ongoing COVID-19-related service disruptions and other future threats. Our experience helped facilitate formal adoption of online interventions in Nepal.

OAC0205

Uptake of oral pre-exposure prophylaxis for HIV infection among men who have sex with men and transgender: lessons learned during the SARS-CoV-2 pandemic from the first PrEP project in Myanmar

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Background: HIV is concentrated among key populations in Myanmar. The first HIV daily pre-exposure prophylaxis (PrEP) programme was initiated for men who have sex with men (MSM) and transgender (TG) by the medical organisation Medical Action Myanmar (MAM). Event-driven PrEP was not yet sanctioned. We assessed the uptake of daily PrEP and HIV-seroconversion. A lockdown following increasing SARS-CoV-2-cases required programmatic changes. We draw lessons learned from early findings.

Description: MAM estimated to enrol 200 HIV-negative MSM/TG on daily PrEP in six months in Yangon. Community-based peer educators (CBPE) raised awareness and provided counselling. Enrolled PrEP-users should visit the clinic after 1 and 3 months and three-monthly thereafter for HIV/STI-screening. Enrolment started July 31, 2020 and SARS-CoV-2-related stay-at-home measures were imposed on September 1. MAM swiftly adapted its strategy; CBPEs received support to use social media platforms and smart phones with a PrEP-appointment application. A PrEP-promotion webpage was launched. COVID precaution measures were implemented at the clinic. Counselling and history taking were done by phone and face-to-face appointments for drug re-supplies and HIV/STI-testing were made flexible.

Lessons learned: Of 695 eligible MSM/TG 243 (37%) were enrolled, 224 (92%) MSM, and 19 (8%) TG. The median age was 23 years (interquartile range: 20–28). Among 452 eligible MSM/TG who refused PrEP, 373 (83%) did so because they did not want to use daily PrEP, especially because social interaction was limited during lockdown. 487 phone consultations and 213 face-to-face consultations were done. Face-to-face client-staff contact time was reduced from 45 to 15 minutes. Among enrolled PrEP-clients, two (1%) had HIV-seroconversion. One tested indeterminate at month 1 and positive when the test was repeated. The other person stopped taking PrEP after 3 months and tested positive on return (month 5).

Conclusions/Next steps: The number of MSM and TG who inquired about PrEP was very high despite the SARS-CoV-2 lockdown. The use of social media and the webpage might have facilitated this. The number of MSM/TG enrolled was substantial but most eligible MSM/TSG refused PrEP because of the daily pill burden as sexual contact was infrequent. Event-driven PrEP could fill this important unmet need. Qualitative data could help understand barriers.

OAC0206

Combination HIV/HCV/HBV/STIs prevention among MSM and use of mobile applications/social networks at the COVID-19 conditions in Ukraine

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Background: The COVID-19 pandemic and restrictions on displacement have made it more difficult to provide HIV testing and PrEP services to MSM in large Ukrainian cities. The purpose of the intervention is to maintain the effectiveness of the provision of these services during COVID-19 and to implement new and innovative interventions in this regard, making the services more mobile.

Description: The methodology consists of conducting two national campaigns aimed at MSM recruiting in 3 largest cities of Ukraine, for conducting of HIV/STI/HCV testing, as well as to attract to the PrEP program, through targeted advertising on gay dating applications, search engines and in social networks for directing to web resources https://gettest.com.ua and https://prep.com.ua, for passing of testing and/or to receive equal counseling on PrEP by appointment, at Alliance.Global`s testing points. All MSM who have been positive result of HIV test, have been provided a social support to receive ART and be involved to the PLHIV/MSM support program. For HIV-negative MSM, we offer to become a member of the free PrEP program and provide of bonuses.

Lessons learned: Thanks to advertising on two web resources, during September-December 2020, 109,797 users visited the GetTest website, of which 841 MSM registered for HIV/HCV/STI testing and 80% of them were tested (the number of HIV-positive results was approximately 4%). 3244 MSM have learned about the PrEP program during this period, approximately 300 new MSM have been attracted to the PrEP program, in particular through bonuses and innovations such as taxi delivery, etc. (the coverage of the PrEP program in 3 cities in 2020 amounted about 1,300 MSM).

Conclusions/Next steps: Thanks to the introduction of two advertising campaigns on the Internet, in the conditions of lockdown and COVID-19 pandemic, as well as such innovative interventions as delivery of clients by taxi to receive PrEP in a medical institution, receiving the free premium accounts in the mobile gay application Hornet, compliance with sanitary norms (free masks, disinfectants, etc.) and mandatory pre-registration (to avoid queues), we were able to successfully provide services, and increase the intensity of testing and staging to the PrEP for MSM compared to the first half of 2020.

OAC03 Mind the gap: Comprehensive HIV prevention and sexual health services among key and priority populations

OAC0301

Outcomes of the Pride Plus Project for MSM/TW in Peru: a combination HIV intervention across the cascade of HIV prevention and care

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Background: Comprehensive HIV prevention and care strategies focused on MSM and transwomen (TW) in Peru remain elusive. We conducted a trial of a combination prevention strategy including establishing a community center led by MSM/TW for MSM/TW, small group training for MSM/TW, health care provider (HCP) training, and navigation for MSM/TW living with HIV.

Methods: In 2017 a cohort of MSM/TW was recruited in a southern neighborhood of Lima to assess intervention outcomes along the HIV prevention and care cascade. One baseline and 3 yearly follow-up assessments were planned (including anal swab NAAT testing for chlamydia/gonorrhea), but a strict lockdown in response to the epidemic of COVID-19 precluded follow-up 3. From June 2017 to July 2020 a community center for MSM/TW was active with trainings and social activities. HCP trainings were conducted in local hospitals and navigators supported MSM/TW living with HIV. To assess the intervention effect, the baseline and 2-year follow-up assessments were compared using 2-sided Fisher's exact tests; modeling is currently underway.

Results: The community center successfully engaged MSM/TW leading to an ongoing leadership core group of 25 individuals, small group sessions with 120 MSM and 76 TW, and weekly social and educational activities. Among the assessment cohort, HIV testing increased from 51% at baseline to 65% at the second follow-up, (p=0.005). Engagement in HIV care increased among cohort participants living with HIV with 46% reporting an undetectable viral load and being ART-adherent at baseline, compared to 59% at the final follow-up (p=0.010). However sexual behavior was not modified (all p-values >0.05) and asymptomatic STIs increased (p-value 0.023).

Outcome	Baseline	Final Follow-up	p-value
HIV Tested past 6 months (non-positives at assessment)	51.0%	65.3%	0.005
Undetectable & ART-adherent (HIV-positives)	45.5%	59.0%	0.010
Success (above two outcomes combined)	49.7%	59.8%	0.045
Positive for Chlamydia/Gonorrhea from rectal swabs	17.2%	27.4%	0.023
Unprotected anal intercourse	37.6%	29.9%	0.114
Condomless anal int. (total sample)[2]	49.0%	47.0%	0.765

[1] Condomless intercourse with participant mitigation (e.g., serosorting, strategic positioning, ART) is counted as a "NO"
[2] Any condomless act, regardless of circumstance is counted as a "YES"

Table 1: Outcome Measures Among a Community-Based Cohort of MSM and Transwomen Before and After a Combination HIV Prevention and Care Intervention

Conclusions: The Pride Plus Project yielded significant gains in HIV testing for HIV negatives and engagement in HIV care among MSM/TW living with HIV, the combined outcome of interest for this study. However, sexual behavior remained unchanged and asymptomatic STIs increased. Further analysis of these results is ongoing.

OAC0302

HIV pattern and cascade of care among incarcerated people in Iran: Findings of three consecutive national bio-behavioral surveillance surveys

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Background: In Iran, HIV outbreak was first noticed among incarcerated population in the mid-1990s, who mostly were infected through the use of shared needle for drug injection. We evaluated the prevalence and pattern of HIV and status of HIV care cascade among incarcerated people in Iran from 2010 to 2017.

Methods: Data were obtained from three consecutive national bio-behavioral surveillance surveys in 2010 (N =4536), 2013(N = 5490) and 2017(N = 5785) through a multistage cluster sampling in Iran. HIV was tested using the ELISA method in the two first rounds and a rapid test in the third round. Information on demographic characteristics, risky behaviors, and HIV testing and treatment was collected using face-to-face interviews. The viral suppression status was evaluated just among incarcerated people living with HIV who consented to be tested (N=20).

Results: The overall prevalence of HIV was decreasing. The prevalence was estimated at 2.1% (95% CI: 1.2%, 3.6%) in 2010, 1.7% (95% CI: 1.3%, 2.1%) in 2013, and 0.8% (95% CI: 0.6, 1.1) in 2017 (trend P-value <0.001). Among incarcerated people with a history of injection drug use, the HIV prevalence was estimated at 8.1% (95% CI: 4.6%, 13.7%) in 2010, 6.3 (95% CI: 4.8, 8.3) in 2013, and 3.9% (95% CI: 2.7, 5.7) in 2017. Based on the 2017 data, 32 out of 50 HIV-positive incarcerated people (64%) were aware of their HIV status. Overall, 9 out of 20 cases (45%) who tested for viral suppression and knew their HIV status were currently on ART of whom 44 %(n=4) reached the viral suppression load.

Conclusions: Despite the decreasing pattern of HIV among Iranian incarcerated people, engagement in treatment and virologic suppression is low. More efforts are needed for incarcerated people living with HIV to be linked in and retain to HIV care and treatment programs.

OAC0303

HIV risk behaviors among retail pharmacy clients seeking sexual and reproductive health services in Kenya

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Background: The delivery of pre-exposure prophylaxis (PrEP) for HIV prevention at retail pharmacies in Kenya may help overcome barriers (e.g., long wait times, stigma) to clinic-delivered PrEP and reach individuals that do not regularly seek clinic-based services. To understand the potential for this novel model of PrEP delivery, we evaluated HIV risk behavior among pharmacy clients seeking sexual and reproductive health (SRH) services in Kenya.

Methods: At four retail pharmacies in Kisumu and Thika, Kenya, willing clients seeking SRH services (e.g., family planning) were screened for PrEP eligibility as part of a pharmacy-based PrEP delivery pilot. To help determine eligibility, we used Kenya's PrEP Rapid Assessment Screening Tool (RAST) routinely used in public HIV comprehensive care clinics. In the RAST, clients report their HIV status and that of their sexual partner(s) as well as a number of behaviors associated with HIV risk, including condom use, engagement in transactional sex, and post-exposure prophylaxis (PEP) use. We reported findings using descriptive statistics.

Results: From November 2020 to February 2021, 227 pharmacy clients completed the RAST to determine PrEP eligibility. Many clients sought contraceptive services (e.g., oral or emergency contraception) (29%) or PrEP (22%). Other services sought included pregnancy testing (8%), sexual performance enhancing drugs (8%), or HIV self-testing (5%). The majority (80%) of clients reported some behavior associated with HIV acquisition risk. Over half of clients (55%) reported inconsistent condom use, more than half (51%) reported not knowing the HIV status of their sexual partner(s), and almost a third (28%) reported multiple sex partners.

Less commonly reported HIV associated risk behaviors included: sex under the influence of alcohol (11%), recurrent PEP use (4%), an STI in the past 6 months (4%), transactional sex (4%), and sex with partner(s) living with HIV (4%).

Conclusions: The prevalence of behaviors associated with HIV risk was high among clients accessing SRH services at retail pharmacies in Kenya. These findings suggest that the delivery of PrEP at retail pharmacies has great potential to expand the reach of PrEP to populations at HIV risk in Kenya and similar settings.

OAC0304

Key population lay providers can successfully link men who have sex with men clients to care after diagnosing sexually transmitted infections in community-based organizations in Thailand

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Background: Through the key-population-led health services (KPLHS) model, trained key population (KP) lay providers deliver comprehensive HIV-related services in community-based organizations (CBOs) in Thailand. To increase access to services for sexually transmitted infections (STIs), we integrated point-of-care (POC) GeneXpert testing for chlamydia (CT) and gonorrhea (NG) into KPLHS in four CBOs in Thailand. Here we assess rates of successful links to treatment after diagnosis.

Methods: POC STI testing was integrated into KPLHS in August 2019. Trained KP lay providers collected and tested single participant pooled urine, pharyngeal, and rectal samples for CT/NG using the GeneXpert assay at the CBOs, and plasma was tested with rapid treponemal test and RPR test for syphilis serology. When an STI was detected, the client was assisted to treatment services by CBO care and support staff to health care facilities with which referral routes (including the acceptance of test results from the CBOs, thereby eliminating the need for repeat testing) were previously established. Successful linkage was assessed by follow-up phone call, and the number of days between diagnosis and treatment was calculated.

Results: Between August 2019 and July 2020, 1,008 participants (875 MSM [86.8%] and 133 TGW [13.2%]) were recruited. Among MSM, CT/NG/syphilis events were detected in 240/1029 (23.3%)/174/953 (18.3%)/98/961 (10.2%), of whom 206/239 (86.2%)/139/172 (80.8%)/82/98 (83.7%) successfully received treatment. Median (interquartile range-IQR) days between diagnosis and treatment was 4(1-10)/6(2-15)/4(2-7). Among TGW, CT/NG/syphilis events were detected in 33/155 (21.3%)/18/138 (13%)/16/140 (11.4%), of whom 22/33 (66.7%)/12/18 (66.7%)/7/16 (43.8%) successfully received treatment. Median (interquartile range-IQR) days between diagnosis and treatment was 4(1.5-11)/4(3-5)/4(2-6).

Conclusions: Integration of CT/NG testing into KPLHS to increase access to STI services among KPs resulted in significant STI diagnoses, with high rates of successful linkage to treatment services among MSM. Rates among TGW were lower, indicating tailored strategies to link this population to care are urgently needed. Despite acceptance of CBO test results by referral facilities, time from diagnosis until treatment completion was long. Time to treatment should be further optimized by exploring methods to expedite treatment, such as fast-track referral options or the integration of treatment services at CBOs to facilitate same-day treatment.

OAC0305

Acceptability and satisfaction of self-collection for chlamydia and gonorrhoea testing among transgender women in the Tangerine Clinic, Thailand: shifting toward the new normal

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Background: Provider-collected swabs are an unappealing procedure for many transgender women due and may have led to suboptimal rates of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) testing. Self-collection for CT and NG testing is recommended for men who have sex with men and cisgender women, but the information is lacking for transgender women. We aimed to determine the acceptability and satisfaction of self-collection for Thai transgender women.

Methods: Thai transgender women who attended the Tangerine Clinic—a transgender-led, integrated, gender-affirming care and sexual health service in Bangkok—between May and July 2020 and had condomless sexual intercourse within the past six months were offered to collect urine and perform self-swabs of pharyngeal, rectal, and if applicable, neovaginal compartments for pooled nucleic acid amplification testing for CT and NG (Abbott Real Time CT/NG, Abbott Molecular Inc., Illinois, USA). Participants were given a diagram of self-collection instructions. Self-administered questionnaires were used to assess satisfaction. The prevalence of CT and NG infections among those who accepted self-collection was compared to our historical cohort consisting of 764 transgender women who underwent provider-collected samples between 2015 and 2017.

Results: A total of 224 transgender women were offered self-collection, and 143 (63.8%) accepted. All had pharyngeal, rectal, and urethral samples collected. Of 28 who had undergone gender-affirmative surgery, all accepted neovaginal self-swab. Acceptance increased from 43.9% in May to 82.7% in July 2020. All transgender women who accepted self-collection were able to perform it without assistance, and 82.8% were highly satisfied with the method. None reported dissatisfaction. No invalid results were reported from these samples. The pooled prevalence of CT and NG infections among transgender women performing self-collection was 23.1% and 17.5%, respectively; comparable to our historical cohort (22.9% CT infection, 14.3% NG infection).

Conclusions: Thai transgender women had high acceptability and satisfaction of self-collection for CT and NG testing. Our results support the implementation of self-collection services to maintain and/or increase sexually transmitted infection testing uptake, particularly during the COVID-19 pandemic where physical distancing is the new normal. A larger study is warranted to determine and confirm the CT and NG test performance between self-collection and provider-collection.

OAC04 Innovative STI/HIV prevention and interventions

OAC0401

Gonorrhea and chlamydia prevalence and associated characteristics among transgender women in 5 U.S. cities, NHBS, 2019

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Background: Studies of sexually transmitted infections (STI) apart from HIV are lacking among transgender women in the United States. This paucity of information has limited guidance on testing and prevention of STIs for transgender women.

Methods: In 2019, National HIV Behavioral Surveillance recruited transgender women via respondent-driven sampling in select U.S. cities. Eligibility included being ≥18 years old, assigned male at birth or intersex, and identifying as a transgender woman or a woman. Participants completed a survey, HIV testing, and in five cities (Atlanta, New Orleans, New York City, San Francisco, Seattle) gonorrhea and chlamydia testing using self-collected pharyngeal swabs, rectal swabs, and urine. We report frequencies of gonorrhea and chlamydia infections. Adjusted prevalence ratios and 95% confidence intervals were obtained using Poisson regression models with robust standard errors accounting for recruitment chain and adjusting for city and network size.

	n (%)	aPR (95% CI)[2,3]
Age		
18-24	36 (16.6)	1.9 (1.4, 2.7)*
30-39	42 (17.4)	2.2 (1.4, 3.3)*
≥40	25 (6.9)	Referent
Race/ethnicity		
Black/AA	38 (12.7)	2.2 (0.8, 5.7)
Hispanic/Latino	34 (12.7)	2.8 (1.2, 6.8)*
Asian	4 (17.4)	5.3 (1.7, 16.8)*
NH/PI	12 (31.6)	8.6 (2.8, 26.7)*
White	5 (4.6)	Referent
Other/Multiple	10 (11.6)	2.4 (0.8, 6.9)
HIV status		
18-24	47 (13.1)	1.0 (0.7, 1.5)
30-39	53 (12.0)	Referent
City		
Atlanta	27 (21.1)	2.5 (1.5, 4.1)*
New Orleans	18 (11.0)	1.3 (0.8, 2.2)
New York City	26 (10.8)	1.4 (0.9, 2.1)
San Francisco	16 (8.3)	Referent
Seattle	16 (16.2)	2.2 (1.03, 4.6)*
Total	103 (12.5)	

Abbreviations: aPR, adjusted prevalence ratio; CI, confidence interval; AA, African American; NH/PI, Native Hawaiian/Pacific Islander
[1] Any anatomic site refers to pharyngeal, rectal, or urine.
[2] aPRs and 95% CIs were obtained using Poisson regression models with robust standard errors accounting for clustering by recruitment chain and adjusting for city and network size.
[3] Asterisk (*) indicates statistical significance at alpha = 0.05 level.

Table: Prevalence of gonorrhea or chlamydia at any anatomic site[1] among transgender women in 5 U.S. cities - National HIV Behavioral Surveillance, 2019

Results: Of 847 eligible participants, 824 (97.3%) consented and provided at least 1 STI specimen. Overall, 6.6% of participants had a positive test result for gonorrhea, 8.0% for chlamydia, and 12.5% for either gonorrhea or chlamydia, at any of the anatomic sites. Rectal STI prevalence was highest at 9.8%, followed by pharyngeal at 4.3% and urogenital at 0.7%. Having either gonorrhea or chlamydia at any of the anatomic sites was associated with younger age; being Hispanic, Asian, or Native Hawaiian/Pacific Islander race/ethnicity; and living in Atlanta or Seattle.

Conclusions: About 1 in 8 transgender women had either gonorrhea or chlamydia at 1 or more anatomic sites. Rectal STI prevalence was highest, signaling the importance of collecting rectal specimens as part of comprehensive STI testing for transgender women. Reaching young transgender women and transgender women of color with culturally appropriate testing, prevention, and treatment efforts will be key to reducing STI burden.

OAC0402

STI incidence among participants in the HIV Pre-exposure Prophylaxis (PrEP) impact trial in England

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Background: Pre-exposure prophylaxis (PrEP) is effective at reducing risk of HIV acquisition. However, there are concerns that widespread PrEP-use may lead to changes in sexual behaviour that increase the transmission of sexually transmitted infections (STIs). We describe STI incidence among participants enrolled in a non-interventional, non-randomised trial of PrEP implementation at sexual health clinics (SHCs) across England.

Methods: Participants were enrolled between 13/10/2017 and 12/07/2020. Demographic, clinical and prescribing data were collected via electronic case report forms and routine STI surveillance. For this analysis, data were included up to 29/02/2020. We compared incidence of chlamydia, gonorrhoea and syphilis across subgroups using univariate and multivariate zero-inflated negative binomial regression models, adjusted for individual follow-up time and testing frequency.

Results: This analysis included 18,358 participants who had at least one post-enrolment visit; median follow-up was 11.9 months [IQR 4.7-20.9].

19,419 STIs were diagnosed among 8,712 participants. Multiple infections were observed in 4,580 (25.4%) participants. Mean incidence of any STI during follow-up was 101.2 (95%CI 99.9-102.7) per 100 person-years: 43.6 (95%CI 42.6– 44.5) for chlamydia, 50.5 (95%CI 49.5-51.5) for gonorrhoea, and 7.2 (95%CI 6.8-7.6) for syphilis.

STI incidence was highest among 16-24 year olds (IRRs 0.93, 95%CI 0.87-0.98 for 25-34yo, 0.79, 95%CI 0.74-0.84 for 35-44yo, 0.66, 95%CI 0.61-0.71 for 45-54yo and 0.59, 95%CI 0.53-0.66 for 55+yo) and in London (IRR 0.86, 95%CI 0.79-0.94 for Midlands and East, 0.84, 95%CI 0.78-0.90 for North and 0.80, 95%CI 0.74-0.89 for South). An STI diagnosis in the year before enrolment (IRR 1.51, 95%CI 1.44-1.58) and being born outside the UK (IRR 1.22, 95%CI 1.16-1.29 for Europe and 1.15, 95%CI 1.09-1.22 for elsewhere) were associated with increased STI incidence, while being on an event-based PrEP instead of daily was associated with lower incidence (IRR 0.91, 95%CI 0.86-0.96). Lower number of tests and STI diagnosis before enrolment, shorter follow-up, and region of residence successfully predicted the chance of having zero STI diagnoses.

Conclusions: There are considerable differences in STI incidence among PrEP users, even after accounting for different attendance and testing frequency. Efforts in prevention should be focussed on the youngest living in London with history of STIs.

OAC0403

The association of exposure to DREAMS combination HIV prevention on sexually acquiring or transmitting HIV amongst adolescent girls and young women living in rural South Africa: a cohort study

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Background: We investigate how risk of sexually acquiring or transmitting HIV in adolescent girls and young women (AGYW) changed following the real-world implementation of DREAMS (Determined, Resilient, Empowered, AIDS free, Mentored and Safe) combination HIV prevention.

Methods: We recruited a randomly selected population-based cohort of AGYW aged 13-22 years (at baseline) living in rural KwaZulu-Natal whom we interviewed annually (2017-2019). We measured exposure to DREAMS as self-reported receipt of an invitation to participate and/or participation in DREAMS activities. HIV status was ascertained through blood tests on Dried Blood Spot. We used multivariable regression to assess the association between exposure to DREAMS and risk of acquiring HIV (incident HIV) or having transmissible HIV (being HIV positive with a detectable HIV viral load of >=50 copies per millitre) on the last available DBS. We adjusted for socio-demographic, sexual relationship, and migration.

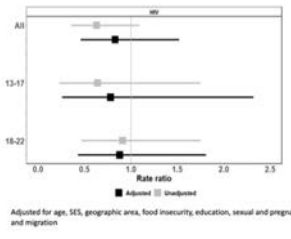

Figure a: HIV rate ratios, comparing AGYW exposed vs not exposed to DREAMS

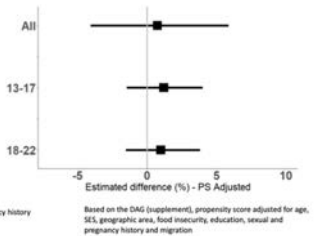

Figure b: Estimated difference in the percentage of AGYW with transmissable viral load, comparing the scenarios that all vs no AGYW were exposed to DREAMS

Results: 2184 (86.4%) of those eligible agreed to participate and 2016 (92.3%) participants provided data for at least one follow-up timepoint. 1030 (54%) were exposed to DREAMS; HIV incidence was 2.2/100 person-years (95% Confidence Interval [CI]: 1.66-2.86). There was no evidence that HIV incidence was lower in those exposed to DREAMS: adjusted rate ratio (aRR) 0.83 (95%CI: 0.46-1.52). HIV viral load was detectable for 169 (8.9%) respondents 1-2 years following enrolment; there was no evidence this was lower in those exposed to DREAMS with an

adjusted risk difference, compared to those not exposed to DREAMS, of 0.99% [95%CI: -1.52-3.82]. Participants who lived in peri-urban/urban setting were more likely to have incident HIV and transmissible HIV. Detectable HIV viral load was also associated with older age and ever having sex. Findings did not differ substantively by respondent age group.

Conclusions: DREAMS exposure was not associated with reductions in risk of sexually acquiring or transmitting HIV amongst a representative cohort of AGYW in rural South Africa.

OAC0404

HPV increases HIV risk in African women: advancing the argument for HPV immunization

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Background: Adolescent girls and young women (AGYW) account for 25% of incident HIV infections in sub-Saharan Africa. Human papillomavirus (HPV) infection is common among AGYW, but its role in HIV acquisition is uncertain. We evaluated the relationship between HPV and HIV acquisition using data from MTN-003, a clinical trial of chemoprophylaxis for HIV among cisgender women in sub-Saharan Africa.

Methods: Using a nested case-control design, we matched 138 women who acquired HIV (cases) to 412 HIV-negative controls. Cervical or vaginal swabs collected at one time-point within 6 months before HIV seroconversion in cases were tested for 37 HPV types using a Luminex-based liquid bead micro array – 14 of which are high-risk carcinogenic types and 23 low-risk types. We estimated the association between HPV and HIV using conditional logistic regressions, controlling for confounders including age, time-varying sexual behaviors, vaginal infections, and other sexually transmitted infections.

Results: Mean age in the study was 24 years (+/- 4 years). Any, high-risk, and low-risk HPV was detected in 84%, 74%, and 66% of cases, and 65%, 55%, and 48% of controls. Infection with ≥2 HPV types was common in cases (67%) and controls (49%). A high proportion (60% of cases and 42% of controls) had >1 type covered by the 9-valent HPV vaccine, and 36% of cases and 22% of controls had >1 type covered by the quadrivalent vaccine. HIV risk increased 2.7-fold with any HPV (adjusted odds ratio [aOR] 2.7, 95% confidence interval [CI] 1.5-5.1) or a high-risk HPV infection (aOR 2.7, 95% CI 1.5-4.8), and 1.9-fold with a low-risk HPV infection (95% CI 1.1-3.0). Each additional HPV type detected was associated with a 20% increase in HIV risk (aOR 1.2, 95% CI 1.1-1.3). HIV acquisition was also associated with HPV types covered by the 9-valent (aOR 2.2, 95% CI 1.3-3.6) and quadrivalent vaccines (aOR 1.8, 95% CI 1.1-3.0).

Conclusions: HPV infection was associated with HIV acquisition among AGYW living in high HIV burden settings. Infection with a 9-valent HPV vaccine-targeted type is prevalent in this population. In addition to preventing HPV-associated cancers, increasing HPV vaccination coverage may reduce new HIV infections in sub-Saharan Africa.

OAC0405

Development of a multiplex assay for use in multi-analyte screening and surveillance

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Background: Diagnostic assays that can simultaneously determine the presence of infection with multiple pathogens are key for diagnosis and surveillance. Single pathogen diagnostic tests for HIV, HSV, hepatitis viruses, syphilis, and rubella are routinely used in disease surveillance in industrialized countries, but world-wide applications are limited due to high cost, lack of expertise, and poor laboratory infrastructure. We developed a multi-analyte, pathogen detection assay for screening and sero-surveillance using the Luminex MAGPIX™ platform that is simple, high-throughput, cost-effective, highly reproducible, and helpful in monitoring multiple diseases.

Methods: The Luminex bead-based 11-Plex immunoassay for the detection of HIV-1, HIV-2, syphilis, hepatitis B, hepatitis C, HSV-1, HSV-2, and rubella was accomplished by coupling beads with specific antigens to detect IgG antibodies in plasma or serum samples. Each coupled antigen was systematically optimized and the performance of the monoplex and the multiplex (11-Plex) were evaluated using a panel of well characterized specimens that contained a combination of antibodies to HIV-1 (positive n=70, negative n=347), HIV-2 (positive n=5, negative n=412), syphilis (positive n=54, negative n=363), hepatitis C (positive n=67, negative n=348), hepatitis B (positive n=78, negative n=337), HSV-1 (positive n=283, negative n=134), HSV-2 (positive n=211, negative n=206), and rubella (positive n=391, negative n=26).

Results: Both the monoplex and multiplex assay formats showed overall sensitivity of 92.2% (95% CI, 90.2-94.0) and specificity of 98.1% (95% CI, 97.6-98.7) when compared to the reference data. The sensitivities and specificities of disease-specific biomarker detection ranged from 68.7-100%, and 95.6-100%, respectively (Table 1). The results showed the 11-Plex had an overall agreement of 96.7% (95% CI, 96.7-97.3) with reference tests and a corresponding kappa coefficient of 0.91 (95% CI, 0.90-0.93).

Conclusions: The 11-Plex bead-based surveillance tool is robust and allows for simultaneous detection of antibodies to multiple antigens in a high throughput format. This assay has the potential to simplify disease surveillance by providing an alternative to expensive, highly specialized individual tests. Additional clinical evaluation using maternal plasma or serum specimens are needed for the 11-Plex to help curb mother-to-child transmission of multiple infections.

OAC05 Your test in your hands: HIV self-testing to improve knowledge of HIV status

OAC0501

The cost and intermediary cost-effectiveness of oral HIV self-test kit distribution across eleven distribution models in South Africa

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Background: South Africa has made progress in reaching the population aged 15-64 with HIV testing, but testing gaps remain among key populations and men. HIV self-testing (HIVST) can help fill these gaps by bringing testing closer. We conducted an economic evaluation of 11 innovative HIVST distribution approaches implemented across urban and rural settings in South Africa between 2018 and 2019 under the Self-Testing AfRica Initiative.

Methods: We analysed the cost and outcomes along the care cascade from self-testing to initiation of antiretroviral treatment (ART) across the country (Table 1). We conducted an ingredients-based cost analysis from the provider's perspective, combining bottom-up and top-down approaches. Cost analysis was limited to a 12-months implementation period for all except two models with shorter implementation periods (transport hub and third-party workplace models). We categorised cost items as capital vs. recurrent. Capital costs were annualised over a 2 years lifespan to reflect the project duration and discounted using a 3% discount rate.

Distribution Setting	Model	Distribution Approach	Target Population
Facility	Horizontal primary healthcare (Antenatal care) / Horizontal primary healthcare (Index) / Vertical primary health care	Pregnant women received kits for their current sexual partner(s) / HIV positive clients attending PHC clinic received kits for their sexual partner(s) / On-site HIV screening for clients attending PHC clinic for a wide array of services	Men & partners of HIV positive people/ General population
Community distribution	Fixed point / Flexible community	Distribution at pre-selected locations within communities, especially where men tend to congregate / Door-to-door distribution of kits	Men/ Men and young people
	Mobile integration / Workplace	Integrating HIVST to community-based mobile HIV testing / Distributing kits at male-dominated sector workplaces	
	Transport hub	Distributing kits in densely populated taxi ranks and train stations with high foot traffic	General population
	Key populations / Sex workers	Distributing kits to sex workers and truck drivers / Sex workers received kits for peers	Key populations / Sex workers

Results: Slightly over a million kits were distributed; 49% through the flexible community model and the least kits (1%) through the mobile integration and PHC models. The self-test positivity rate varied between 4% in the workplace model and 23% in the horizontal PHC model, with most models reporting a 5% positivity rate. The average cost per kit distributed ranged from $4.87 in the sex worker model to $18.07 in the mobile integration models. Facility models exhibited higher unit costs than community models. The average cost per reactive HIVST ranged from $28 in the sex worker model to $414 in the mobile integration model. The cost per confirmed positive result was between $66 in the sex worker model and $1229 in vertical PHC. Finally, the cost per ART initiation was between $116 in the sex worker model and $1,278 in vertical PHC.

Conclusions: HIVST distribution cost varied widely across models, with the sex worker, transport hub, and workplace models being the most efficient and least costly distribution approaches.

OAC0502

A successful launch of the first HIV self-testing pharmacy-based service demonstration project, Bangkok, Thailand

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Background: The Thai Ministry of Public Health (MoPH) considers HIV self-testing (HIVST) a complementary approach to increase access to and uptake of HIV testing especially among men who have sex with men (MSM) and Transgender women(TGW), who historically have low access to HIV testing. We present results of the first HIVST pharmacy-delivered model to assess the acceptance of unassisted HIVST among these populations in Bangkok.

Methods: Oral HIVST kits were available through 36 retail Boots pharmacies located in Bangkok. Participants who were directed to the project website during August and December 2020 and who met the inclusion criteria (i.e., Thai MSM/TGW ≥ 18 years of age, who lived/worked in Bangkok, had a smart phone with internet connection, and had never been diagnosed with HIV) were invited to register online. All eligible participants provided written informed consent online, completed baseline and follow-up questionnaires, picked up the free HIV test (OraQuick®) at the pharmacy, and performed the test unassisted. Participants testing HIV positive were encouraged to confirm test results at designated health facilities. Hotline was provided for additional counseling if needed. Questionnaire data including demographics, behavioral and HIV treatment information were collected electronically.

Results: Of 1,511 MSM/TGW who consented, 826(55%%) were eligible. Of these, 776(94%) were MSM, 239(31%) were 18-25 years old, 576(70%) completed ≥bachelor's degree, 653(79%) were employed, over 70% had self-perceived HIV risk, and 343(42%) had never tested for HIV. As of January 2021, 440(53%) picked up the test kit at the pharmacy, 274(62%) performed the test. Of these, 15(5%) reported reactive test results and 205(75%) reported that the test kit was easy to use. Few (n=41) participants called the hotline for additional counseling.

Conclusions: This is the first project in Thailand that demonstrates the use of unassisted HIVST delivered via pharmacies. Based on our findings, HIVST is an effective way to reach MSM/TGW who have never

tested for HIV. Those who reported use of HIVST kits expressed high acceptability, suggesting HIVST as an acceptable and complementary strategy to HIV case finding strategy for these populations. More in-depth analysis on linking HIV-positive clients to confirmatory testing is underway.

OAC0503

User assessment of HIV self-testing (HIVST) in Brazil: an acceptable tool with great potential for reaching key populations and maximize positivity yield

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Background: Innovative strategies are paramount in a country that has a huge social disparity and an HIV epidemic concentrated in key populations (KP), who commonly experience barriers to access health services (HS). Aiming to reach the estimated 99.000 (11%) undiagnosed PLHIV, in 2018 Brazilian MoH started in 2018 a free HIVST distribution, focused on KP and young people. The aim of this study was to evaluate HIVST Brazilian users experience to guide public health policies.
Methods: From December 2018 to January 2021, we conducted a cross-sectional study using an online self-administered structured questionnaire to assess user acceptance and experience using HIVST. The study collected socio-demographics, sexuality, risk behavior and previous testing data from HIV self-testers.
Users were encouraged to answer the post-test anonymous questionnaire by using the QR code printed in the informative folder delivered with the HIVST.
Results: We obtained 813 answers. 363 (45%) of respondents were MSM and 50% were between 18 and 29 years old. 45% reported unprotected anal sex in the last 6 months and 32% of users were first time testers (46% in the 18-24 age group). Half of respondents (50%) realized the HIVST alone and 30% with a friend, partner or family member, 12% were assisted by an NGO member and 8% by a healthcare professional.
3% bought the test in pharmacies, 41% got it in a HS, 40% in outreach strategies and 13% received the test from a friend.
Regarding the testing experience, 91% of users found it easy to do, 98% would do an HIVST again and 99% would recommend it to a friend. The main advantages of HIVST pointed out were privacy (72%) and personal empowerment (51%).
Positive results were related by 28 (3.4%) people (Brazilian prevalence is 0.5%). Among the positive, 79% reported having already sought a HS to confirm the diagnosis.
Conclusions: HIVST is high acceptable, easy to perform and can maximize positivity yield. People prefer to self-test alone or with someone they trust. Most people seek confirmation after a positive result. HIVST were mostly obtained outside HS, successfully reached first time testers, young people and KP.

OAC0504

Feasibility of HIV self-testing among female sex workers in Iran: the SELFii study

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Background: The HIV epidemic in Iran may be shifting from injection to sexual transmission, presenting challenges to reach new key populations at high risk. Considering severe stigma, discrimination, and criminalization, female sex workers' (FSW) in Iran face barriers to HIV testing at health facilities. New testing strategies such as HIV self-testing (HIVST) present a possible solution. We assessed the feasibility of HIVST among FSW in two cities of Iran.
Methods: Through peer-referral sampling from 3/2019-8/2020, 492 FSW (aged 18 years or older who sold sex in the last month) in Tehran and Isfahan were invited by 18 peer-educators to use HIVST. We collected data on their experiences in using HIVST, test outcomes, and feasibility of reporting results through peer-educators.
Results: Of 492 FSW participants, 54% were age 30-49 years, 44% used a condom at last sex, and 60% had never tested for HIV. The most common places where FSW used the HIVST were at home (43%), followed by hotspots for sex work or houses that temporarily served as brothels (20%), and public places (18%). Most FSW were assisted by a peer-educator to do the HIVST (76%). Two FSW (0.4%) self-reported a positive HIVST result to a peer-educator; both were referred and received confirmatory testing by the health system. At follow-up, 33% of FSW reported using a condom at last sex; 32% reported no sexual contact after the HIVST. Half (50%) of FSW reported high stress to learn if they are positive before testing; 17% reported stress after the HIVST. Three-fourths (75%) reported the HIVST was easy to use; 83% will recommend it to other FSW. A majority of FSW (54%) were willing to pay up to $2 USD for the HIVST.
Conclusions: Our study found that HIVST can be distributed by peer-educators to FSW, with high acceptability for use at sex-work venues or at home. Most accepted the assistance of peers to perform the test and record results. The issue of stress reported by some FSW needs further exploration to address this potential barrier. We found no indication that the self-test results increased condomless sex.

OAC0505

Reaching for the "first 95": a cross-country analysis of HIV self-testing in 177,572 people in nine countries in sub-Saharan Africa

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Background: HIV self-testing (HIVST) offers a promising approach to increase diagnosis of HIV and advance progress towards the UNAIDS 95-95-95 targets. We aimed to understand patterns of awareness and utilization of HIVST in nine sub-Saharan African (SSA) countries, with a goal to identify populations to target in disseminating this technology.

Methods: We pooled individual-level population-based data from nine Demographic and Health Surveys (DHS) in SSA from 2015-2019 (Burundi, Cameroon, Guinea, Malawi, Senegal, Sierra Leone, South Africa, Zambia, Zimbabwe). The primary outcomes of interest were awareness and utilization of HIVST. We then used logistic regression analyses with survey fixed effects to explore the relationship between sociodemographic characteristics and both (1) awareness and (2) utilization of HIVST. All models were adjusted for sex, age, rural/urban residence, education, wealth, marital status. We accounted for complex survey design.

Results: The total study sample included 177,572 people (66.0% women, mean age 29 ± 10 years), among whom 86.6% (95%-CI 86.4-86.7) had never heard of HIVST, 11.7% (95%-CI 11.6-11.9) had heard of HIVST but never tested and 1.7% (95%-CI 1.6-1.8) had tested with HIVST. In adjusted models, women were less likely to be aware of HIVST (OR 0.75 95%-CI 0.71-0.79), but more likely to have ever used HIVST (OR 1.17 95%-CI 1.03-1.32) compared to men. Moreover, rural residents were less likely to be aware of or use HIVST; in addition, there were significant gradients in both wealth and education, with those who were least educated and poorest also least likely to have heard of or used HIVST (Table 1).

	Awareness of HIVST		Use of HIVST	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Rural[a]	0.81 (0.75-0.88)	<0.001**	0.74 (0.62-0.89)	0.001*
Primary education[b] Secondary education Higher education	1.03 (0.96-1.11) 1.81 (1.68-1.95) 4.89 (4.45-5.37)	<0.001**	0.79 (0.65-0.97) 1.64 (1.36-1.98) 4.20 (3.43-5.16)	<0.001**
Poorer[c] Middle Richer Richest	1.26 (1.16-1.37) 1.45 (1.32-1.58) 1.70 (1.54-1.88) 2.36 (2.12-2.62)	<0.001**	1.28 (1.04-1.59) 1.22 (0.96-1.55) 1.48 (1.17-1.86) 1.66 (1.31-2.11)	<0.001**

*p < .05. ** p < .001. Abbreviation: HIVST= HIV self-testing. Reference categories: a) urban, b) no education, c) poorest. Additionally adjusted for sex, age and marital status.

Table 1. Multivariable logistic regression analysis

Conclusions: Overall awareness of HIVST was modest and uptake to date is low. Marginalized groups were least likely to have heard of or used HIVST. Efforts to scale-up HIVST in these settings should aim to reach rural, less educated and lower income populations.

OAD01 From clinics to communities: Testing and prevention

OAD0101

Identifying implementation barriers and facilitators of an integrated PrEP and HIV service delivery model at public facilities in urban Uganda

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Background: Practical HIV pre-exposure prophylaxis (PrEP) delivery models for limited-resource settings are critical for improving PrEP coverage and interrupting HIV transmission.This research uses technical assistance (TA) reports—a pragmatic data source—to understand implementation barriers and facilitators of an innovative PrEP delivery model that integrates PrEP and antiretroviral therapy (ART) delivery for HIV serodifferent couples in public health facilities in Kampala, Uganda (NCT03586128).

Methods: We used data from the Partners PrEP Program (PPP); a stepped-wedge cluster randomized trial that is testing an integrated model of oral PrEP and antiretroviral therapy (ART) delivery for HIV serodifferent couples at 8 purposively sampled public health facilities in Kampala, Uganda. Technical advising teams, comprised of PPP staff, conducted monthly TA visits to implementing facilities to identify and address implementation challenges alongside facility staff. Findings were recorded in TA reports, which were completed using standardized forms, informed by the Consolidated Framework for Implementation Research (CFIR), to identify implementation barriers and facilitators. We used a content analysis approach to evaluate TA reports from January to December 2019 and assigned CFIR strength and valence ratings to understand the strength and magnitude of identified barriers and facilitators.

Results: Among the 39 reports from 8 facilities (~5 per facility), we identified 11 CFIR constructs. Key implementation facilitators included sensitizing and educating facility staff about PrEP (Knowledge and Beliefs about the Innovation); establishing formal and informal feedback and accountability mechanisms (Reflecting and Evaluating); and empowering facility staff to address implementation challenges (Self-Efficacy). Key implementation barriers were related to ineffective recruitment and referral of eligible individuals from nearby facilities (Cosmopolitanism) as well as stockouts of laboratory reagents and testing supplies (Available Resources).

Conclusions: This analysis provides important context related to early implementation barriers and facilitators to inform scale-up efforts for PrEP delivery within and beyond Uganda. Further, we found TA reports to be a pragmatic data source for assessing and documenting implementation challenges. Technical assistance reports provide a practical tool for assessing and addressing implementation challenges associated with expanded PrEP delivery. Future work will explore the identified key themes through in-depth qualitative interviews with staff from implementing facilities.

OAD0102

Home-based testing strategies for older adults in rural South Africa: a randomized controlled trial

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Background: Many older adults in rural South Africa still lack knowledge of their HIV status despite a high burden of HIV in this population. HIV self-testing may offer a powerful approach to increase HIV testing in older populations. This study sought to establish the comparative effectiveness of three different home-based HIV testing strategies for older adults in rural South Africa.

Methods: We randomized 3,578 individuals in the 'Health and Ageing in Africa: a Longitudinal Study of an INDEPTH Community in South Africa (HAALSI)' cohort study 1:1:1 to:

(1) home-based HIV rapid testing plus counseling;

(2) home delivery of HIV self-testing kits, and

(3) both home-based HIV rapid testing plus counselling and home delivery of HIV self-testing kits.

In a modified Poisson regression analysis yielding risk ratios, we estimate the treatment effects on our primary outcomes of

(1) ever testing for HIV and

(2) testing since trial enrollment.

Results: There was no significant difference in testing uptake or knowledge of HIV status across groups (see Table). However, respondents in the treatment arms containing self-test kits were significantly more likely to test at home compared to the rapid testing only group, suggesting a preference for self-testing in this population. We also found no adverse effects due to self-test kits in any of our secondary outcomes, namely knowledge of HIV status, linkage to care for HIV and comorbidities, recent sexual partners, or HIV treatment uptake. Finally, being in either treatment arm with self-testing significantly decreased depression scores by 0.5 to 0.6 points on the CESD-20 scale.

	Ever tested	Tested since visit	Knows HIV status	Tested at Home
Counselor & RDT only	1 [1,1]	1 [1,1]	1 [1,1]	1 [1,1]
Self-test kit only	0.996 [0.984, 1.008]	0.99 [0.912, 1.076]	0.995 [0.979, 1.010]	1.171** [1.031, 1.329]
Counselor, RDTs, & self-test kit	1.002 [0.991, 1.013]	1.013 [0.933, 1.100]	0.994 [0.979, 1.009]	1.191*** [1.049, 1.353]
Obs.	2972	2969	2972	1559
Mean	0.983	0.527	0.969	0.495

Exponentiated coefficients; 95% confidence intervals in brackets
Modified Poisson Regression - coefficients represent risk ratios
All specifications are clustered at the HH level
* p< 0.1, ** p < 0.05, *** p < 0.01

Table

Conclusions: Our results indicate that HIV self-testing is a safe and preferred home-based testing option for older adults in rural South Africa, offering another promising policy tool in the effort to achieve the UNAIDS 90-90-90 targets.

OAD0103

Integrating Pre-exposure Prophylaxis Delivery in Decentralized Community HIV-testing sites in rural KwaZulu Natal, South Africa

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Background: Several demonstration projects have been conducted in urban-based clinics across South Africa to explore Pre-exposure Prophylaxis (PrEP) uptake in routine programmatic implementation conditions. However, retention in care (RIC) and adherence of integrating PrEP into decentralized community HIV- testing sites within a larger rural community remains unclear. We present preliminary results from a study evaluating PrEP delivery in rural community HIV testing sites under programmatic conditions.

Methods: This was a single arm study. From March 2019 to March 2020, daily oral PrEP was offered to HIV-negative females aged 18 to 35 years, at four Médecins Sans Frontières (MSF)-supported community HIV-testing sites in Eshowe/Mbongolwane area, KwaZulu Natal, South Africa. Risk reduction counselling, adherence counselling, HIV-testing, screening and treatment of sexually transmitted infections (STIs) were conducted at 3, 6 and 12 month follow-up visits. PrEP adherence was assessed measuring tenofovir diphosphate (TFV-DP) blood concentrations at every visit. A threshold of ≥700 fmol/punch TFV-DP concentration indicated adherence. Descriptive analysis of patient demographics, RIC and adherence were conducted.

Results: 1,564 participants were offered PrEP and 172 (11%) participants accepted PrEP initiation and enrolled in the study across sites. Participants' mean age was 25 years (SD 5.6). 6.4% (11/172) participants tested positive for at least one STI at enrollment. Overall STI incidence was of 0.15 cases per 100 person-years (95%CI:0.06-0.36).

Overall study retention at 12 months was 39.2%. Median discontinuation time was 145 days (IQR:57-210) and PrEP was discontinued by 41(24.0%) of the 172 participants at month three. Additionally, 17.5% (23/131), 29.6% (32/99),14.5% (11/67) of women discontinued PrEP at months 6, 9 and 12, respectively. Retention rate was higher in older participants (aged 25-35 years) than in younger participants (aged 18-24 years), 48.4% and 28.4% respectively. Adherence at 3 months was 57% (53/93) and 53.4% (31/58) at 6 months.

Conclusions: We observed relatively low PrEP uptake, retention and adherence. However, PrEP retention was higher amongst older women. This study underscores existing evidence that PrEP adherence remains a challenge. Strategies to address retention and adherence, including adherence support groups, peer-mentors, and cash incentives should be further explored.

OAD0104

From Internet to the health center: WhatsApp as a tool to promote HIV testing among men who have sex with men recruited online

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Background: HIV testing uptake remains low among MSM in Peru. As a result, many people are not aware of their status and cannot be linked to HIV care. The objective of this study was to assess the efficacy of a mobile app-based intervention to increase HIV testing among MSM recruited online.

Methods: In this randomized controlled trial, Peruvian MSM, 18 years or older, HIV negative, without a recent HIV testing (last 6 months) were recruited online and randomly assigned to an intervention or control group. Participants were recruited online using Ads in Facebook and in two of the most visited local websites by gay men. After being recruited online, participants completed a short baseline survey. Later, a trained health worker used the mobile application WhatsApp to follow each participant during 12 weeks. They shared different topics of interest with emphasis on HIV prevention in the second half of the period of follow-up. Participants in control groups received standard of care. The main outcome was the number of participants who got an HIV test at one of the health centers of the research project.

Results: Participants were recruited between July and November 2015. 400 participants were randomly assigned to the intervention group (n=200) or the control group (n=200). 82 participants (41%) in the intervention group and 17 (8.5%) in the control group went to the health center to receive an HIV test (adjusted odds ratio: 7.64; 95% CI: 4.3 - 13.5).

Conclusions: Our combined strategy based on trained health workers using a mobile application for follow-up, was efficacious to take MSM recruited online to a health center for HIV testing. It is important to use mobile applications that are already widely used and accepted by the target population.

OAD0105

Barriers to expanding PrEP uptake among cisgender African American women in the South

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Background: Pre-exposure prophylaxis (PrEP) is a potent biomedical tool for HIV prevention; however, PrEP is underutilized among African American (AA) women in the Deep South of the United States, despite an inequitable HIV burden. This study explored patient and provider perceptions, attitudes, and preferences for PrEP service delivery, aiming to identify social, behavioral, and cultural factors influencing uptake among AA women.

Methods: In-depth, semi-structured qualitative interviews were conducted among cisgender AA women at risk for HIV (based on sexual activity in the last 6 months), both with PrEP experience (N=6) and without PrEP experience (N=15), as well as providers (N=20) from two federally qualified health centers (FQHCs) and HIV service agencies serving rural communities in Alabama. Data were coded in NVivo software (v.12), and analyzed using content analysis.

Results: Overall attitudes and perceptions of PrEP among AA women and providers were positive; however, numerous barriers to widespread PrEP uptake were discussed. Barriers to effective patient-provider relationships reported by AA women included perceived discrimination (e.g., based on patients' income, education, and/or race), a lack of provider empathy (e.g., feeling judged due to one's health status or circumstances), a lack of shared medical decision-making, general healthcare-related anxiety, difficulty assessing one's true HIV risk, and a desire for providers to view patients' health more holistically. Both patients and providers desired an "under one roof" approach, whereby all PrEP-related services are consolidated (e.g., prescribers, pharmacy, labs, educational materials), along with mechanisms for reducing PrEP-related costs and improving access. Participants also discussed a need for normalization of PrEP use specifically among AA women, via increased and frequent visibility in public-facing contexts (e.g., marketing campaigns, incorporation of PrEP information into standard medical appointment checklists), as well as increased PrEP training for providers.

Conclusions: These data identify key determinants that will influence PrEP uptake among cisgender AA women in the South receiving care at FQHCs and HIV service organizations. Individual, structural, and system level barriers were identified that will inform adaptations of effective patient-provider communication interventions to be formally tested using implementation science frameworks (i.e., Exploration, Preparation, Implementation, Sustainment [EPIS] and Dynamic Adaptation Process [DAP] frameworks).

OAD02 Addressing inequalities

OAD0201

Improving health equity and ending the HIV epidemic in the United States: a distributional cost-effectiveness analysis in six cities

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Background: In the United States, Black and Hispanic/Latinx individuals continue to be disproportionately impacted by HIV. Applying a distributional cost-effectiveness framework, we estimated the distributional health impacts and cost-effectiveness of two combination implementation approaches to determine the approach that best meets objectives of improving population health and reducing racial/ethnic health disparities.

Methods: We adapted a dynamic HIV transmission model to characterize HIV microepidemics in six US cities: Atlanta, Baltimore, Los Angeles, Miami, New York, and Seattle. We considered combinations of 16 evidence-based interventions to diagnose, treat and prevent HIV transmission, implemented by race/ethnicity in proportion to:

1) existing service levels (proportional services approach) and;

2) the distribution of new diagnoses by race/ethnicity (between Black, Hispanic/Latinx, and white/other individuals; equity approach).

We estimated total costs, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratios of strategies implemented from 2020-2030 (health-care perspective; 20-year time horizon; 3% annual discount rate).

We identified city-specific optimal strategies as the cost-effective bundle that produced the highest health benefit. Using optimal strategies under each approach, we estimated three measures of health inequality (Between-Group Variance, Index of Disparity, Theil Index), HIV incidence, and incidence rate ratios.

Results: In all cities, optimal combination strategies under the equity approach generated more QALYs than those with proportional services, ranging from a 3.1% increase (95%CrI:1.4%-5.3%) in New York to more than double (101.9% [75.4%-134.6%]) in Atlanta. Compared to proportional services, the equity approach delivered lower costs over 20 years in 4/6 cities, differences ranged from $74.0M ($6.9-$164.6M) in Miami to $574.3M ($252.3-934.6M) in Atlanta. Incidence reductions in 2030 were greatest under the equity approach in all cities (up to 80.7% [71.0%-86.1%] in Baltimore, Figure).

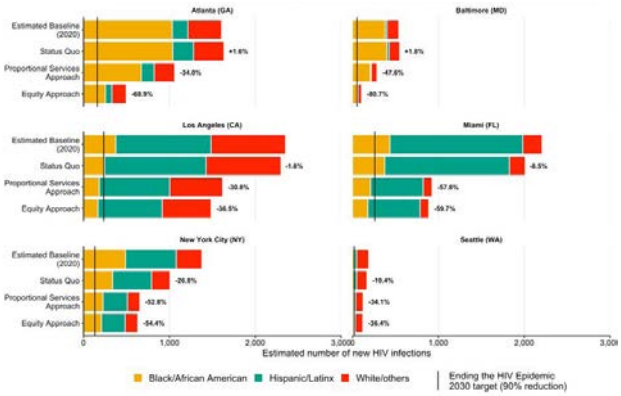

Figure. Estimated number of new HIV infections in 2020 and in 2030 under the status quo and the proportional services and equity approaches, by race/ethnicity, with total percentage change compared to 2020, in six US cities.

Conclusions: Equity-focused HIV combination implementation strategies that reduce disparities for Black and Hispanic/Latinx individuals can significantly improve population health, reduce costs, and drive progress toward Ending the HIV Epidemic.

OAD0202

Leveraging community ART dispensation through community health volunteers to enhance ART retention among the pastoralist PLHIVs of lower socioeconomic status in Kajiado: a case of Oltepesi Dispensary

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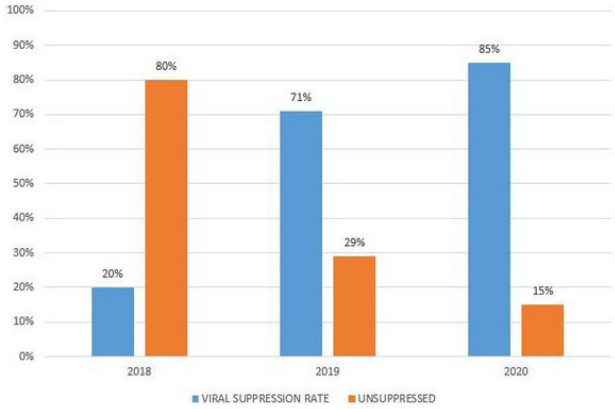
Background: Oltepesi Dispensary is in Kajiado West, which has vast distances between villages and nearest healthcare facilities. Major barriers to retention are distance to healthcare facility and socioeconomic status. Funded by Global Fund-Kenya Red Cross Society since 2018, ADEO supports PLHIVs at the dispensary using CHVs. CHVs are allocated a 15-20 PLHIV cohort for adherence support to improve adherence, reducing defaulter rate, and ensure clients take charge of their health.

Description: Community ART dispensation strategy was adopted. CHVs pick ARVs from the facility, and deliver to PLHIV at home. It deviates from Community ART Groups where PLHIV pick drugs for their peers. It strengthened home visits where health talks are done involving adherence counseling, nutritional education, and psychosocial support. The PLHIV's inability to pick drugs from the facility due to distance barrier and transport cost prompted the intervention. CHVs voluntarily used their motorcycles in delivering drugs to PLHIVs and conducted enhanced adherence counseling. In 2018, viral suppression rate was 20%. Aggressive community dispensation using CHVs during home visits increased it to 71% in 2019. In 2020, 53 clients were on care; 23 of 27 with a viral load result were suppressed (85%).

Lessons learned: Evidence-based interventions modeled on community ART dispensation are essential in reaching nomadic communities and clients where distance to the nearest healthcare facility and be-

tween households is large. CHVs bridge the distance between PLHIVs and their care facilities. SCHMTs, CHAs, and implementing partners must customize interventions for specific demographics.



Graph showing viral suppression rate at Oltepesi Dispensary since 2018 when ADEO started implementing the TCS program.

Conclusions/Next steps: CHVs are vital in retaining PLHIVs on ART. Strengthening community ART dispensation in remote areas with limited infrastructure is essential in attaining the 90-90-90 objectives. HIV/AIDS programs must consider integrating community dispensation using CHVs in areas where distance to the healthcare facility is large.

OAD0203

Targeted virtual HIV-sensitive case management of children and adolescents living with HIV amidst COVID-19 in Zimbabwe: insights from Family AIDS Caring Trust (FACT) Orphaned and Vulnerable Children (OVC) Programme in Zimbabwe

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Background: With support from US President's Emergency Plan for AIDS Relief, FACT Zimbabwe is implementing Children Tariro (CT) programme to mitigate impacts of HIV/AIDS among Zimbabwe's OVC, 0 to 17years. CT contributes towards the achievement of UNAIDS' 95-95-95 global goals by supporting the most HIV-affected children and their families in 6 districts in Manicaland and Masvingo; two provinces in Zimbabwe to access HIV treatment, care and support and GBV prevention and clinical care.

Description: In Q1 October 2020, CT enrolled 5381 out of the targeted 6524 Children and Adolescents Living with HIV (CALHIV) from 238 public and faith-based health facilities for HIV antiretroviral treatment (ART) adherence support. The remaining 1143 CALHIV on ART line-listed for saturation follow-up. CT partnered with the health facilities and community health workers (CHWs) to identify, track, and support the targeted CALHIV and their families with ART adherence and psychosocial support, viral load testing, and enhanced ART adherence counselling for those with high viral load. CT also referred to the Department of Social Development CALHIV with high viral load and their caregivers in desperate need for food consumption support. COVID-19's outbreak in Zimbabwe in March 2020 resulted in lockdown and mobility restrictions that affected access to the indicated support. CT provided partner health facilities and CHWs with airtime to continue implementing the interventions virtually through SMS, WhatsApp and phone calls.

Lessons learned: From the first to the second quarter 2020, we retained 6009 CALHIV on CT support. This represented a 10% increase in enrolment of CALHIV and indicated effective follow-up of 628 of the 1143 CALHIV. In quarters three and four, our reach declined to 6002 and 5932 CALHIV, respectively. These declines were because 59 CALHIV had aged out of CT support, 14 moved to non-CT districts, and 4 deceased from opportunistic infections. The data demonstrated uninterrupted access to CT support by targeted CALHIV and their families even after pivoting to virtual case management

Conclusions/Next steps: CT program results highlight the efficacy of virtual case management for the most HIV-affected CALHIV amidst COVID-19.

OAD0204

Men missing from the HIV care continuum: a meta-analysis and meta-synthesis

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Background: Men continue to fall off the HIV care continuum. Understanding where and how this happens is critical to achieving UNAIDS 95-95-95 goals. We sought to estimate the proportions of men meeting each of the 95-95-95 goals across studies in sub-Saharan Africa and summarize qualitative evidence on factors influencing their care engagement.

Methods: We conducted a systematic review of peer-reviewed literature in PubMed and Embase between 2014 and 2020. The meta-analysis included studies in sub-Saharan Africa involving men >=15 years with data from 2009 onward and reporting on one or more of the 95-95-95 goals. We estimated pooled proportions using DerSimonion-Laird random effects models. We quantified heterogeneity by country, setting (healthcare vs. community), outcome definition (e.g., threshold for viral load suppression), and study quality. We used meta-synthesis to summarize qualitative studies exploring barriers to men's HIV care engagement in sub-Saharan Africa and to develop a third order interpretation of the data.

Results: From 14,670 studies screened, 130 studies were included in the meta-analysis. 47 studies reported data on knowledge of serostatus, 45 studies reported data on ART use, and 75 studies reported data on viral suppression. We estimated the proportions of men meeting the 95-95-95 goals: knowledge of serostatus, 0.49 (95% CI, 0.41-0.58); being on ART, 0.57 (95% CI, 0.50-0.64); and achieving viral suppression, 0.79 (95% CI, 0.77-0.80). In studies including both men and women, compared with women, a lower proportion of men knew their serostatus (0.53 [95% CI, 0.44-0.63] vs. 0.66 [95% CI, 0.59-0.73], P=0.04) or were virally suppressed (0.79 [95% CI, 0.77-0.80] vs. 0.81 [95% CI, 0.80-0.83], P=0.01). Heterogeneity was high and partially explained by variation in study

population, study setting, and outcome definition. The meta-synthesis included 40 studies and identified three third-order labels encompassing barriers to men's care engagement: mistrust of the health system, poverty, and perceived threats to heteronormative masculinity.

Conclusions: Men in sub-Saharan Africa are falling behind especially in testing and treatment. Interventions that improve trust in the health system, provide affordable, convenient care, and which fundamentally change masculine norms are needed to better engage men in HIV care.

OAD0205

Structural vulnerability and the impacts of the COVID-19 pandemic on HIV risk behaviors and prevention needs among people who inject drugs

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Background: In many regions of the United States, continued high levels of opioid and polysubstance use have contributed to new HIV outbreaks among people who inject drugs (PWID). The unprecedented COVID-19 pandemic, as well as measures undertaken to mitigate it, may have altered the HIV prevention needs of PWID. To inform HIV prevention services for this population, we explored PWID experiences in the COVID-19 context.

Methods: From July-December 2020, we partnered with diverse syringe service programs (SSPs) across Massachusetts to recruit individuals ≥18 years old reporting past-month injection drug use. SSP staff introduced interested individuals to offsite study personnel using secure video-conferencing on tablets in private indoor and outdoor spaces. Trained interviewers obtained verbal informed consent before administering brief quantitative surveys and in-depth qualitative interviews via video. Thematic analysis identified common experiences related to HIV risks and prevention needs in the COVID-19 context.

Results: Among 27 participants, median age was 35 years (IQR: 30-43). Sixteen (59%) identified as male, 11 (41%) as female; 24 (89%) identified as white, 10 (37%) as Hispanic, 3 (11%) as Black. All 27 (100%) injected heroin/fentanyl and 22 (81%) also injected cocaine/crack (past month); additional drugs used recently included benzodiazepines (n=12; 44%) and methamphetamine 9 (33%). Injection frequency was high, with 12 (44%) injecting ≥10 times daily. In the COVID-19 context, most participants described having the "same routine," with minimal changes to their injection behaviors or syringe access. However, participants discussed numerous structural challenges worsened by COVID-19, including difficulty securing income (e.g., reduced ability to "hustle") and reduced access to housing, healthcare, and addiction treatment. Participants also described stigmatizing experiences of being "presumed positive" for COVID-19 within healthcare and social service settings.

Conclusions: Rather than drastically altering individuals' injection behaviors, our findings illustrate how large-scale public health emergencies like COVID-19 may impact HIV vulnerability among PWID indirectly through changes in social and structural contexts. Despite initial SSP closures, expanded mobile outreach across this region helped PWID maintain access to sterile syringes. PWID narratives instead highlighted how COVID-19 exacerbated structural vulnerability by destabilizing access to essential services while intensifying stigma through the conflation of addiction, homelessness, and infectious diseases.

OAD03 Gender, violence and HIV

OAD0301

Gender-based violence shadows COVID-19: Increased sexual violence, HIV exposure and teen pregnancy among girls and women in Uganda

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Background: The COVID-19 pandemic is associated with increased gender-based violence (GBV) perpetration. However, the COVID-19 response did not prioritize GBV services, negatively impacting post-violence care service access among girls/women in Uganda. We analyzed routine program data to correlate COVID-19 restrictions with GBV violence reports, post exposure prophylaxis (PEP) uptake and teen pregnancy among Ugandan females.

Methods: Violence data from the Uganda Health Management System (HMIS) and Ministry of Gender Labor and Social Development reports (Uganda Child-Helpline (UCHL)) were analyzed. Analysis included reports involving females (all ages) from HMIS and females aged <18 years from UCHL. Two 6-month time periods were compared: October-2019 to March-2020 (pre COVID-19 period) and April-2020 to Septempter-2020 (COVID-19 period). From HMIS, selected outcome variables for sexual violence were post-rape reports and PEP uptake; from UCHL selected outcomes were sexual violence (SV) reports and reported teen pregnancy. Frequency distributions to measure prevalence and chi-square statistics were calculated to assess significant differences and computed odds of occurrence associated with time period.

Results: In pre COVID-19 period, 17,702 females reported for post-rape care and 3,274 received PEP compared to 22,013 and 3,348, respectively, during COVID-19 period. This translates to a 24% increase of post-rape reports and 18% reduction in PEP uptake between two periods. The odds of receiving PEP during COVID-19 period was 0.79 times (95% CI 0.75-0.83) lower compared to pre COVID-19 period. Over 50% of those who reported for post-rape care after the recommended 72-hour intervention timeframe cited lockdown restrictions as the main reason for coming late.

In pre COVID-19 period, 593 girls reported SV, and 73 reported teen pregnancy compared to 860 SV and 117 teen pregnancies in COVID-19 period. The odds of reporting SV during COVID-19 period was 1.30 times (95% CI: 1.12-1.51) higher compared to pre COVID-19 period. There was a 17% increase in teen pregnancy between two periods, not statistically significant (OR 1.121, 95% CI, 0.82-1.53).

Conclusions: During Uganda's COVID-19 lockdown, sexual violence reports increased, increasing HIV exposure in national data, taking into consideration possible underestimated true GBV increase associated with COVID-19 related disruptions. Investment in unhindered, flexible and adaptable GBV mitigation is important during pandemics.

OAD0302

Violence across the life course and opportunities for intervention design: findings from the Maisha Fiti study with female sex workers in Nairobi, Kenya

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Background: Violence against women and girls is associated with increased risk of HIV acquisition, with effects both direct (e.g. rape) and indirect (e.g. from child maltreatment). We examined violence experiences among Female Sex Workers (FSWs) and how this relates to HIV risk using a syndemics and life-course perspective, in order to identify opportunities for interventions.

Methods: Maisha Fiti is a mixed-methods longitudinal study with FSWs aged 18-45 years randomly selected from across Nairobi. Baseline behavioural-biological surveys (n=1003) were conducted June-December 2019. Violence was assessed using the WHO Adverse Childhood Experiences (ACE) and Violence Against Women questionnaires. Harmful alcohol and substance use were assessed using the WHO ASSIST Tool. Descriptive statistics, and multivariable logistic regression models were used to examine violence across the life-course, and correlates of recent (past 6 months) sexual or physical violence experience.

Results: 1003 FSWs participated; HIV prevalence was 28.0%. Reports of adverse experiences in childhood were high: 41.4% were orphaned, 12.0% lived on the streets, and 79.3% experienced physical or sexual violence. We found substantial overlap between violence in childhood, and subsequent partner and non-partner violence in adulthood, with 72.2% reporting multiple types of violence.

We also found high levels of recent violence (past 6 months), with 64.9% reporting physical or sexual violence, 30.7% police arrest, 2.4% gang rape and 2.8% rape in the past 7 days. In adjusted analyses, recent sexual or physical violence (by any perpetrator) was associated with a high ACE score (AOR 5.3 (95%CI 3.3-8.7)), forced sexual debut (AOR 1.4 (1.0-2.0)) ever being married/co-habiting (AOR 1.5 (1.0-2.1)), recent hunger (AOR 1.3 (1.0-1.8)), recent police arrest (AOR 2.3 (1.6, 3.2)), current harmful alcohol or substance use (AOR 1.6 (1.2-2.2)) and condomless last sex (AOR 1.4 (1.0-1.9)).

Conclusions: We report strong evidence of concurrent and sequential violence victimization across the life-course by different perpetrators, and syndemics with harmful alcohol and substance use and HIV risk. Large-scale holistic violence interventions are needed to reduce violence against women and girls in this setting.

Interventions which focus on violence prevention during childhood and adolescence should help prevent future adverse trajectories, including HIV risk.

OAD0303

Sexual violence is longitudinally associated with reduced likelihood of viral suppression among transgender women living with HIV in Brazil

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Background: Globally, transgender women (TGW) are disproportionately affected by HIV and gender-based violence (GBV), defined as physical, sexual and emotional violence perpetrated against an individual based on their gender identity or expression. While a growing body of evidence demonstrates that GBV prevents engagement in HIV care and treatment among cis-gender women, less research has examined this association among TGW. We conducted a longitudinal analysis to assess the impact of GBV on viral suppression among TGW living with HIV in Brazil.

Methods: A pilot trial of a peer navigation intervention to improve engagement in HIV care and treatment among TGW was carried out in São Paulo, Brazil between 2018 and 2019. TGW living with HIV were recruited and randomized into the intervention or control and participated in a baseline and 9-month follow-up survey. Surveys assessed self-reported lifetime experiences of physical and sexual abuse. Laboratory confirmed viral suppression, defined as viral load less than 1000 copies/mL, was extracted from patient medical charts.

We conducted an intent to treat analysis, whereby those with missing medical records data (n=23) were assumed to not be virally suppressed. We used generalized linear model regressions with a Poisson distribution to estimate the relative risk (RR) for the association of physical and sexual violence at baseline with viral suppression at follow-up, adjusting for baseline sociodemographic characteristics.

Results: A total of 113 TGW were enrolled. Retention was 70% at follow-up. At baseline, the mean age was 33 years and 27% were living below the international poverty line. Over half of the participants (62%) reported lifetime physical violence and 45% reported lifetime sexual violence. At follow-up, 32% had confirmed viral suppression. In adjusted models, lifetime physical violence was not significantly associated with viral suppression (RR: 0.69; 95% CI: 0.40, 1.20; p=0.19). Lifetime sexual violence was significantly associated with a 58% reduction in viral suppression (RR: 0.42; 95% CI: 0.22, 0.81; p=0.01).

Conclusions: Our findings are among the first to demonstrate that lifetime experiences of sexual violence are longitudinally associated with reduced likelihood of viral suppression among TGW. Interventions seeking to improve antiretroviral therapy adherence should assess and address experiences of GBV among this population.

OAD0304

Do childhood and adolescence sexual violence experiences relate to HIV testing and PrEP uptake in young adulthood among MSM of color living in an urban area of the United States?

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Background: Meta-analyses have established that gay, bisexual and other men who have sex with men (MSM) who experienced childhood sexual abuse are significantly more likely to report HIV-related outcomes, such as condomless anal intercourse, sex after alcohol and drug use, and HIV acquisition. A recent study in the United States (US) on the impact of "adverse childhood experiences" (ACEs) on MSM sexual health found that ACEs were significantly associated with condomless anal intercourse. However, no significant association was reported between ACE exposure and HIV testing, the gateway to post-/pre-exposure HIV prophylaxis (PEP/PrEP), a cornerstone of the HIV prevention strategy in the US. Limited data is available on the association between childhood/young-adulthood sexual violence experiences (SVEs) and PrEP use in later life among MSM of color.

Methods: Using baseline data from TRUST, an NIH-funded randomized and attention-control trial of an HIV self-testing intervention for young, Black/African-American MSM, and standard uni- and bivariate descriptive statistics (Chi-square and t-tests), we assessed relations among SVEs on recent HIV testing in the past 3 months and recent PrEP use among 372 HIV-negative MSM of color. SVEs assessed perceptions of "first experience of anal sex" and asked participants to recall if it was "forced," "coerced," "non-consensual" or "for survival." We also assessed if they had a "sexual experience prior to age 18 that was forced, pressured, or otherwise unwelcome."

Results: Nearly a third of the sample (mean age=24 years, SD=5) experienced forced or pressured first sexual experiences; nearly two-thirds reported a sexual experience prior to age 18 with a partner five or more years older and/or that was forced, coerced, or otherwise unwanted. In bivariate analyses, no associations were found between SVE and recent HIV testing or PrEP use among this sample of MSM of color.

Conclusions: Although no associations were identified between childhood/adolescence SVEs and HIV testing and PrEP uptake in later life, provider knowledge of exposures is needed to deliver optimal, trauma-informed sexual health care to MSM of color. More research is needed to determine whether experiences of adulthood violence and/or an accumulation of childhood SVEs/ACEs over time relate to multiple HIV preventive behaviors among MSM of color.

OAD0305

Using the Girl Group Leadership Model (GGLM) in improving economic strengthening to reduce new HIV incidences among adolescent girls and young women in Homabay County, Kenya

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Background: Adolescent Girls and Young Women (AGYW) need leadership skills for personal development, economic empowerment and networking. Most AGYW lack opportunities to assume leadership in their health and life goals.

Description: The aim of GGLM IS to decrease the AGYW involvement with cross-generational sex, multiple partners and transactional sex through economic empowerment. This model increased the networks and safety nets of the AGYW and championed gender-based prevention of HIV. The GGLM incorporated leadership training in all facets of economic empowerment where the AGYW self-lead themselves through economic empowerment processes. The GGLM involved a lot of girl groups whose membership was between 25 to 30 AGYW.

Lessons learned: GGLM created an opportunity for AGYW to gain social protection hence boosting their ability to reduce the risks of acquiring new HIV infections. Through GGLM, the AGYW have been able to start businesses and village savings and loaning groups. Half of the Girl groups created in the implementation period have since transacted more businesses than when they hadn't been exposed to this girl leadership model. The AGYW have been able to receive interventions such as entrepreneurship training, microenterprise start-up support, and facilitated access to employment and internships. GGLM as a best practice has enabled AGYW to rise into positions of leadership not only in their groups but also in the programmatic implementation as program associates.

Some groups have been registered with the ministry of Youth Gender and Social services to operate businesses across the country. These girl groups enabled AGYW to survive the COVID 19 pandemic period in the country. For example, Superstars – a girl group in Homabay County who have adopted the GGLM started soap making business during the COVID 19 pandemic and made 10,000 Kenyan Shillings ($92) in loans to its members.

Conclusions/Next steps: Systematic strengthening of AGYW in Leadership gives them an edge to express themselves better, network and champion matters affecting them. Girl Group Leaders through a comprehensive model has enhanced retention and motivation for DREAMS beneficiaries in uptake of services. GGL model is an enabler for adaptation, resiliency and economic empowerment for vulnerable girls and young women towards sustainability.

OAD04 Yield in the field: Understanding HIV testing efficiency and reach

OAD0401

Trends in HIV testing yield need to be interpreted within the context of changing testing patterns: analysis of individual-level programme data from Zimbabwe's national sex work programme, 2009-2019

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Background: Yield is used as a marker of HIV programme performance, but is increasing yield a valid indicator of success? Understanding the influence of HIV testing delivery and individual testing frequency could enhance our interpretation of this indicator and improve programme implementation. We analysed yield in the context of increased testing coverage among women accessing Zimbabwe's national sex work programme (Sisters).

Methods: We analysed HIV test data and self-report testing history among female sex workers attending Sisters clinics between 2009-2019. We defined yield as the proportion of tests delivered by the programme that were HIV-positive. We used logistic regression to analyse yield over three time periods: 2009-2013, 2014-2016 and 2017-2019. We adjusted for confounding by demographic factors and included testing frequency in our model, defined as a woman having last tested within 6 months, to investigate its mediating role.

Results: During the ten-year study period, 54,503 tests were recorded among 39,462 women, with increasing numbers of clinic sites and women reached and tested over time. While individual testing frequency increased, both within and outside Sisters, progamme testing yield decreased (Figure 1). Between 2017-2019, yield was 9.6% (2,608/27,024), compared to 47.9% (1,934/4,039) between 2009-2013 (aOR 6.1 95%CI 4.7-7.9), and 18.8% (4,417/23,440) between 2014-2016 (aOR 2.2 95%CI 1.9-2.4). Including testing frequency in our model reduced odds ratios for yield between 2009-2013 (aOR 2.8 95%CI 2.1-3.6) and 2014-2016 (aOR 1.9 95%CI 1.7-2.1) compared to 2017-2019.

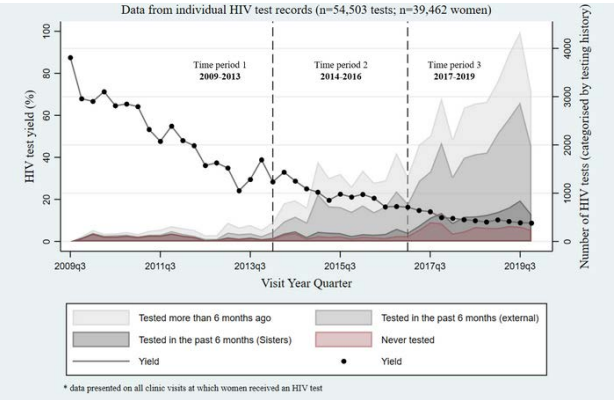

Figure 1. HIV test yield & test coverage at Sisters clinics between 2009-2019. Data from individual HIV test records (n=54,503 tests; n=39,462 women)

Conclusions: Yield decreased among women testing through Sisters, with evidence this was mediated by more frequent testing. Earlier in the programme, HIV-positive tests were likely longer standing undiagnosed infections, with more recent infections being picked up in later time periods. We recommend that, for yield to be a useful programme indicator, consideration needs to be given to the impact of changing testing patterns and what can be learnt from this.

OAD0402

Acceptability and challenges of self-collected rectal swab for sexually transmitted infections testing among men who have sex with men and transgender women in Kigali, Rwanda

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Background: Rectal sexually transmitted infections (STI) are highly prevalent among men who have sex with men (MSM) and transgender women (TGW), but reticence to provider-collected rectal swabs has been reported in Sub-Saharan Africa (SSA). Though self-collection of rectal specimens is commonly used globally, there are limited data on its implementation across SSA. Here, we report experiences of self-collecting rectal specimen for STI testing among MSM and TGW in Kigali.

Methods: From March-August 2018, 738 MSM/TGW ≥ 18 years of age were recruited in a cross-sectional study using respondent driven sampling in Kigali. *Neisseria gonorrhea* (NG) and *Chlamydia trachomatis* (CT) were tested using Cepheid GeneXpert CT/NG platform on self-collected rectal swabs. Likert scales were used to assess the difficulty and comfort with collecting the rectal swab. Multinomial logistic regression analyses were performed to characterize factors associated with difficulty in self-collecting a rectal swab.

Results: Overall, 14% identified as TGW. The prevalence of CT was 9.1%(67) and NG was 8.8%(65) at any site. Overall, 27% and 6% of CT infections and 52% and 19% of NG infections were rectal and dual-site respectively. In total, 78%(577) reported that collecting the rectal swab was easy/very easy while 7%(52) and 15%(108) were neutral or found it difficult/very difficult respectively. The majority, 92%(679), were comfortable/very comfortable with the test and 98%(730) said they would repeat the test in the future. A total of 10%(76) of rectal swabs returned indeterminate results (66 invalid results and 10 errors).

In multivariable multinomial logistic regression adjusting for demographic characteristics, factors positively associated with difficulty collecting the rectal swab were discomfort with the test (adjusted relative risk ratio ((aRRR):11.8(95%:6.5-21.3)) and a history of STI (aRRR:1.8(95%:1.00-3.16). TGW were less likely to report difficulty performing the test compared to cisgender MSM (aRRR:0.34(95%:0.13-0.89).

Conclusions: Among MSM/TGW in Kigali, self-collected rectal swabs were highly acceptable, easy to perform and comfortable. Patient education on self-collection of rectal specimens should be introduced

to reduce discomfort associated with this test, as it can support clinic- and community-based STI testing. The high proportion of indeterminate results have significant cost implications, thus measures to ensure adequate sample collection and processing are necessary.

OAD0403

Impact of a brief community health worker-administered index case testing screening tool on pediatric HIV case identification: early results from Malawi

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Background: Nearly 100% of pregnant/lactating women living with HIV (WLHIV) in Malawi are on ART, yet only 68% of children living with HIV (CLHIV) are. This treatment gap between mothers and children signifies a missed opportunity to identify CLHIV. Index Case Testing (ICT) is a WHO-endorsed model for identifying CLHIV. A contributor to suboptimal ICT implementation is the lack of methods to systematically track HIV status of children of WLHIV. We evaluated the impact of a screening tool on WLHIV screened for ICT, pediatric HIV testing, and CLHIV identified.

Methods: The brief (<5 minutes) ICT screening tool assesses HIV testing status of children of WLHIV at ART clinic. Data captured includes number of children 0-19 years, children's names, ages, and HIV status. Completed tools are attached to mother's ART record for review at subsequent visits. WLHIV attending clinics in 118 health facilities in Malawi were screened from 1 October to 31 December 2020. De-identified program data from ICT registers were used to determine WLHIV screened, children tested, and CLHIV identified.

Results were compared to pediatric testing and case identification over the same period in 2019. A single sample t-test was used to test differences in mean number of women screened. Paired t-tests were used to test differences in mean number of children tested and CLHIV identified.

Results: Total number of women screened, children tested, and CLHIV identified increased iduring ICT tool implementation (Table 1). Mean number of WLHIV screened weekly was 1411 in 2020 compared to 950 in 2019 (p-value=0.042). Mean number of children tested weekly was 319 in 2020 compared to 192 in 2019 (p-value=0.018). In 2020, mean number CLHIV identified weekly was ten compared to six in 2019 (p-value=0.059). In both periods, ~3% of children tested HIV-positive.

Outcome	Oct - Dec 2019 (without ICT tool)	Oct - Dec 2020 (with ICT tool)	Change
Total women screened	12,350	18,342	+49%
Total pediatric clients tested	2,500	4,075	+63%
Total pediatric clients tested HIV+	78	123	+58%

Table 1.

Conclusions: Systematic documentation of children's ICT status using a brief ICT screening tool is a useful approach to identify untested children of WLHIV. Further examination of characteristics of WLHIV with untested children may inform programmatic interventions to identify CLHIV.

OAD0404

An evaluation of family index testing amongst biological children of people living with HIV in Nigeria

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Background: HIV case-finding among children is a significant challenge in Nigeria. Of the estimated 150, 000 children aged 0 – 14 years and 110, 000 adolescents aged 10 -19 years living with HIV in Nigeria, only 36% and 40% respectively are on treatment.

PEPFAR recommends family index testing (FIT) as a targeted strategy for improving case finding in children. FIT entails HIV testing for all biological children of people living with HIV (PLHIV).

The Pediatric Program at Institute of Human Virology Nigeria (IHVN) conducted a program evaluation to determine the proportion of biological children of PLHIV in its treatment network not yet tested for HIV.

Methods: The evaluation was conducted between September and October 2020 at eight randomly- selected high-burden sites across four states-Rivers, FCT, Nasarawa, and Katsina. A representative sample of adult PLHIV ≥ 18 years old with living biological children aged 0 – 19 years were randomly selected per site. Participants were interviewed via phone calls; those with untested children were invited to either bring their child(ren) to the facility for HIV testing, or given the option of home-based testing.

Results: In total, 803 eligible adult PLHIV were interviewed (67% female). Of the 1, 732 children and adolescents elicited, 63% (1,083) had a known HIV status, with 6% (67) identified as "known HIV-positive".

Age at HIV diagnosis could be remembered for only 82% (55/67) of known positives, and indicated that 62%, 27%, 9% and 2% were diagnosed at 0 – 4, 5 – 9, 10 -14, 15 – 19 years of age, respectively.

Ninety-two percent (597/649) of children with unknown HIV status were tested, with a yield of 1.7% (10/597) HIV-positive.

Of children newly-identified positive, 30%, 0%, 30% and 40% were identified from the 0 -4, 5- 9, 10 -14 and 15 – 19 year age bands, respectively.

Conclusions: Significant progress has been made in scaling up FIT in Nigeria, however, a third of biological children of PLHIV in our evaluation had unknown HIV status. Intensified and coordinated efforts across Adult, PMTCT, Vulnerable Children and other community-based programs are needed to reach and test eligible children. Children in all age bands should remain prioritized for FIT.

OAD0405

Increasing efficiency in HIV testing services for prison inmates through the use of risk assessment: experience from EpiC Nigeria

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Background: Correctional facility inmates are a distinct key population (KP) group reached by the Key Population Investment Fund (KPIF) program, which is implemented by the FHI 360-led EpiC project in Nigeria with support from USAID and PEPFAR. The HIV positivity rate among prison inmates is about 2.8%, which is lower than that of other KP groups. The project team deployed a specially designed risk assessment tool (RAT) to help increase the efficiency of HIV testing services (HTS) among this population in Niger State, Nigeria.

Description: As part of routine program implementation, the team assessed the outcome of deploying the RAT for HTS in 6 prisons. The RAT is a questionnaire administered by trained HTS providers to assess recent risky behaviors, such as having anal or vaginal sex without using a condom, engaging in transactional sex, and sharing sharp objects. Only clients assessed to be at high risk of HIV were offered HTS. A retrospective comparative analysis was conducted using data collected 10 weeks before and after the deployment of the RAT.

Lessons learned: During the 10 weeks (February to April 2020) prior to RAT deployment, 5 (0.78%) of the 643 inmates who were offered HTS tested HIV positive (a rate similar to the HIV prevalence among the age 15–64 general population in Niger State). Within 10 weeks (April to June 2020), testing volume was reduced to 250 inmates, but 27 of those individuals (10.8%) tested positive. The monthly HIV positivity rate increased from 0–1% to 4–27% with the use of the RAT (Figure 1)

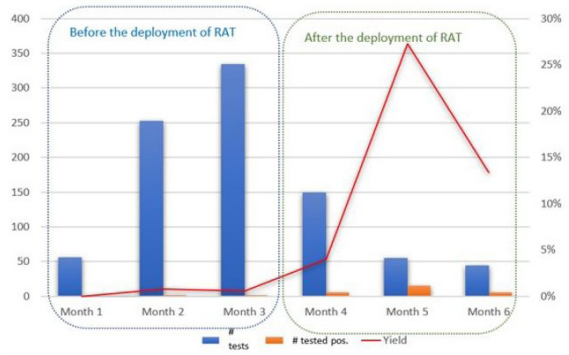

Figure 1. 6 month HIV testing data before and after deployment of RAT

Conclusions/Next steps: The deployment of the RAT among inmates helped reduce HIV testing volume, increased testing efficiency, and resulted in increases in case detection. Plans are underway to scale up the tool's use across all EPiC-supported correctional facilities in Nigeria.

OAD0406

"It is a process" – a qualitative evaluation of provider acceptability of HIV assisted partner services in western Kenya: experiences, challenges and facilitators

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Background: Assisted partner service (APS) is effective for increasing HIV testing services (HTS) uptake among sexual partners of people diagnosed with HIV with rare social harm. The acceptability of APS to HTS providers is important for the quality and effectiveness of APS delivery. Within an ongoing implementation science study of APS in western Kenya, we qualitatively evaluated the provider acceptability of APS.

Methods: From May-June 2020, we conducted virtual, semi-structured in-depth interviews with 14 HTS providers recruited from 8 of 31 study health facilities in Homa Bay and Kisumu counties. Participants were selected using criteria-based purposive sampling to maximize variation on patient volume (assessed by the number of index clients tested for HIV) and APS performance (assessed by sexual partners elicitation and enrollment). Interviews inquired providers' experiences providing APS including challenges and facilitators and the impact of contextual factors. Data were analyzed using an inductive approach.

Results: Overall, HTS providers found APS acceptable. It was consistently reported that doing APS was a continuous process rather than a one-day job, which required rapport development and persistent follow-ups. Benefits of APS including efficiency in HIV case finding, expanded testing coverage in men, and increased HIV status awareness and linkage to care motivated the providers. Advantages of provider referral were identified such as independent contact with partners on behalf of index clients and efficiency in partner tracing. Challenges of providing APS involved protecting clients' confidentiality, difficulty obtaining partners' accurate contact information, logistic barriers of tracing, and clients' refusal due to fear of being judged for multiple sexual partners, fear of breach of confidentiality, and HIV stigma. Building rapport with clients, communicating with patience and non-judgmental attitude and assuring confidentiality were examples of facilitators. Working in rural areas and bigger facilities, training, supportive supervision, and community awareness of APS promoted APS delivery while low salaries, lack of equipment, and high workload undermined it.

Conclusions: HTS providers found APS acceptable. Taking APS as a process was the key to success. Future scale-up of APS could consider encouraging provider referral instead of the other APS methods to improve efficiency and reduce potential harm to clients.

OAD05 Empowered and embedded: Implementation researchers improving the quality of treatment programmes

OAD0501

Quality improvement collaborative approach to improving viral load suppression in the 15-24-year age group in four regions of Namibia, 2018-2020

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Background: Namibia's antiretroviral therapy (ART) program has been successful in achieving a high level of viral load suppression (VLS) of 91% (NAMPHIA, 2017). Sub-populations and geographic areas need approaches to reach optimal VLS. In August 2018, VLS in four high-burden HIV regions was 92% (n=2527) overall, but only 44% (n=407) among 15-24 years of age. We aimed to improve VLS in the 15-24 age group using a quality improvement collaborative (QIC) approach; a methodology that accelerates improvement where a performance gap is identified.

Description: Twenty-five ART healthcare facilities in Kavango, Omusati, Oshana and Oshikoto regions that provide care to almost 66,400 people living with HIV (PLHIV) were selected to participate. A team of three healthcare workers (ART nurse, data clerk and medical officer) per facility attended the inaugural QIC learning session on July 2018. Regional HIV mentors were trained as quality improvement (QI) coaches while the national QI coaches provided overall coordination and data management. Each facility set up a QI team and identified specific ideas to test using the model for improvement (Plan, Do, Study Act cycles). Facilities compiled and submitted monthly reports to the national level using an Excel template. VLS was defined as being active on ART with a viral load <1000 copies/mL.

Lessons learned: The key outcome was VLS in the 15-24 years age group improved from a baseline of 44% (n=407) in August 2018 to 74% by December 2020 (n=719). Change ideas that were successfully implemented in the 25 participating sites to improve adherence to ART, patient tracking and management included use of high VL registers (100% of the sites), enhanced adherence counselling (80%), multidisciplinary team management (72%), direct observation therapy (52%), use of pillboxes (32%), initiating and strengthening teen clubs (64%) and timely switch to working regimen (100%).

Conclusions/Next steps: A QIC model applied with a dedicated team of healthcare workers and QI coaches led to the improvement in VLS in the 15-24 years age group. Facility level teamwork and QI learning sessions were critical to the success of the initiative. The QIC model may be used in other settings to optimize treatment outcomes for other indicators.

OAD0502

Applying machine learning and natural language processing of qualitative client-reported data to design client-centered interventions for maximal impact

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Background: As countries approach HIV epidemic control, client-centered interventions are necessary to address persistent barriers to HIV prevention, care, and treatment. We describe a deep-learning model to rapidly analyze qualitative client-reported data to design client-centered interventions.

Methods: We purposively asked each client from 104 facilities in 32 districts why they missed appointments (N=2,267) or had unsuppressed viral loads (N=2,196); we classified open-ended responses into eight intervention categories (Table 1). We used R (v4.0.2; quanteda package) for natural language processing (e.g., stemming "facility"/"facilities" to "facil") and generated a matrix with scaled frequencies of stemmed words/phrases for each open-ended response. We randomly subsetted data into training (60%) and test (40%) datasets, trained the model 30 times (neuralnet package; backpropagation through eight hidden neural network layers; 10^5 maximum steps), and validated the model by comparing *a priori* and model classifications on the test dataset.

Client-reported open-ended text examples	*a priori* intervention classifications to address client-reported root causes	Natural language processing of client-reported data		Model accuracy (% of test dataset with consistent model and *a priori* intervention classifications)
		Dominant stemmed words in dataset	Dominant stemmed word pairs	
Active, no documentation, file was misplaced, I came I did not find health workers, rude healthworker, staffs not around	Assess and address clinic operational issues	activ, document, staff, rude, healthwork	activ_document, staff_around, rude_healthwork	99%
Harassment by the caretaker, depressed, stigma, suffered GBV, mental ill health, drug abuse, laziness and taking alcohol, discordance, feared disclosure, fear of being seen	Psychosocial support to address home/family, mental health, and substance abuse	stigma, disclosur, nondisclosur, fear, suffer, intervention, alcohol, depress	gender_base, base_violenc, drug_abus, fear_disclosur, violenc_isso, mental_ill	98%
Busy schedule, I had visitors at home, committed to personal business, had gone to court, attend to land disputes, I arrived late at facility, poor time management, I was nursing a sick child, delivered a baby	Interventions for busy clients (e.g., flexible hours, fast-track for stable clients, multi-month drug dispensing)	sick, work, relat, time, demand, train, busi, child, home, facil, health	sick_relat, work_demand, long_wait, wait_time, sick_child, nurs_sick, attend_sick, busi_schedul, famili_affair, visitor_home, given_birth	97%
I dident have transport, long distance, it rained and roads were blocked, caretaker was sick	Interventions to address distance/mobility issues, including unavailability of caretaker	transport, lack, weather, caretak, rain	lack_transport, long_distanc, transport_long, didn't_transport, rainl_weather, transport_problem, distanc_lack	98%
Had travelled, I was away, had gone for a visit, child gone for holidays, doing exams at school, migrant worker, female sex worker always away, I got a new job in wakiso district	Interventions for traveling clients (e.g., multi-month drug dispensing)	travel, school, away, intervention, gone, worker, child, visit	exam_school, migrant_worker, child_school	94%
I dont know how to read and I had no one to help, I forgot the appointment date, other scheduled appt, return date not written, I misinterpreted the date, I lost my bag which had my records, I lost my card, other scheduled appt	Remind clients in advance of appointment to prevent forgetting or double-scheduling	forget, date, forgot, appt, intervention, misunderstood, lost	forget_date, forgot_appoint, appoint_date, misinterpret_date, appt_date, schedul_appt, lost_card	95%
Had an accident, had lost a relative, I had taken my wife to the hospital, I was sick and admitted, died, I was imprisoned, had gone for burial, getting drugs from another facility, relocated, self-transferred,	Ensure follow-up with client; no intervention needed for extenuating circumstances or relocating client	sick, relat, lost, burial, admit, reloc, ill, imprison, accid, die	lost_relat, sick_admit, self_transfer, gone_burial	96%
Had balance, still had drugs, drug holiday, felt better, pill burden, side effects, I had no food, religious reasons	Pharmacologic interventions, including regimen and adherence counseling	balanc, drug, pill, still, food	still_drug, pill_balanc, lack_food, drug_holiday, side_effect	91%
			Overall Model Accuracy:	96%

Table 1.

Results: The model achieved 96% accuracy (1,817 classifications consistent with 1,889 a priori classifications). Model and a priori analyses revealed the same conclusions, validating the model for use in various contexts. For example, model and a priori analyses concluded that disproportionately more males than females need interventions for traveling. The model prioritized addressing distance/mobility issues (for 22.2% of clients) and post-missed-appointment contact (18.5%) for this population, consistent with a priori analysis (22.1%, 19.3%, respectively). The model was robust for smaller samples (e.g., 91 0-14 year-olds constituting 4.8% of test dataset, prioritizing pre-appointment reminder (26.4% of clients in model; 27.5% a priori), contact (17.6%; 17.6%), distance/mobility (16.5%; 19.8%)).

Conclusions: While these findings might improve outcomes in other facilities and countries, the major impact is this novel model's ability to rapidly analyze other datasets to identify emerging and persistent population-specific challenges needing intervention (e.g., by age, sex, facility, district). This model can facilitate client-centered healthcare necessary to maintain HIV epidemic control.

OAD0503

#SaferNowPH: a COVID-adapted, key population-responsive, community-led integrated marketing communications campaign on HIV combination prevention in the Philippines

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Background: The COVID pandemic calls for an intensified promotion of innovative approaches in delivering HIV prevention information and services to minimize key populations' (KP) vulnerability to HIV, given their reduced access to sexual health services, and to take advantage of their increased online time-use.

Description: Informed by an online survey, FGDs and KIIs with 1,000+ combined KP respondents, the community-led National HIV Prevention Month (NHPM), themed #SaferNowPH, was launched August 2020 to promote four HIV prevention methods: condoms & lube, PrEP, PEP and treatment-as-prevention. The campaign hosted online mobilization activities (webinars, photography & free PrEP contests, a PLHIV dating show, an LGBT- & PLHIV-themed film festival, and a game show featuring local advocates and influencers) and disseminated posters and videos fronted by health professionals with KP-targeted messaging. Online content reached 236,000+ individuals. Over 45 localized online, in-facility and community activation events were held nationwide through partner community-based organizations, with support from Global Fund and other institutional/corporate partners. Combination prevention IEC materials and campaign-branded kits were distributed for HIV & COVID protection. An interactive chatbot was also introduced to provide KPs recommended prevention method/s based on their responses to behavior questions, and subsequently direct them to nearby HIV service providers.

Lessons learned: No single prevention approach can stop the HIV epidemic. The NHPM & #SaferNowPH campaign allowed for focused, sustained awareness activities on HIV combination prevention, while giving due emphasis on each prevention method. It illustrated how innovation and differentiation is essential, not only in HIV service delivery, but also in education, demand generation, and the use of new media. Tapping influencers was effective at amplifying campaign reach while engaging community partners from campaign development to evaluation was integral in ensuring their ownership and commitment throughout campaign implementation. These combined reach helped increase partner co-financing.

Conclusions/Next steps: The campaign successfully modeled KP-targeted communications and the combination prevention approach to HIV education provided in the Philippine HIV Strategic Plan. Government endorsement is anticipated to sustain the NHPM annually. Community engagement is crucial to adapt key messages to varying KP and geographic needs, and to more effectively inform, generate demand from, and link KP to prevention services.

OAD0504

Structured support groups improves PrEP uptake among female sex workers in Nairobi: a case study of BHESP

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Background: Bar Hostess Empowerment & Support Program (BHESP), is a female sex worker led organization fthat advocate for the human rights and facilitate access to health services for sex workers (FSW) in Kenya. BHESP implements health and advocacy programs targeting the same population.

To increase uptake of sexual reproductive health services BHESP is running Drop in Centers (Clinics) that are friendly to FSW. BHESP implemented oral Pre- Exposure Prophylaxis (PrEP) roll out targeting FSW at substantial risk of HIV infection in Nairobi. From October 2018, 6,900 FSW were enrolled on oralPrEP and at the end of September 2019, only 1,250 (18%) were continuing with PrEP which is an 82% self discontinuation.

Methods: BHESP administered Exit interviews to FSWs who discontinued from PrEP use to establish the reasons. It was found that lack of knowledge, myths, misconception and stigma contributed to 60% of PrEP discontinuation among FSWs between 2018 and 2019.

To address on this gap, BHESP introduced well-structured PrEP support groups targeting newly enrolled and those that have missed their pill appointments. Support groups were deliberately planned to coincide with the PrEP refill/appoinment days.

Objectives of the support group was to provide a peer support environment in which FSW on PrEP can come together and share experiences safely and openly. It also aimed to increase knowledge and awareness of transmission, prevention of HIV and STIs, PrEPnadherence and to reduce stigma and feelings of isolation and discrimination among support group members.

Results: October 2019 toSeptember 2020, BHESP PrEP continuation for the enrolled FSW increased to 60% from 22% (3,540/ 2,120) in the previous year of implementation. After conducting exit interviews, FSWs who discontinued the use of PrEP reported to be as a result of reduced risk to HIV. Cases of missed appointments had also significantly reduced within the same period.

Conclusions: PrEP support groups for newly enrolled on PrEP and those missing refill appointments strengthened adherence and retention in the regimen as well as to increase knowledge and awareness on PrEP use. If PrEP support groups are well planned and structured, they can improve the uptake and adherence of oral PrEP among FSWs.

OAD0505

Optimizing antiretroviral treatment and viral suppression for adolescents and young people living with HIV by implementing Operation Triple Zero (OTZ) in four states in Nigeria

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Background: In Nigeria, adolescents (10-19 years) account for about 23% of the total population, and 7% of people living with HIV (PLHIV); treatment outcomes for adolescents and youth living with HIV (AYPLHIV) are quite low. RISE-Nigeria commenced Operation Triple Zero (OTZ) in 33 facilities across four states in February 2020 to improve treatment outcomes. This analysis reviews the effect of OTZ on treatment outcomes among AYPLHIV six months after implementation.

Description: The OTZ model focuses on health system modifications, adolescent-centeredness and involvement in health, and education of caregivers and health workers. Case managers were identified and trained on non-judgmental approaches to counselling and optimal antiretroviral therapy (ART) for AYPLHIV; Clinic settings modified with adolescent-friendly themes; all services integrated and systems for peer-to-peer adherence support strengthened; Extended and weekend clinic hours established, with an appointment system for age bands 10–14, 15-19 and 20–24 years; Viremia clinics established for the virally-unsuppressed AYPLHIV; Case-based learning introduced for capacity building of health workers; Talent nurturing and skill development incorporated into AYPLHIV club meetings; and HIV status disclosure support offered to caregivers with opportunity for caregivers interaction during OTZ meetings facilitating peer-to-peer learning.

Lessons learned: After 6 months, AYPLHIV enrollment into OTZ increased from 615/3306 (18.6%) to 3595/4304 (83.5%); p-value <0.001. Optimal regimen utilization pre-intervention was 284/765 (37.1%%), 285/760 (37.5%), and 709/1526 (46.5%) preintervention, and increased to 807/819 (98.5%), 985/991 (99.4%), and 2478/2484 (99.8%); p-value <0.001 post intervention for age bands 10-14, 15-19, 20-24 years respectively. Viral load coverage (VLC) was 255/765(33.3%), 230/761(30.2%), 492/1772(27.7%) pre-intervention and increased to 740/819(90.1%), 806/991(81.3%) and1794/2484 (72.2%); p-value <0.001 in respective age bands post-intervention. Viral suppression (VS) rate increased from 390/586(66.6%), 286/552(51.8%) and 1155/1690(68.3%) pre-intervention to 611/749 (81.6%), 700/844(82.9%), and 2030/2384(85.2%); p-value<0.001 in respective age bands post-intervention. Overall VS was higher 2487/2935 (84.7%) among OTZ enrollees compared to non-enrollees 852/1040 (81.9%); p-value 0.03.

Conclusions/Next steps: OTZ implementation improved the use of optimal ARV regimen, VLC, and VS among AYPLHIV. These results validate the use of integrated, asset-based strategies to improve HIV treatment outcomes among AYPLHIV.

OAD06 You want it, you got it: From acceptability to desirability in HIV Care

OAD0601

Fast and friendly is key to keeping men on HIV treatment! Results from a discrete choice experiment to understand men's preferences in Johannesburg, South Africa for HIV treatment services

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Background: Men have been shown to be less likely to engage in care across the HIV care cascade, in particular retention in care and treatment. Understanding men's preferences for HIV treatment models would provide data to optimise service delivery to improve retention and outcomes. A discrete choice experiment (DCE) was conducted to explore HIV treatment preferences of men in Johannesburg (South Africa).

Methods: We conducted a DCE in late 2020 with adult men (≥18 years) recruited from 6 community sites (e.g. hostel, homeless shelter, taxi rank) to ensure representation from men with varied HIV treatment experience. Each participant completed a DCE with 9 choice sets focusing on preferences for 8 HIV treatment attributes. Using conditional logistic regression the strength of preference for each attribute level was estimated.

Results: 150 respondents completed the DCE (median age 35 years; 12% HIV+). Participants indicated a strong preference (OR=2.55; 95%CI: 2.16-3.01) that providers are friendly, welcoming and non-judgmental. There was a preference for consultations not to occur in groups (OR=0.69; 95%CI: 0.58-0.82), not to be scheduled for dates early in the month (OR=0.77; 95%CI: 0.61-0.98); and not to dispense 3 (OR=0.77; 95CI:0.60-0.98) or 6 months (OR=0.77, 95%CI: 0.60-0.96) of drug at a time. There was a preference for services to be free (OR=1.66; 95%CI:1.29-2.13), but no clear preference for location of services, alternative drug formulation (pill vs. injection) or waiting time.

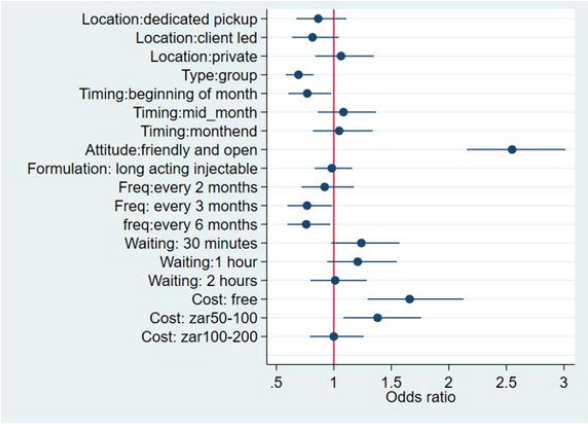

Figure 1. Results of the conditional logit model of DEC data on mens' HIV treatment preferences in Johannesburg, South Africa

Conclusions: As has been seen with other populations provider attitude is a critical service delivery attribute for men accessing treatment. The preference for individual consultations and relatively frequent drug pickups suggests that typical models of differentiated care, which leverage peer group meetings and long dispensing intervals, may not be appropriate for retaining these men in care. Current service delivery models should consider these factors when designing interventions to retain men in care and treatment.

OAD0602

"I wish to continue receiving the reminder Short Messaging Service": a mixed methods study on acceptability of digital adherence tools among adults living with HIV on antiretroviral treatment, Tanzania

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Background: The rapid increase in the use of mobile phones across sub Saharan Africa over the past years have opened the door to the use of Digital adherence tools (DATs) to promote adherence to antiretroviral treatment (ART) for HIV.
However their effectiveness and acceptability in limited resource settings has been challenging. In this study, we examine the acceptability of DATs to improve adherence to ART.
Methods: This study was part of a three-arm randomized controlled trial (REMIND) which investigated the effect of two different DAT's: SMS text messages (SMS) or real-time medication monitoring (RTMM) on treatment adherence; compared to standard of care. Exit interviews and in-depth interviews were conducted at 48 weeks follow-up, to collect data on their experiences (successes, challenges, and barriers) and behaviours regarding the implementation of the interventions. Translated transcripts, memos and field notes were imported to NVivo software version 12.
We used a thematic framework analysis which drew from Sekhon's theoretical framework of acceptability (TFA), which comprises of seven constructs (affective attitude, perceived burden, perceived effectiveness, ethicality, self-efficacy, intervention coherence and opportunity costs).
Results: Of the 166 participants enrolled, 143 (86%) were interviewed (68 in the SMS arm and 75 in the RTMM arm). Participants were highly satisfied (98%) with the DAT system and the majority of them reported it motivated them to take their medication (99%).
The majority of participants reported they were confident in their ability to comply with the intervention and understood how the intervention worked (97%). Very few reported negatively about the devices (carrying the device), with only 6% reporting that they did not feel comfortable and 8% had ethical concerns with the SMS-content
A few participants reported challenges with their connectivity/network and that the visits were too time-consuming.
A few participants reported that they incurred extra cost for the sake of the study.
Conclusions: Overall, the acceptability of these DATs was high. However, several factors may hamper their acceptability including the content and number of SMS, carrying the devices and the network availability.

OAD0603

Preferences for care engagement among people with HIV experiencing homelessness or unstable housing: a discrete choice experiment

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Background: In San Francisco, 39% of people with HIV (PWH) experiencing homelessness or unstable housing (HUH) were virally suppressed, compared to 75% overall. We conducted a discrete choice experiment (DCE) to evaluate preferences for strategies to improve care engagement for PWH-HUH.
Methods: From July-November 2020, we enrolled PWH-HUH at Ward 86 in our drop-in, incentivized care program ("POP-UP") and PWH-HUH in traditional primary care who had an unsuppressed viral load (≥200 copies/mL) in the prior year. The DCE included five service attributes: single vs team of providers; incentives for clinic visit ($0, $10, $20); clinic location (Ward 86 only or additional site); drop-in vs scheduled visits; in-person only vs optional telehealth visits; and patient navigator assistance with visits. We estimated relative utilities using mixed-effects logistic regression and conducted latent class analysis to evaluate preference heterogeneity.
Results: We enrolled 115 participants (59 POP-UP, 56 traditional care); 78% cisgender men, 54% used methamphetamines daily, 40% lived outdoors. Overall, strongest preferences were for same provider (β=0.94, 95%CI 0.48-1.41), incentives (β=0.56 per $5; 95%CI 0.47-0.66), and drop-in visits (β=0.47, 95%CI 0.12-0.82; Figure).
Latent class analysis revealed two distinct groups: 78 (68%) preferred a flexible care model including an additional clinic location (β=0.55, 95%CI 0.25-0.84), navigator assistance (β=0.61, 95%CI 0.24-0.99), drop-in visits (β=0.61, 95%CI 0.17-1.06), and incentives (β=0.77, 95%CI 0.62-0.92); 37 (32%) preferred continuity with the same provider (β=3.12, 95%CI 2.26-3.98).

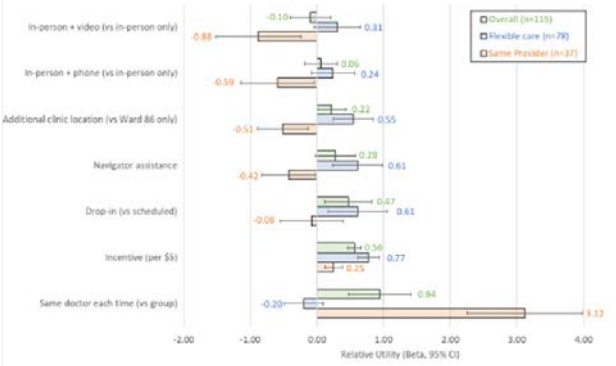

Figure. Relative preference for clinic features among people experiencing homelessness or unstable housing - latent class analysis

Conclusions: We identified heterogeneous care preferences among PWH-HUH via a unique DCE analysis, with one-third of respondents preferring provider continuity and two-thirds preferring a more flexible care model. All respondents preferred incentives. There was no preference for telehealth, even when facilitated by a navigator.
These findings highlight the importance of in-person incentivized care for PWH-HUH with the option to choose between provider continuity and flexibility.

OAD0604

Patient and provider perspectives on a novel, low-threshold PrEP program for people who inject drugs and experience homelessness

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Background: New HIV clusters continue to be identified among people who inject drugs (PWID) and experience homelessness in the Northeastern U.S. and other regions. Antiretroviral pre-exposure prophylaxis (PrEP) is efficacious and recommended for HIV prevention; however, uptake remains low in this marginalized population. We explored patient and provider experiences with a novel, low-threshold program designed to support PrEP uptake, adherence, and persistence among PWID experiencing homelessness.
Methods: Boston Health Care for the Homeless Program (BHCHP) implemented PrEP services for PWID experiencing homelessness in October 2018. From March-December, 2020, we conducted qualitative interviews with current and former adult PrEP program patients and providers (e.g., BHCHP clinicians, patient navigators, outreach workers; and collaborators from affiliated organizations).
Semi-structured interviews were conducted in private outdoor areas using secure video-conferencing on tablets. Rapid thematic analysis identified common patient and provider experiences with BHCHP's PrEP program.
Results: Among 21 PrEP program participants, median age was 35.5 years (IQR: 31-37.5), 15 (71%) identified as male, 6 (29%) as female. Thirteen (62%) identified as white, 4 (19%) Hispanic and 4 (19%) Black. Sixteen (76%) were currently taking PrEP.
All participants reported past-month heroin/fentanyl and polysubstance use (commonly methamphetamine [n=19], cocaine/crack [n=18], non-prescribed benzodiazepines [n=17] and gabapentin [n=13]). Injection frequency was high: 12 reported injecting 4-9 times daily; 4 injected ≥10 times daily. Eleven providers had a median of 6 years working with PWID (IQR: 4.5-13). Program participants and providers expressed concerns about ongoing HIV transmission, linking it to polysubstance use and sexual behaviors (including transactional sex work and sex with HIV-positive partners). They described same-day and short-term prescribing (7-day prescriptions), on-site medication storage, and coordination with other local service agencies as particularly helpful elements of the PrEP program. Participants also discussed the approachability and persistent street presence of PrEP nurses and program staff in facilitating their PrEP uptake and ongoing adherence and retention.
Conclusions: Our findings illustrate how innovative, culturally-competent strategies can help engage and retain PWID experiencing homelessness in low-threshold, outreach-based PrEP services. Specific elements of this program could be considered in a range of community-based settings, including syringe service programs and shelter to mitigate future outbreaks.

OAD0605

A people-centered approach to develop intervention packages for HIV partner notification: facilitators and barriers under a socioecological framework

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Background: The rate of HIV infections among MSM in China has been on the rise in recent years despite public health efforts to reach key populations for HIV prevention. The limited acceptability and usage of partner notification services (PS) would be one reason. People-centered approach such as crowdsourcing, which collects ideas from the public to solve a certain problem, may be promising for developing more effective intervention packages in promoting PS.
Methods: This study used mixed methods to develop PS intervention strategies and analyze emerging themes of facilitators and barriers for PS. First, we used a community-based participatory approach to organize a crowdsourcing contest that solicited innovative works for promoting PS among MSM in China. Second, descriptive analysis was used to examine the demographic characteristics of the participants and the features of the eligible entries. Finally, we conducted content analysis using inductive and deductive coding methods under a socioecological framework, to identify facilitators and barriers of PS.
Results: 77 people from 31 cities submitted a total of 92 submissions, of which 53 remained eligible. Among participants with eligible entries, 60% were male, more than half identified as homosexual or bisexual, and 11% disclosed as living with HIV. Content analysis identified novel strategies to facilitate PS, including differentiation of care and stepwise notification. In addition, people-centered principles were highlighted, as emerged themes from the submissions emphasized on index education and self-empowerment, and the necessity to provide safe and supportive disclosure services.
Conclusions: The contest engaged a diverse population of participants to contribute to the development of people-centered PS for MSM living with HIV in China. Differentiation of care and stepwise notification could be valuable for the nest-step design of a more comprehensive, integrated intervention package. The emphasis on people-centered PS is also insightful for HIV-related policy design in China.

OAD07 Healthcare providers

OAD0701

Between empathy and anger: healthcare workers' perspectives on patient disengagement from antiretroviral treatment in Khayelitsha, Cape Town

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Background: The individual and public health benefits of antiretroviral treatment (ART) are undermined by suboptimal or poor engagement with care. Healthcare workers (HCW) attitudes and punitive treatment of patients have been repeatedly linked to poor engagement, but little is known about their perspectives or understanding of *disengagement.*

Methods: We used qualitative methodology to explore HCWs' perspectives on ART disengagement, in Khayelitsha, an HIV-prevalent, peri-urban area in South Africa. HCWs were purposively recruited and included doctors, nurses, counsellors, social workers, data clerks, security guards, and allied health professionals. 30 semi-structured in-depth interviews were conducted. HCWs were asked to give examples of patients who interrupt treatment and how they feel when dealing with a patient who is returning to care. Transcripts were analysed using an inductive thematic analysis approach.

Results: Findings from this study show that staff had contradictory feelings towards disengaged patients, experiencing both empathy and anger. Most staff were knowledgeable about the complexities of disengagement and highlighted potential barriers to sustaining adherence to ART, including mental health challenges and non-disclosure to family and partners. Empathy for patients who interrupted treatment was frequently reported when discussing potential barriers to engagement. However, many also expressed feelings of anger and frustration towards these patients, partly because of increased workload from additional medical and psychosocial support needs of patients. Some staff, particularly those taking chronic medication, perceived that patients who disengage from ART do not take adequate responsibility for their health.

Conclusions: Punitive HCW behaviour and negative attitudes can drive poor engagement and act as a barrier to re-engagement, undermining patients' willingness, and ability to sustain lifelong engagement with ART services. Whilst the extent of negative attitudes towards patients identified is highly concerning, the understanding of the challenges that patients face and the empathy HCWs express represents an important opportunity for service improvement. We propose implementing measures to promote non-judgmental patient-centered care and contribute to reducing incidences of disengagement. For example, a dedicated support mechanism for staff would help to reduce feelings of resentment or overburdened with work for patients requiring intense psychosocial and medical support.

OAD0702

The impact of the COVID-19 pandemic on provision of HIV care: perspectives of HIV-dedicated healthcare workers in East Africa

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Background: The COVID-19 pandemic presents unprecedented challenges. In resource-limited settings, one concern is to what extent the pandemic has negatively affected HIV care, leading to setbacks in the remarkable progress of the past decade. Reports from frontline healthcare workers (HCWs) provide amongst the earliest opportunities to understand the impact of the pandemic on HIV care.

Methods: We surveyed HCWs providing care to people living with HIV at 7 primary care facilities in Uganda and Kenya (affiliated with East Africa International Epidemiology Databases to Evaluate AIDS (IeDEA)) and who were part of an ongoing longitudinal study of care providers. HCWs completed an online self-administered questionnaire regarding care delivery during April, May and June 2020.

Results: All 184 HCWs approached agreed to participate. Among these, 66% were women; the median age was 33 years; and 5% were doctors, 16% clinical officers, 33% nurses, 5% pharmacists/pharmacy technicians, 18% social workers/counsellors, 1% nutrition assistants and 22% non-formally trained assistants (e.g., peer mentors). More than 50% of HCWs reported cessation, reduction, or delays in a variety of routine functions at their clinics (Table).

In response to these challenges, 76% of HCWs reported an increase in communication with patients via phone or text, 86% reported a larger than usual supply of antiretroviral therapy (ART) being given to patients, and 79% reported initiation or increased delivery of ART to patients in community settings.

Activities at HIV Clinic	Stopped	Reduced or delayed	Not affected	Not sure
New patient intake	3%	56%	39%	2%
ART initiation in new patients	2%	35%	59%	3%
Follow-up visits at the clinic	3%	74%	20%	3%
Evaluation of patients by clinicians during follow-up	7%	58%	32%	3%
ART adherence counselling at the clinic	5%	49%	44%	2%
Preventative screening for co-morbidities/coinfections	11%	47%	40%	2%
HIV viral load testing	1%	38%	59%	2%
Home visits	49%	39%	9%	3%

Table. HIV Care Providers' Report of Activities During COVID-19 Pandemic

Conclusions: Among a representative sample of HIV care providers in East Africa, there were ample reports of HIV care disruptions as a result of the pandemic. There were, however, many attempts at rapid solutions to these disruptions, and dissemination of best practices might benefit other clinics.

Our findings motivate formal investigation of the ultimate relevant outcomes — HIV-related morbidity and mortality. The work also highlights elements of requisite preparedness for the next pandemic.

OAD0703

Evaluating the integration of telehealth in same-day antiretroviral initiation service during COVID-19 in Bangkok, Thailand

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Background: Same-day antiretroviral therapy (SDART) initiation has been implemented since 2017 at the Thai Red Cross Anonymous Clinic (TRCAC), an HIV testing center in Bangkok, Thailand. Clients who are willing and clinically eligible start ART on the day of HIV diagnosis. In response to the COVID-19 pandemic, a lockdown was announced in Thailand in March 2020, limiting access to health care facilities. Telehealth for SDART follow-up was established at TRCAC to minimize clinic visits. We present an evaluation of its implementation.

Methods: Pre-COVID (until February 2020), clients who initiated SDART received a two-week drug supply and returned to the clinic after two weeks for clinical evaluation and referral to long-term care facilities. If no adverse events (AEs) were established, an eight-week supply was provided while referral was arranged. During COVID-19 lockdown (March–May 2020), a four-week ART supply was provided, and the option of a video call for clinical consultation and physical examination instead of clinical visit at two weeks was given. Clients with severe AEs were required to return to TRCAC; those without received another six-week supply by courier to bridge transition to long-term facilities. A subset of clients was interviewed to assess experiences and preferences.

Results: During the lockdown, 238 clients were diagnosed with HIV at TRCAC, 183 (76.9%) were eligible for SDART, 176 (96.2%) accepted, and 160 (90.9%) enrolled. Of 159 (99.4%) follow-up visits completed, 52 (34.4%) occurred virtually—all with clients who did not have AEs prompting a clinic visit. Seven clients were interviewed; all experienced telehealth as positive and found it convenient and time saving. Due to the success of telehealth with ART delivery, it was continued. Post-COVID (June–August 2020), 406 clients were diagnosed with HIV, 319 (78.6%) were eligible for SDART, 297 (93.1%) accepted, and 283 (95.3%) enrolled. Of 232 (99.2%) follow-up visits completed, 83 (38.8%) occurred virtually.

Conclusions: Telehealth follow-up with ART delivery for SDART clients is a feasible and safe option for providing differentiated ART initiation services at TRCARC, leading to its continuation beyond COVID-19. Therefore, telehealth in hospitals and for purposes beyond ART initiation should be explored.

OAD0704

Successful implementation of telemedicine and pharmacy enhanced HIV services as response to COVID-19 quarantine among health insured patients in Argentina

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Background: Due to the spread of SARS-CoV-2 in Argentina, authorities implemented quarantine and community containment measures for 234 days during 2020, which may have hindered HIV care continuum. Our institution is the main ambulatory HIV care center for health-insured patients in Argentina, with 10500 patients in active follow up, mostly from Buenos Aires city (and surrounding areas) with a countrywide network. Since years, the institution achieved UNAIDS objectives of 90% ART coverage and 90% virological suppression. In order to minimize impact of quarantine in medical follow up, ART pharmacy withdrawals and virologic suppression, telemedicine (E-visits) and pharmacy enhanced services were implemented since April 2020 as contingency plan in pandemic lockout context.

Description: Telemedicine was based on linkage between institutional electronic medical record and WhatsApp through a specific application, allowing patient-physician video call through mobile devices. After each E-visit, a satisfaction survey (Likert type scale 1="bad" to 5="excellent") was submitted to the patient. Pharmacy enhanced services consisted in pharmacy delivery for patients in vulnerable situation (from our main pharmacy to either patient´s home or next-door pharmacy) and bimonthly withdrawals. To evaluate impact of these services, we analyzed number of medical visits, ART coverage, pharmacy withdrawals and virologicsuppression (viral load <200 copies/ml) in our population in 2020 vs. 2019 (non-pandemic year).

Lessons learned: During 2019, 34843 medical visits were done (no E-visits). ART coverage, pharmacy withdrawals and virologic suppression were 97.5%, 95.9% and 97% respectively. During 2020, 32400 medical visits were done, being 10355 (32%) E-visits. Median patient satisfaction was 5 points (IQR: 5-5). ART coverage, pharmacy withdrawals and virologic suppression were 98.7%, 98.1% and 94% respectively, showing success of these contingency measures in preserving patient follow-up and ART coverage, adherence and suppression >90%.

Conclusions/Next steps: Telemedicine and pharmacy enhanced services were successful interventions in pandemic context for preserving institutional standards according UNAIDS targets. Due to high patient satisfaction, telemedicine should be implemented as standard-of-care in our population.

OAD0705

CUSTOMIZE: overall results from a hybrid III implementation-effectiveness study examining implementation of cabotegravir and rilpivirine long-acting injectable for HIV treatment in US healthcare settings; final patient and provider data

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Background: CUSTOMIZE examined implementation strategies for provider-administered long-acting (LA) injectable ART in diverse US healthcare settings. Findings from staff and patients after 12 months of cabotegravir+rilpivirine (CAB+RPV) LA implementation are reported.
Methods: Twenty-four staff [physicians, injectors, administrators (n=8 each)] from 8 clinics completed surveys and interviews at baseline, interim (M4), and Month 12 (M12, n=23). All patients received monthly CAB+RPV LA and completed surveys (n=109 and 102), a subset completed interviews at baseline and M12 (n=34 and 31), respectively. Interviews were recorded, transcribed, and analyzed using ATLAS.ti (v8.1).
Results: Staff found CAB+RPV LA acceptable, appropriate, and feasible to implement across clinic types (Table). At baseline, providers' (80.8%) top concern was patient ability to maintain monthly appointments; at M12, only 51.3% had this concern. Most providers (78.3%) felt optimal implementation was achieved within 1-3 months. Providers reported 3 key successful implementation strategies with patient adherence: good communication about target dosing window, appointment reminder systems, and designated staff accountable for appointment tracking. Top strategies for successful clinic implementation were good staff communication, teamwork, and web-based treatment planner. Qualitative insights varied by clinic type. Federally Qualified Health Centers' initial concerns on leadership support were mitigated by clinical data and implementation ease. University-based clinics' initial concern about patients keeping appointments was mitigated through tracking and patient-friendly reminder systems. Private practices were initially concerned about injection visit frequency and length; by M12, visit length was short and increased touchpoints benefited patient-provider relationships. Some clinics noted patients' enthusiasm and monthly compliance were key to success. Sustainability and scalability tactics included increasing/training new staff and effective injection schedule management. By M12, 74% of patients reported nothing interfered with their ability to receive CAB+RPV LA; 94% preferred LA over oral dosing.
Conclusions: In CUSTOMIZE, LA ART was successfully implemented across a range of US healthcare settings. Barriers were mitigated with minor process adjustments. Patients reported few barriers to monthly appointments and most preferred CAB+RPV LA over daily oral therapy.

OAD0706

Patterns of patient-provider communications in public HIV clinics in Zambia: a latent class analysis using RIAS

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Background: Poor patient-provider communication is a clinic-based barrier to long-term adherence and retention in care among HIV patients. Objective assessments of this key metric of patient experience are lacking in sub-Saharan Africa. We used the Roter Interaction Analysis System (RIAS) to quantitatively parse and assess distinctive patterns of patient-provider communication at public health HIV clinics in Zambia.
Methods: We enrolled adults at 24 Ministry of Health facilities providing antiretroviral therapy (ART) in Lusaka province, supported by the Centre for Infectious Disease Research in Zambia (CIDRZ). Clinic visits

	Federally Qualified Health Centers (FQHCs) (n=6) Agreed/Completely Agreed % (Mean Scale Score)	University Clinics (n=6) Agreed/Completely Agreed % (Mean Scale Score)	Private Practice (n=5) Agreed/Completely Agreed % (Mean Scale Score)	AIDS Healthcare Foundation (AHF) (n=3) Agreed/Completely Agreed % (Mean Scale Score)	Health Management Organization (HMO) (n=3) Agreed/Completely Agreed % (Mean Scale Score)	Total (n=23) Agreed/Completely Agreed % (Mean Scale Score)
Acceptability of Intervention Measure (AIM)	100% (4.29)	100% (4.75)	100% (4.40)	100% (5.00)	66.7% (3.67)	95.6% (4.45)
Intervention Appropriateness Measure (IAM)	100% (4.33)	100% (4.83)	100% (4.60)	100% (5.00)	100% (4.33)	100% (4.61)
Feasibility of Intervention Measure (FIM)	100% (4.38)	100% (4.75)	80% (4.40)	91.6% (4.58)	100% (4.00)	94.5% (4.46)
AIM, IAM, and FIM are each 4 item measures scored 1-5; 1= completely disagree and 5= completely agree. Mean Scores and Mean proportion who agreed (4) or completely agreed (5) to each of 4 statements for each measure are reported.						

Table. Staff Participant Acceptability, Appropriateness, and Feasibility by Clinic Type at Month 12

were audio-recorded and coded by RIAS trained research staff who demonstrated high levels of intercoder reliability (Pearson correlation 0.8). We performed latent class analysis to identify visit interactions falling within distinctive patterns of communication.

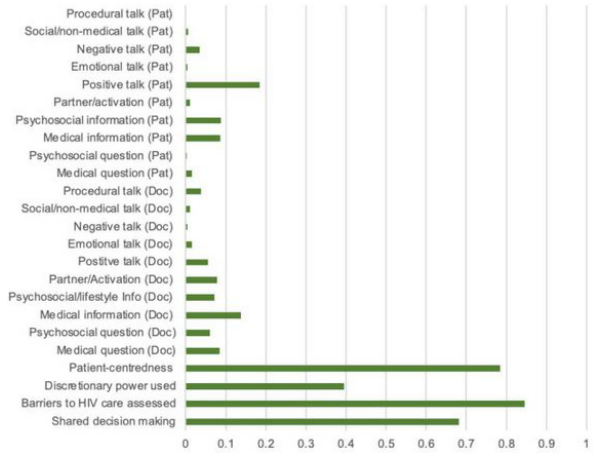

Figure 1. Patient-centred interaction (21.2%)

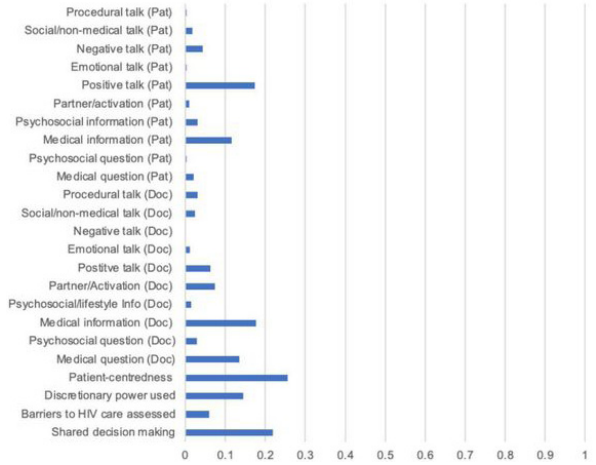

Figure 2. Primary medical interaction (63.6%)

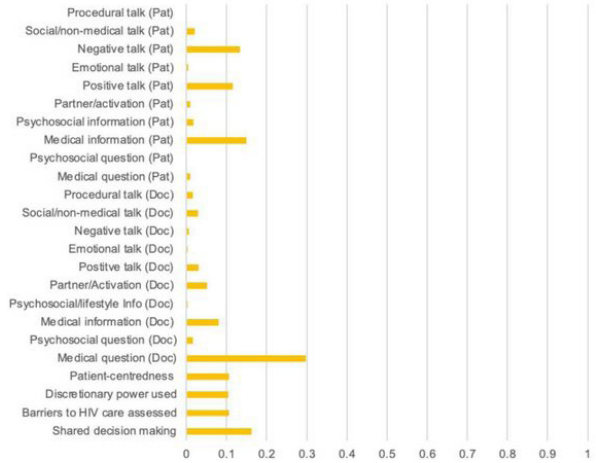

Figure 3. Negative medical interaction (15.2%)

Results: Among 120 patient-provider pairs (patients: 63% female; providers: 45% female, 84% physicians, 16% nurses), 3 distinct profiles of patient-provider communication were identified (Figure 1): (1) "Patient-Centered Interactions" (21.2% of interactions) characterized by relatively high levels of patient-centered communications, including shared decision making, discussion of psychosocial concerns and barriers to care, and positive use of discretionary power; (2) "Positive Medical Interactions" (63.6%) characterized by a predominantly biomedical focus with providers both asking and providing information and patients responding to the provider with informative and positive statements; and (3) "Negative Medical Interactions" (15.2%) similarly characterized by a biomedical focus but predominated by medical provider questions with relatively little information exchange between patients and providers, as well as patient expression of more negative than positive statements.

Conclusions: Patient-provider communication patterns primarily focused on medical aspects of living with HIV. Strengthening communication behaviors may be an important strategy for improving retention in HIV treatment programs.

ORAL ABSTRACT SESSIONS WITH LIVE Q&A

OALA01 When titans collide: HIV syndemic co-infections

OALA0101

SARS-Cov-2 immunity in COVID-19 convalescent individuals living with HIV: bulk immune profiling and SARS-CoV-2 specific humoral and cellular immune responses

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Background: SARS-CoV-2-specific immune response features in PLWHA remain to be fully elucidated. The impact of HIV over the immune profile of lymphocyte populations in PLWHA recovered from COVID-19, as well as the humoral and cellular response secondary to COVID-19 were evaluated.

Methods: Samples from donors to the Argentinean Biobank of Infectious Diseases with COVID-19 diagnosis: 21 PLWHA on ART and 21 HIV-negative (HIVneg) were included. Plasma and PBMC were obtained. SARS-CoV-2-specific IgG/IgM levels and IgG titers were determined by ELISA (COVIDAR test). Antibody neutralization capacity was evaluated against wild-type SARS-CoV-2. IFN-g-secreting cells were detected by ELISPOT using SARS-CoV-2 Spike, RBD or Nucleocapsid protein (10 mg/mL) or overlapping peptide pools spanning Spike or Nucleocapsid proteins (1mg/mL). Frequency and phenotype of bulk T, B and NK cells were assessed by flow cytometry.

Results: PLWHA median age was 47 (IQR:39.5-54); LTCD4=513 cells/uL (IQR:351-873). HIVneg median age was 41 (IQR:35-57). All individuals presented mild/moderate COVID-19. Mean time from symptoms onset to donation was 44 days (IQR:29.5-55) for HIVneg and 62 (IQR:35-93) for PLWHA. 75% of PLWHA and 85% of HIVneg had detectable SARS-CoV-2-specific antibodies, with IgG levels not differing between groups. Among PLWHA, neutralization capacity correlated with IgG titers (r:0.90, p<0.001), LTCD4 count (r:0.85, p:0.001), LTCD8 count (r:0.97, p<0.001) and age (r:0.63, p:0.021). All donors, including those with undetectable antibody response, had SARS-CoV2-specific cellular immunity. While HIVneg displayed IFN-g-secreting cells in response to S protein, RBD and S peptide pools, PLWHA responses were detected to S protein and N peptide pool, although with decreased magnitude (both p<0.01). Both groups displayed similar Treg (CD127-CD25+CD4+T) frequency, similar effector/memory and T-helper profile for LTCD4, and comparable exhaustion and memory profiles for LTCD8. No differences on NK, B or antibody-secreting cell proportions were observed. PLWHA presented increased Tfh (CD4+CXCR5+T-cells, p<0.01) and CXCR1+Tfh (p<0.05) cell frequency, enhanced expression of PD1+ on LTCD4 (p<0.05), HLA-DR on LTCD8 (p<0.05), and higher expression of CD95 (p=0.002), CD25 (p=0.004), HLA-DR (p<0.0001), NKp46 (p=0.035) and CD38/HLA-DR (p=0.002) on NK cells.

Conclusions: Although PLWHA showed an immune profile with enhanced activation and exhaustion, severity of COVID-19 was not exacerbated. Among PLWHA, SARS-CoV-2 infection could exert a significant humoral and cellular response, which could be associated to increased proportions of Tfh cells. Cellular response was lower compared to HIVneg individuals; nevertheless, a preserved LTCD4 count emerged as a key factor to achieve better antibody responses with higher neutralization capacity. This data reinforces the impact of ART not only in HIV control but in the capacity of control other infections.

OALA0102

SARS-CoV-2-seronegative subjects target CTL epitopes in the SARS-CoV-2 nucleoprotein cross-reactive to common cold coronaviruses

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Background: The beta-coronavirus SARS-CoV-2 induces severe disease (COVID-19) mainly in elderly persons with risk factors, whereas the majority of patients experience a mild course of infection. As the circulating common cold coronaviruses OC43 and HKU1 share some homologous sequences with SARS-CoV-2, cross-reactive T-cell responses could influence the susceptibility to SARS-CoV-2 infection and the course of COVID-19. To investigate the role of beta-coronavirus cross-reactive T-cells, we analyzed the T-cell response against a 15 amino acid long peptide (DP15: DLSPRWYFYYLGTGP) from the SARS-CoV-2 nucleoprotein sequence with a high homology to the corresponding sequence (QLLPRWYFYYLGTGP) in OC43 and HKU1. As HIV-1 infection is a potential risk factor for COVID-19, we studied a cohort of HIV-1-infected patients on antiretroviral therapy.

Methods: PBMC from HIV-1-infected patients and from healthy controls were stimulated with peptide SCoV-DP15. Outgrowing cells were tested for recognition of DP15 by g-IFN-ELISPOT assays and by flow cytometric assays. Epitopes were mapped using truncated peptides in ELISPOT assays. SARS-CoV-2 antibodies were measured by a flow cytometric antibody assay.

Results: 44 out of 116 HIV-1-infected patients (37.9 %) and 4 out of 23 (17.4%) healthy donors showed a specific recognition of the SCoV-DP15 peptide or of shorter peptides within DP15 by $CD4^+$ T-cells and/or by $CD8^+$ T-cells. All responders were SARS-CoV-2-seronegative. We could define several new cross-reactive HLA-I-restricted epitopes in the SARS-CoV-2 nucleoprotein. Epitope specific $CD8^+$ T-cell lines recognized corresponding epitopes within OC43 and HKU1 to a similar degree or even at lower peptide concentrations suggesting that they were induced by infection with OC43 or HKU1.

Conclusions: Our results confirm that SARS-CoV-2-seronegative subjects can target SARS-CoV-2 not only by cross-reactive $CD4^+$ T-cells but also by cross-reactive $CD8^+$ cytotoxic T-cells (CTL). The delineation of cross-reactive T-cell epitopes contributes to an efficient epitope-specific immunomonitoring of SARS-CoV-2-specific T-cells. Further prospective studies are needed to prove a protective role of cross-reactive T-cells and their restricting HLA alleles for control of SARS-CoV-2 infection. The frequent observation of SARS-CoV-2-reactive T-cells in HIV-1-infected subjects could be a reason that treated HIV-1 infection does not seem to be a strong risk factor for the development of severe COVID-19.

OALA0103

Viral hepatitis cascade of care among adults living with HIV in Asia-Pacific

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Background: Data on viral hepatitis (VH) diagnosis, treatment, and cure rates among PLHIV from the Asia-Pacific region are limited. With targets set to eliminate VH as a global epidemic by 2030, this study aims to identify gaps in the hepatitis B virus (HBV) and hepatitis C virus (HCV) cascade of care (CoC) among PLHIV in the region.

Methods: PLHIV enrolled in a regional HIV observational cohort, on antiretroviral therapy (ART), and in follow-up between 2010-2019 were included. Patients were considered as having VH co-infection if they ever tested positive for HBV surface antigen (HBsAg) or anti-HCV (HCVAb). The CoC included proportion of patients with positive HBV or HCV, HBV/HCV serology testing, received therapy, and subsequently reached HBV or HCV suppression.

Results: Of 22,340 patients included, most were male (64%) with a median age of 35 years (Interquartile range (IQR) 30-42) with heterosexual contact as the main mode of HIV-exposure. Among those included, 39% (8612/22,340) had HBsAg screening tests with 8% (672/8,612) testing positive. Of 672 HBsAg-positive patients, 71% (474/672) initiated HBV treatment; 67% (318/474) had a subsequent HBV DNA test, with 18% (58/318) reaching HBV suppression (Figure 1a).

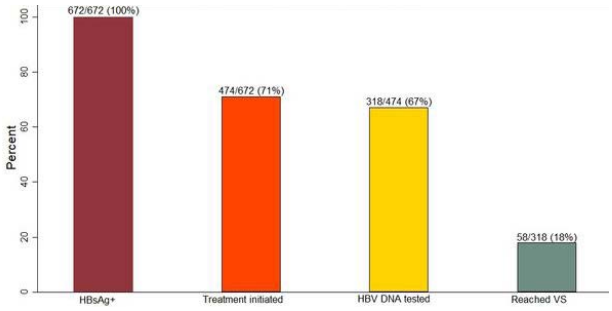

Figure 1a. Hepatitis B cascade of care

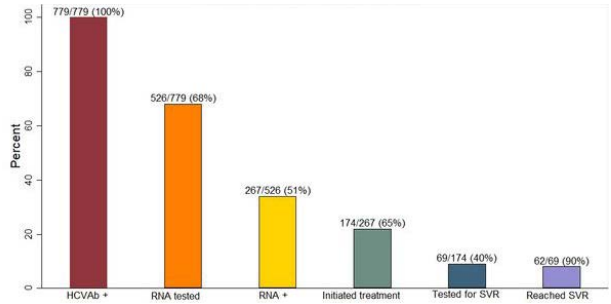

Figure 1b. Hepatitis C cascade of care

Screening for HCVAb was done on 37% (8,231/22,340) of those included, of whom 9% (779/8,231) tested positive. Of the 779 HCVAb-positive participants, 68% (526/779) had a subsequent HCV RNA test, of whom 51% (267/526) tested positive. 65% (174/267) of those positive for HCV RNA initiated treatment. Of those treated, 40% (69/174) were tested for sustained virological response (SVR) and 90% (62/69) had confirmed SVR (Figure 1b).

Conclusions: Our study identified low VH screening and low treatment monitoring with HBV DNA and HCV RNA testing. These findings suggest the need for improved access to affordable testing for screening and monitoring treatment response for VH through treatment programs in the region.

OALA02 Waving the wand: Untangling HIV reservoir dynamics

OALA0201

The passenger hypothesis: HIV exploits CD4 T cell homeostasis to promote long-term persistence of its reservoirs

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Background: The reservoir of latently infected CD4+ T cells ensures HIV persistence during suppressive antiretroviral therapy (ART). Proliferation of reservoir cells carries provirus along as a passenger and produces clonal HIV lineages that outlive single infected cells. We tested the hypothesis that differentiation between CD4+ T cell subsets helps sustain the reservoir.

Methods: We quantified HIV reservoir size and clonality longitudinally at 1-3 time points in 37 participants on ART in 5 resting CD4+ T cell subsets: naïve (T_N), stem-cell memory (T_{SCM}), central memory (T_{CM}), transitional memory (T_{TM}), and effector memory (T_{EM}). We tested 10 mathematical models including proliferation, death, and differentiation mechanisms to select the most parsimonious model of the HIV reservoir in CD4+ T cell subsets. Deuterium labeling measurements were performed to impute cellular subset turnover rates into the model.

Results: Integrated HIV DNA was stable or decreased in each subset; median rates ranged from 0 (no clearance, T_N) to a 42 month half-life (T_{EM}). However, cellular turnover rates were substantially more rapid, ranging from 3 (T_{EM}) to 30 (T_N) month half-lives, suggesting that infected cells are constantly being replaced via cellular proliferation. The best model followed linear differentiation from T_N through to T_{EM}. Estimated differentiation rates were on the order of but generally slower than turnover rates (T_{CM} -> T_{EM} was most rapid), suggesting many but not all proliferation events result in differentiation. Proliferation was the predominant mechanism of persistence in all subsets, with contributions of cellular longevity (especially T_N) and differentiation (especially T_{EM}). Depending on the participant and cell subset, model estimates revealed 10^2 to 10^4 new HIV-infected cells were created per million CD4+ T cells in a typical year. Greater oligoclonal expansions in

T_{CM} (higher Gini index) were associated with more rapid clearance in the HIV reservoir (Spearman ρ=0.4-0.7 for all subsets), suggesting T_{CM} clones heavily influence total reservoir dynamics.

Conclusions: We show proliferation of HIV-infected CD4+ T cells appears to be the predominant mechanism of reservoir persistence across T cell subsets. HIV proviruses additionally passage between subsets through cellular differentiation. Thus, reservoir reduction interventions should consider both proliferation and differentiation of T cell subsets.

OALA0202

Identifying host genetic determinants of HIV-1 reservoir markers reveals PTDSS2 and IRF7 as potential modifying factors in HIV-1 patients

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Background: Combination antiretroviral treatment (cART) cannot eradicate HIV-1 from the body due to the establishment of persisting viral reservoirs which reinitiate new rounds of HIV-1 replication after treatment interruption. These HIV-1 reservoirs mainly comprise long-lived resting memory CD4+ T cells and show a high variability in size or activity among virally suppressed individuals. Therefore, the identification of host factors that contribute to this observed variation could open avenues for new HIV-1 treatment strategies.

Methods: In this study, we conducted a genome-wide quantity trait locus (QTL) analysis to probe functionally-relevant genetic variants linked to levels of cell-associated (CA)-HIV-1 DNA, CA-HIV-1 RNA and RNA:DNA ratio in CD4+T cells isolated from whole blood from a cohort of 207 (Caucasian) HIV-1 patients under long-term suppressive cART (median = 6.6 years). CA-HIV-1 DNA and CA-HIV-1 RNA levels were measured with corresponding droplet digital PCR assays and genotype information of 522,455 single nucleotide variants (SNV) was retrieved via the Infinium Global Screening array platform.

Results: The QTL mapping analysis involved an additive linear regression model with a correction for age, gender, CD4 nadir and HIV-1 duration and identified one significant genetic association with CA-HIV-1 DNA (PTDSS2, p-value < 5×10^{-8}), while four associations were found for RNA:DNA ratio (RNH1, IRF7, DEAF1 and RP11-1149M10.2, p-value < 5×10^{-7}). Next, we validated that the IRF7 SNV is significantly correlated with higher expression (qPCR) of the IRF7 gene in peripheral blood mononuclear cells (PBMC) from HIV-1 patients and influences the IFN-γ production capacity of *ex-vivo* stimulated PBMCs with TLR2/4/7 agonists, supporting its functional role in HIV-1 infection.

Conclusions: The presented data suggests that the amount of CA-HIV-1 DNA and RNA:DNA ratio could be influenced by the PTDSS2 and IRF7 loci. Especially, the IRF7 SNV is functionally linked to higher expression levels of its gene product and modifies IFN-γ levels which contribute to the control of the relative HIV-1 transcriptional activity and associated immunologic burden. These observations provide novel knowledge on the molecular mechanisms involved in HIV-1 reservoir establishment and/or maintenance and could indicate targets for future therapeutic strategies to lower HIV-1 reservoir size or activity in patients.

OALA0203

Naïve CD4+ T cells form the bulk of the translation competent HIV-1 reservoir in vertically infected children and adolescents

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Background: Our inability to cure HIV/AIDS stems from the fact that HIV establishes and maintains cellular reservoirs where it shelters from the effects of combination antiretroviral therapy (cART) and host immunity. Whereas reservoir components are well known in adults, the composition and evolution of these reservoirs in vertically infected children are incompletely understood.

Our objective was to examine the effects of the timing of cART initiation and achievement of sustained viral suppression (SVS) on the size and nature of the HIV reservoir in children and adolescents.

Methods: Using the HIV-Flow method (Pardons et al., PLoS Pathog 15:e1007619, 2019), size and cell subset distribution of the translation competent viral reservoir were assessed in purified CD4+ T cells from vertically infected children and adolescents (n=34) with and without SVS, who were enrolled in the EPIC[4] study and stratified according to age (0-5, 5-10, 10-18 years).

Results: Differences in reservoir size between male and female participants or across age groups were not statistically significant (p=0.5003, p=0.9410). Naïve CD4+ T cells were the main contributor to the pool of p24-producing cells in all age groups as compared to central memory (CM), effector memory (EM), and terminally differentiated (TD) (p=0.001, p<0.0001, p<0.0001). The large representation of naive CD4+ cells in the total CD4+ T cells pool (~68% to >80%) can explain this contribution. CM cells tended to carry higher frequencies of p24+ cells in adolescents compared to younger age groups but differences were not statistically significant (p>0.4442).

A negative correlation was observed between the frequency of p24-positive T cells and the cumulative proportion of life under SVS (r=-3588, p=0.0403). Finally, the frequency of p24-positive T cells was positively correlated with age at initiation of first cART (r=0.4323, p=0.0216).

Conclusions: Unlike HIV-infected adults, the cellular reservoir harboring translation competent HIV in vertically infected children and adolescents is mostly comprised of naïve CD4+ T cells, with a distribution profile progressively transitioning to that of adults. Importantly, the

frequency of p24-positive T cells was associated with adequacy of SVS and age of cART initiation. These results inform and reinforce evidence-based guidance for the management of vertical HIV infection.

OALB03 Modern ART and COVID-19 in PLHIV

OALB0301

Unsuppressed plasma HIV-RNA viral load is associated with worse COVID-19 outcomes among people living with HIV

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Background: Information about the relationship between HIV-associated immune suppression and COVID-19 outcomes is scarce. We characterized the sociodemographic and clinical features, and impact of immunosuppression on COVID-19-related outcomes among persons living with HIV (PLWH).

Methods: PISCIS is a population-based cohort of PLWH aged ≥16 years in care at 16 Catalan hospitals, which collects sociodemographic and clinical data between 01/01/1998 and 15/12/2020. We linked PISCIS data with the Public Data Analysis for Health Research and Innovation Program of Catalonia (PADRIS) to obtain COVID-19 diagnosis related data and other comorbidities. Only patients with microbiologically confirmed SARS-CoV-2 infection (NAAT, antigen detection or antibodies) were included in the analysis. Factors associated with COVID-19 diagnosis and severe outcomes were assessed using multivariate Cox regression models. We estimated the impact of immunosuppression on severe outcomes (hospital admission or death) using survival analysis.

Results: Of 13,142 PLWH on follow-up, 749 (5.7%) were diagnosed with SARS-CoV-2. Among them, 618/749 (82.5%) were males and the median age was 43.5 years ([IQR] 37.0-52.7). 103 (13.8%) were hospitalized, 7 (0.9%) were admitted to the ICU and 13 (1.7%) died. SARS-CoV-2 diagnosis was more common among migrants (aHR, 1.55 [95% CI, 1.31-1.83]), MSM (aHR, 1.42 [95% CI, 1.09-1.86]) and those with ≥4 comorbidities (aHR, 1.46 [95% CI, 1.09-1.97]). Age ≥75 years (aHR, 5.2 [95%CI:1.8-15.3]), non-Spanish origin (aHR, 2.1 [95%CI:1.3–3.4]) and chronic comorbidities (neuropsychiatric aHR, 1.69 [95% CI, 1.07-2.69], autoimmune disease aHR, 1.92 [95% CI, 1.14-3.23] respiratory disease aHR, 1.84 [95% CI, 1.09-3.09] and metabolic disease aHR, 2.59 [95% CI, 1.59-4.23]) were associated with higher risk of severe outcomes. A Kaplan-Meier estimator showed differences in the risk of severe outcomes according to CD4 levels in patients with detectable HIV viral load (P<.039) but no differences were observed in patients with undetectable HIV viral load (P=.15).

Conclusions: SARS-CoV-2 diagnosis in PLWH was more common among migrants, those with ≥4 comorbidities and MSM. Among co-infected patients, those with detectable HIV viral load, older age, chronic comorbidities and migrants had higher risks of severe outcomes. Of note, detectable HIV viral load and not CD4 count <200cells/mm^3 was a risk factor for severe COVID-19.

OALB0302

Long-acting subcutaneous lenacapavir dosed every 6 months as part of a combination regimen in treatment-naïve people with HIV: interim 16-week results of a randomized, open-label, phase 2 induction-maintenance study (CALIBRATE)

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Background: Lenacapavir (LEN, GS-6207), a potent first-in-class inhibitor of HIV-1 capsid function, is in development as a long-acting agent for treatment and prevention of HIV.

Methods: CALIBRATE is an ongoing, phase 2, randomized, open-label, active-controlled, induction-maintenance study in treatment-naïve people with HIV-1 (TN-PWH) with CD4+ cell count≥200/μL. Participants were randomized (2:2:2:1) to treatment groups (TGs) A to D (Figure). TG-A and B received subcutaneous (SC) LEN with oral daily emtricitabine/tenofovir alafenamide (F/TAF); at W28, those achieving HIV-1 RNA (VL)<50c/mL switched F/TAF to oral daily TAF (TG1) or bictegravir (BIC) (TG2). TG-C received oral daily LEN with F/TAF. TG-D received oral daily B/F/TAF. Primary endpoint is VL<50c/mL at W54 by FDA Snapshot. We report the pre-specified W16 interim efficacy and safety analyses, for which there were no planned statistical comparisons.

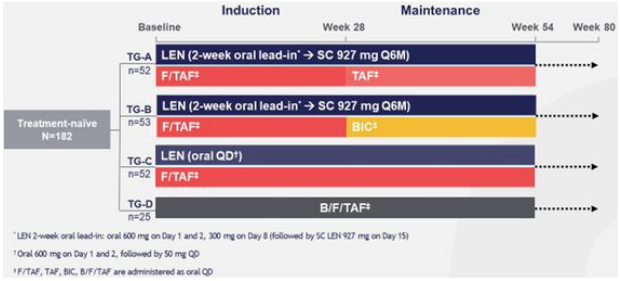

Figure. CALIBRATE study design

Results: 182 participants (7% female, 54% Black) were randomized/dosed (n=52, 53, 52, 25 in TG-A to D). Median age was 29y; 15% had VL>100,000c/mL. At W16, 92% (48/52), 94% (50/53), 94% (49/52), and 100% (25/25) had VL<50c/mL in TG-A, B, C, and D, respectively, by

missing=failure, and 98% (48/49), 98% (50/51), 96% (49/51), and 100% (25/25) by missing=excluded. Four participants had VL>50 c/mL: 3 with VL<100c/mL (1 TG-A, 2 TG-C) and 1 with VL>5000c/mL (TG-B). Resistance analysis is ongoing. No participant died, experienced a study drug-related serious adverse event (AE), or discontinued study drug due to AE, and no Grade 3 or 4 AEs were considered study-drug related. Most frequent AEs were injection site erythema, injection site pain (12% each), injection site swelling (11%) and headache (10%). All injection site reactions were mild or moderate.

Conclusions: LEN, given subcutaneously or orally, in combination with F/TAF led to high rates of viral suppression in TN-PWH by W16. LEN was generally safe and well-tolerated. Results support ongoing evaluation of LEN for treatment and prevention of HIV.

OALB0303

Switching to the 2-drug regimen of dolutegravir/lamivudine (DTG/3TC) fixed-dose combination (FDC) is non-inferior to continuing a 3-drug regimen through 24 weeks in a randomized clinical trial (SALSA)

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Background: Long-term non-inferior efficacy of the 2-drug regimen (2DR) DTG/3TC compared with 3/4-drug regimens (3/4DRs) has been demonstrated in treatment-naive (DTG + TDF/FTC through 144 weeks) and treatment-experienced individuals with HIV-1 (TAF-based regimens through 96 weeks), with a good safety profile and a high barrier to resistance. We evaluated the efficacy and safety of switching to DTG/3TC fixed-dose combination (FDC) in adults with HIV-1 on any current antiretroviral regimen (CAR).

Methods: SALSA is a randomized, controlled, open-label study. Participants with HIV-1 RNA <50 c/mL for >6 months on a 3/4DR without prior virologic failure or NRTI or DTG resistance-associated mutations were randomized 1:1 (stratified by baseline third agent class) to switch to DTG/3TC or continue CAR for 52 weeks. Primary endpoint was proportion of participants with plasma HIV-1 RNA ≥50 c/mL at Week 48 (FDA Snapshot algorithm, ITT-E population). Planned Week 24 interim analysis assessed non-inferiority with a 5% margin.

Results: Overall, 493 participants were randomized (59% white; 39% women; 39% aged >50 years; 50%/40%/10% on NNRTI/INSTI/PI at baseline). DTG/3TC was non-inferior to continuing CAR at Week 24 using Snapshot virologic failure, and results were consistent with the Snapshot virologic success analysis (Table).

No participants in either arm met confirmed virologic withdrawal criteria; therefore, no resistance testing was done. Overall safety outcomes were comparable between the DTG/3TC and CAR groups for frequency of any AEs (60% vs 60%), AEs leading to withdrawal (2% vs <1%), and serious AEs (1% vs 6%), respectively.

n (%)	DTG/3TC (N=246)	CAR (N=247)	Adjusted difference (95% CI)
HIV-1 RNA ≥50 c/mL[a]	0	1 (<1)	−0.4% (−1.2%, 0.4%)
HIV-1 RNA <50 c/mL (virologic success)	234 (95)	237 (96)	−0.8% (−4.5%, 2.8%)
No virologic data	12 (5)	9 (4)	—

[a]Estimates and confidence intervals were based on a stratified analysis using Cochran-Mantel-Haenszel weights adjusting for baseline third agent class.

Table. Week 24 Study Outcome by Snapshot Analysis

Conclusions: In SALSA, switching to DTG/3TC was non-inferior to continuing CAR in maintaining virologic suppression at Week 24, with a safety profile consistent with the DTG and 3TC labels. Through 24 weeks, DTG/3TC 2DR offers a switch option with fewer antiretroviral drugs compared with traditional 3DRs, without increased risk of virologic failure or resistance. The study is ongoing; the conference presentation will include lipid data and Week 48 results.

OALB04 ART and PrEP monitoring in specific population: How much is enough?

OALB0401

More frequent viral load testing, with point-of-care tests has no impact on viral suppression in postpartum HIV-positive women in a randomized controlled trial in 2 clinics in Johannesburg, South Africa

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Background: Elevated maternal viral load (VL) increases HIV transmission risk for breastfeeding infants. We describe results from a non-blinded randomised controlled trial in Johannesburg comparing 3-monthly point-of-care (POC) VL testing (arm 2), to 6-monthly standard-of-care (SOC) laboratory-based VL testing (arm 1) in HIV-positive post-partum women on first-line antiretroviral treatment. We evaluated differences in VL suppression rates per arm at 6, 12, and 18 months.

Methods: Mother-child dyads were enrolled at the child's 6/10/14-week clinic visit. Women were randomized 1:1 to arm 1 or 2. For arm 2, trained nurse clinicians and field workers used Cepheid GeneXpert IV for POC VL testing.

We fit a generalized linear mixed model with VL suppression at enrolment, 6, 12, and 18 months as the outcome, indicator variables for time, study site, study arm, and interaction variables(time x site, time x arm, site x arm, time x site x arm). The model included a random effect for study ID to account for correlation among multiple VL from the same woman over time.

All interaction terms were nonsignificant and were removed from the model. The final model tested for a difference by study arm, pooling across timepoints.

Results: At baseline, women in arms 1 and 2 were well-balanced for socio-economic status (Table 1). VL suppression rates were high throughout the study, with no difference at each time point between arms (p-value 0.8937) after adjusting for baseline VL suppression; in arm 1 and 2 respectively, 94.0% and 88.6% at baseline, 96.2% and 91.2% at 6 months, 94.1% and 91.6% at 12 months and 94.1% and 94.3 % at 18 months.

		Total n(%N) N=405	Standard of care (SoC) arm (1) n(%N) N=204	Point of care (POC) arm(2) n(%N) N=201	P-value* *Comparison between SOC and POC arms
Age in years, mean (standard deviation)		30.3 (5.35)	30.5 (5.5)	30.1 (5.2)	.4463
Country of birth	South Africa	188 (46.5)	97 (47.5)	91 (45.3)	.6462
	Other	217 (53.5)	107 (52.5)	110 (54.7)	
Married/cohabiting		225 (55.8)	113 (55.4)	112 (55.7)	.9468
Secondary or higher education		396 (98.3)	201 (98.5)	195 (97.0)	.3012
Unemployed		221(54.8)	105 (51.5)	116 (57.7)	.2072
Financial support	Receives any financial support	352 (87.3)	172 (84.3)	180 (89.6)	.1181
	Financial support child's father	303 (75.2)	150 (73.5)	153 (76.1)	.5483
	Receives a social grant	67(16.6)	35 (17.2)	32 (15.9)	.7378

Table 1: Baseline socio-economic characteristics

Conclusions: In our study, there was no significant difference in VL suppression rates between 6-monthly SOC and 3-monthly POC VL testing in HIV-positive postpartum women. VL suppression rates were high overall, indicating PMTCT programme success.

OALB0402

Obsession with suppression: comparison of virally suppressed and unsuppressed children and adolescents living with HIV (CALHIV) treated with dolutegravir regimens in Mbeya and Mwanza, Tanzania

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Background: Current guidelines recommend using dolutegravir (DTG) as a preferred ART regimen in eligible CALHIV. However, descriptions of CALHIV who remain virologically unsuppressed despite treatment with DTG remain unknown. We aimed to describe the cohort of CALHIV in care at the Baylor Tanzania HIV clinics who remain in treatment failure despite being on a DTG regimen.

Methods: Retrospective chart review was conducted to assess the clinical characteristics of CALHIV receiving DTG as part of their ART at the Baylor College of Medicine Children's Foundation – Tanzania Centres of Excellence (COEs) in Mbeya and Mwanza, Tanzania between 1 March 2019 (when DTG became available) and 30 November 2020. HIV viral load (VL) suppression was defined as VL<1000 copies/mL.

Results: A total of 1703 CALHIV received DTG, among which 1084 (63.7%) had a documented VL after being prescribed DTG and were included in the analysis. Among those with post-DTG VL results, 7.6% (82/1084) remained virally unsuppressed despite their DTG regimen.

Compared to CALHIV virally suppressed on DTG (N=1002, 94.4%), those unsuppressed on DTG had higher rates of malnutrition (3.6% vs 0.7%, p<0.01) and previous ART exposure (99% vs 97%, p<0.01), as well as lower rates of previous viral suppression (70% vs 97%, p<0.01) (Table 1). There were no differences among the group regarding sex, age, time on ART, history of TB disease, history of IPT use, or single vs multiple tab DTG regimens (pill burden).

Characteristic	Suppressed on DTG N=1002	Unsuppressed on DTG N=82	p-value
Female	525 (52%)	41 (50%)	0.727
Average age (yr) Median age (yr)	13.3 14.0	13.1 14.0	0.623
Time on ART (ave, yr) Time on ART (med, yr)	4.8 5.0	4.4 5.0	0.327
Any malnutrition	7 (0.7%)	3 (3.6%)	<0.01
TB disease	5 (0.5%)	1 (1.2%)	0.411
IPT (ongoing/completed)	949 (95%)	77 (94%)	0.692
ART exposed	875 (87%)	81 (99%)	<0.01
Single tab regimens (TLD)	623 (62%)	50 (61%)	0.858
Previously suppressed VL	852/875 (97%)	57/81 (70%)	<0.01

Table 1

Conclusions: While DTG was highly effective in virally suppressing the majority of CALHIV, 7.6% remained unsuppressed. Unsuppressed patients were more likely to have prior ART exposure and prior lack of VL suppression, likely reflecting a subset of CALHIV with complex adherence challenges. Pill burden of DTG regimens did not appear to make a difference between groups. These unsuppressed CALHIV will require unique, patient-centered support to improve their treatment success.

OALB0403

A rapid enzymatic assay for selective detection of HIV drugs that indicate long-term and short-term PrEP adherence

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Background: Tenofovir diphosphate (**TFV-DP**) and emtricitabine triphosphate (**FTC-TP**) are nucleotide analog drugs used in PrEP that indicate long-term (1-3 month) and short-term (1-week) medication adherence, respectively. We recently developed the REverSe TRanscrIptase Chain Termination (**RESTRICT**) assay for rapid measurement of nucleotide analogs based on their inhibition of DNA synthesis by HIV reverse transcriptase (**RT**) enzyme and demonstrated proof of concept TFV-DP measurement in clinical samples. Here we design RESTRICT assays for selective measurement of both TFV-DP and FTC-TP.

Methods: RESTRICT assays were completed by incubating RT, nucleotides, DNA templates, and primers at 37˚C for 30 min followed by addition of PicoGreen® dye to provide fluorescence output. We designed a guanosine-rich DNA template for selective detection of FTC-TP (cytidine analog) by Watson-Crick-Franklin base pairing and excluded thymidine bases to prevent TFV-DP (adenosine analog) binding. Similarly, we designed a thymidine-rich DNA template (excluding guanosine bases) for selective TFV-DP detection. We spiked 1 μM of TFV-DP and FTC-TP into RESTRICT assays with each DNA template and measured endpoint fluorescence. We normalized fluorescence output using "no-enzyme" negative controls and "no drug" positive controls.

Results: "No enzyme" controls produced no fluorescence since no DNA synthesis occurred, while "no drug" controls produced maximum fluorescence since there was inhibition of DNA synthesis (Figure 1).
RESTRICT assays with guanosine-rich DNA templates produced low fluorescence (4.0 ± 4.3%) with FTC-TP and high fluorescence (86.2 ± 26.3%) with TFV-DP indicating selective FTC-TP detection without cross-reactivity with TFV-DP (p = 0.0060). Conversely, thymidine-rich DNA templates produced high fluorescence (105.7 ± 3.1%) with FTC-TP and low fluorescence (2.4 ± 1.5%) with TFV-DP indicating selective TFV-DP detection (p < 0.0001).

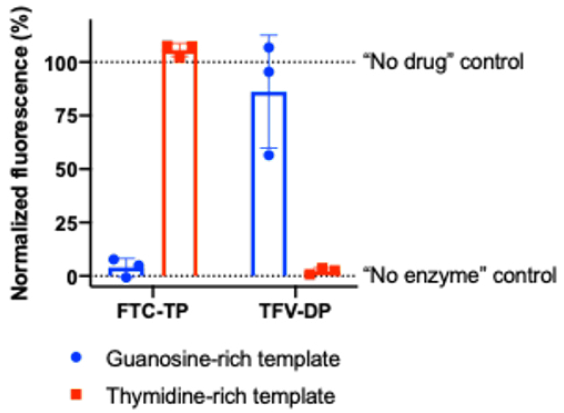

Figure 1

Conclusions: The RESTRICT assay enables rapid and selective detection of TFV-DP and FTC-TP. RESTRICT could help to monitor short-term and long-term PrEP adherence in near-patient settings.

OALC05 Pills and potions: The expanding repertoire of PrEP choice

OALC0501

Outcomes of participants switching from F/TDF to F/TAF for PrEP: week 48 results from the DISCOVER open label phase

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Background: DISCOVER is an ongoing, multinational, double-blind, randomized controlled trial of F/TAF vs F/TDF for PrEP which demonstrated noninferior efficacy and improved bone mineral density (BMD) and renal safety biomarkers at week (W) 48 and 96 of the blinded phase. Here we report the W48 outcomes of the open label (OL) phase, where participants initially randomized to F/TDF switched to F/TAF.
Methods: After W96 of the blinded phase, participants could opt to receive F/TAF in the OL phase. We evaluated BMD, glomerular function (eGFR), biomarkers of proximal tubular injury (PTI; β2M/Cr, RBP/Cr), lipids and weight at OLW48 in participants who switched from F/TDF to F/TAF (switch group) and those remaining on F/TAF (stay group).

Results: The F/TAF OL phase included 2,128 switch group and 2,080 stay group participants. Participants in the switch and stay groups had 2,076 and 2,075 person-years of F/TAF exposure in the OL phase, respectively. There were two HIV infections in the switch group and three in the stay group (Table).
Hip and Spine BMD increased in the switch group. Switch group participants had lower eGFR at OL onset, which increased by OLW48. Both groups had improvements in PTI markers, which was greater in the switch group. LDL and HDL cholesterol increased in the switch group, with minimal change in total cholesterol:HDL ratio; fasting glucose change was small and not significantly different between groups. Weight gain was seen in both groups and was greater in the switch group.

	F/TDF→F/TAF (switch)	F/TAF (stay)	P value
HIV Incidence	0.093 (0.011, 0.336)	0.140 (0.029,0.410)	0.65
BMD hip (% change)	0.80 (-0.51, 2.29)	-0.20 (-1.536, 1.104)	0.026
BMD spine (% change)	1.14 (-0.49, 2.79)	-0.43 (-1.93, 2.06)	0.012
eGFR (mL/min at OL onset)	114.0 (96.9, 13.4)	119.3 (102.0, 141.6)	<0.0001
eGFR (mL/min change)	0.3 (-7.8, 9.0)	-2.8 (-11.4, 6.4)	<0.0001
β2M:Cr (% change)	-30.8 (-63.7, 3.7)	-7.3 (-36.8, 30.0)	<0.0001
RBP:Cr (% change)	-26.8 (-49.2, 2.0)	-9.9 (-33.0, 20.2)	<0.0001
LDL (mg/dL change)	13 (2, 28)	7 (-7, 22)	<0.0001
HDL (mg/dL change)	3 (-2, 8)	0 (-4, 5)	<0.0001
TC: HDL ratio (change)	0.2 (-0.17, 0.64)	0.15 (-0.23, 0.56)	0.015
Glucose (mg/dL change)	1 (-5, 8)	2 (-5, 8)	0.86
Weight (kg change)	2 (-0.3, 4.6)	1.2 (-1.2, 3.7)	<0.0001

Change values are from OL phase initiation to OL W48. HIV incidence is rate per 100 person-years with 95% exact confidence interval, all other values are median (Q1, Q3). P values are from: ANOVA model for BMD and weight; CMH test for eGFR, 82 M:Cr; and Wilcoxon test for LDL, HDL, total cholesterol to HDL ratio, and glucose. BMD, bone mineral density; eGFR, estimated glomerular filtration rate by Cockcroft-Gault; β2M:Cr, β2 microglobulin to creatinine ratio; RBP:Cr, retinol binding protein to creatinine ration; TC, total cholesterol.

Table. DISCOVER outcomes from open label phase onset to open label week 48

Conclusions: Participants switching from F/TDF to F/TAF in the OL phase of DISCOVER had a low HIV incidence rate, increased BMD, and improved renal biomarkers. LDL, HDL and weight increased in these participants, consistent with removal of TDF's weight and lipid suppressive effects. These data support F/TAF as a safe and effective switch option for people currently taking F/TDF for PrEP.

OALC0502

Preferences for implementing long-acting injectable pre-exposure prophylaxis among cisgender men who have sex with men in the US

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Background: Long-acting injectable HIV pre-exposure prophylaxis (LAI-PrEP) is efficacious and may overcome some challenges of daily oral PrEP. LAI-PrEP has great potential to reduce HIV incidence in high-risk populations, including men who have sex with men (MSM). Information about potential user preferences can be used to improve

uptake, adherence, and persistence and ultimately reduce HIV incidence. We sought to understand the preferences for implementation and perceived potential barriers of LAI-PrEP among MSM.

Methods: We recruited participants online through the 2019 American Men's Internet Survey. Eligible participants were HIV-negative, sexually active MSM aged ≥15 and living in the US. We designed and analyzed a discrete-choice experiment to identify preferred implementation profiles of LAI-PrEP among the respondents. Attributes included perceived side effects, injection frequency, out-of-pocket cost, service location, and negative judgement. We used mixed logit regression to calculate preference weights then relative importance by dividing the difference between the maximum and minimum preference weights within each attribute by the sum of the differences across all attributes, and multiplying by 100.

Results: N=2,241 participants responded. Perceived side effects was the most important potential barrier to LAI-PrEP (52% of the total relative importance), followed by out-of-pocket cost of up to $100 (30%). Injection frequency comprised only 11% of the relative importance, with quarterly and semiannual injections slightly preferred over every 2 months. Perceived negative judgement from others (PrEP stigma) was relatively unimportant compared to other attributes (5%). Service location was the least important attribute (2%); participants only slightly preferred a private doctor's office over a sexual health clinic and a pharmacy. See Figure.

Conclusions: This analysis provides insight into potential barriers to implementation of LAI-PrEP among MSM in the US. A LAI-PrEP product with perceived severe side effects is likely to be a significant barrier to uptake, though potential users would probably tolerate mild-to-moderate side effects. Minimizing out-of-pocket costs is likely to increase uptake of LAI-PrEP and is important to equitable access to populations most at risk. Reduction of injection frequency could marginally increase likelihood of PrEP utilization. Service location and potential negative judgement are unlikely to be barriers to uptake in this population.

OALC0503

Understanding participant experiences and preferences in an injectable PrEP trial: a qualitative sub-study of barriers, facilitators, and preferences for PrEP use among MSM and TGW

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Background: HPTN083, a randomized, double-blind international clinical trial of long-acting injectable cabotegravir (CAB-LA) versus daily oral emtricitabine/tenofovir disoproxil fumarate (TDF/FTC) for HIV prevention among cisgender men and transgender women who have sex with men (MSM/TGW), demonstrated a 66% reduction in HIV incidence in participants randomized to CAB-LA versus TDF/FTC. Participants' experiences prior to unblinding in May 2020 provide initial insights into preferences and best practices for implementing injectable PrEP.

Methods: Participants enrolled in HPTN083 were purposively sampled for individual qualitative interviews (n=35) during the injection phase from three study sites (two U.S., one international), and categorized as adherent (n=24), non-adherent (n=10), or early-discontinuers (n=1). Data were organized using NVivo (version 12) and analyzed using content analysis.

Results: Reasons for enrolling in HPTN083 and using PrEP included a preference for using medication for HIV prevention versus for HIV treatment, that study participation was believed to be a means to enhance health via education and access to services, and a sense of contributing to community via research participation. Interviewees contrasted experiences with study staff and research sites with available clinical care, and emphasized increased scheduling flexibility, frequent and thorough communication, and the open, affirm-

ing environment of research sites (e.g., compassion, encouragement, less stigma). Injection experiences were positive overall with respect to ease of use; some described early anxiety around injections and shared perceptions about the study product (e.g., that efficacy would wane over time and/or before the next scheduled injection) and strategies for managing injection site discomfort. Facilitators of injection visit adherence generally centered around motivational factors (e.g., preservation of health, desire to contribute to research), use of reminder strategies, social support, and clinic factors (e.g., flexibility). Barriers included structural factors (e.g., financial constraints, distance to clinic, homelessness) and competing demands (e.g., work schedules).

Conclusions: MSM/TGW viewed their participation in an injectable PrEP trial as a positive experience and a means by which to enhance wellbeing. Site/clinic flexibility and an open and affirming clinic environment were key facilitators to adherence. To support injection adherence over time, interventions that target structural barriers and flexible means of injection delivery may be most effective.

OALC06 Caring for the whole person: Integrating gender-affirming hormone therapy within HIV prevention services

OALC0601

No impact of tenofovir/emtricitabine in estradiol exposure among transwomen on oral PrEP: results from the 12-week drug-drug interaction PrEParadas substudy

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Background: An important HIV prevention barrier for transwomen (TGW) is the concern that oral PrEP containing tenofovir (TDF) and emtricitabine (FTC) negatively affects the efficacy of feminizing hormone therapy (FHT). We aimed to assess the impact of PrEP on FHT among transwomen.

Methods: We performed a drug-drug interaction substudy among TGW enrolled in a TDF/FTC daily oral PrEP and using FHT (estradiol valerate plus spironolactone) in a demonstration study for TGW and PrEP in Rio de Janeiro, Brazil (NCT03220152). Participants had a first pharmacokinetic (PK) assessment and initiated PrEP 15 days after FHT initiation (W0), followed by a second PK evaluation 12 weeks later (W12). Blood samples were collected prior and after the directly observed therapy (0.5, 1, 2, 4, 6, 8, and 24 hours). Estradiol and spironolactone PK parameters were estimated by non-compartmental analysis (Pharsight WinNonlin v. 7.6, Certara) and compared using Wilcoxon rank-sum test (alpha=0.05). We assessed PrEP adherence with DBS levels.

Results: Among 24 transwomen that completed the study, median age was 26.0 years (23.0-34.5) and body mass index was 22.7 kg/m2 (20.6-26.0). Condomless anal sex in the last 6 months was reported by 92%. At W12, 6, 13, and 5 participants had DBS levels consistent with 7+ doses/week, 4-6 doses/week, <2 doses/week. Estradiol exposure did not differ between W0 and W12: AUC/D 596.0 (387.0-757.0) at W0 and 511.0 (367.0-707.0) h*pg/mL/mg at W12 (p-value= 0.056), Cmax 36.0 (24.0-48.0) at W0 and 28.3 (22.0-43.0) pg/mL at W12 (p-value=0.095). Although spironolactone AUC/D was significantly lower at W12 compared to W0 (2.8 [1.5-3.5] and 3.0 [2.1-5.1] h*ng/mL/mg, respectively, p-value=0.008), its Cmax did not differ between the two assessments (W0: 0.9 [0.7-1.3], W12: 0.8 [0.7-1.2] ng/mL, p-value= 0.96).

Conclusions: Our results reassure that oral PrEP and FHT may be used concomitantly. This adds to limited data on potential impact of oral PrEP on FHT among transwomen.

OALC0602

Hormone levels among transgender women and transgender men in a transgender-led, integrated, gender-affirming care and sexual health service at Tangerine Clinic in Bangkok, Thailand: a real-world analysis

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Background: Gender-affirming hormone therapy (GAHT) is used among many transgender individuals who would like to achieve physical changes—feminizing hormone therapy (FHT) for transgender women and masculinizing hormone therapy (MHT) for transgender men. Without proper monitoring, GAHT can lead to suboptimal effect or put users at risk for adverse events. We aimed to determine hormone levels among transgender women and transgender men who were using GAHT.

Methods: Transgender individuals who were using GAHT at entry to Tangerine Clinic and tested for hormone levels (blood estradiol [E2] and total testosterone [TT] levels for transgender women; TT for transgender men) between 2015 and 2020 were included. Hormone target levels were E2 of 100–200 pg/mL and TT of <50 ng/dL for transgender women; TT of 400-700 ng/dL for transgender men. Baseline and available hormone levels during the 12-month follow-up period were assessed to determine changes.

Results: A total of 1,534 transgender women were included: 2.5% underwent orchiectomy, 70.8% used single-hormone regimen, and 5% were HIV-positive. Median E2 and TT levels at baseline were 29 (14.3–45.3) pg/mL and 298.5 (22–646) ng/dL, respectively. A total of 524 (32.2%) had any hormones within target levels: 28 (1.8%), both; 11 (0.7%), only E2; and 485 (31.6%), only TT. HIV status was not associated with the outcome of hormone target levels. Among 302 transgender women who came to follow-up visit(s), 165 (54.6%) achieved or maintained either hormone within target levels. A total of 200 transgender men were included: none had gender-affirming surgery and all were HIV-negative. Median (IQR) TT levels were 45.5 (32.5–531.6) ng/dL, and 141 (70.5%), 26 (13.0%), 33 (16.5%) had suboptimal, optimal, and supraphysiologic TT levels, respectively. Median hematocrit was significantly higher among those with optimal or supraphysiologic TT levels compared to those with suboptimal TT levels (46.7 vs. 41.0% and 47.0 vs. 41.0 %, respectively, p<0.001 in both comparisons), and seven had erythrocytosis. Median high-density lipoprotein cholesterol (HDL) levels were significantly higher among transgender men with suboptimal TT levels compared to those with supraphysiologic levels (61 vs. 50.5 mg/dL, p=0.02). Among 152 transgender men who came to follow-up visit(s), 51 (33.6%) achieved or maintained optimal TT levels.

Conclusions: One-third of transgender women who were using FHT had any hormones within target levels and 13% of transgender men who were using MHT had optimal TT levels in this real-world analysis. At follow-up visits, there was an increase in the proportion with optimal hormone levels for both transgender groups, emphasizing a positive effect of supervised GAHT in a transgender-competent health care facility.

OALC0603

Preference for long-acting injectable pre-exposure prophylaxis among transgender women clients of the Tangerine Clinic in Bangkok, Thailand

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Background: Long-acting injectable (LAI) cabotegravir demonstrated superior efficacy to oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) when used as pre-exposure prophylaxis (PrEP) among men who have sex with men and transgender women (TGW). Alternative PrEP options are crucial for TGW as low uptake and retention have been seen in oral PrEP programs. We explored preference of LAI PrEP among Thai TGW clients who had ever used oral PrEP.

Methods: Tangerine Clinic is a trans-led, integrated gender-affirming care and sexual health clinic in Bangkok, Thailand. Between August and December 2020, we conducted a cross-sectional study, recruiting consecutive HIV-negative TGW clients at Tangerine who reported ever using oral PrEP. Participants completed a self-administered questionnaire on demographics and risk behaviors, oral PrEP adherence, perceived PrEP benefits, and preference for LAI PrEP. Logistic regression analysis was conducted to identify factors associated with LAI PrEP preference.

Results: Of 173 TGW who completed the survey, 94.2% were currently undergoing feminizing hormone therapy (FHT) and 24.2% had undergone gender-affirming surgery. In the past six months, 86.1% had practiced receptive anal sex, 18.4% receptive neovaginal sex, 26.0% insertive anal sex, and 67.2% reported inconsistent condom use. Sexually transmitted infections (STIs) were diagnosed among 30.7% of respondents during the past six months. Median age was 27 (IQR 24–29) years. Of all TGW, 76.3% were current PrEP users with a mean of 6.2 PrEP pills (SD=0.8, min=4 max=7) taken per week, while 23.7% TGW had already discontinued PrEP. 123 of 166 (74.1%) who responded indicated a preference for LAI PrEP; 74.0% among current PrEP users and 74.3% among those who discontinued PrEP. Perceived benefits of PrEP (aOR 4.4, 95%CI 1.2-16.9, p=0.021) and recent STI diagnosis (aOR 3.8, 95%CI 1.2-12.1, p=0.020) were associated with preference for LAI PrEP.

Conclusions: Around three-quarters of Thai TGW who had used oral PrEP reported a preference for LAI PrEP. Perceived benefit of PrEP and awareness of risk through STI diagnosis increased LAI PrEP preference. Future studies exploring LAI PrEP acceptability among TGW who have never used PrEP, potential interactions between FHT and LAI PrEP, and alternative injection sites for TGW with buttock implants, are urgently needed.

OALD07 Delivering treatment where people live

OALD0701

HIV service delivery to key populations in the time of COVID-19: experiences from India

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Background: In March 2020, the Government of India revised HIV service delivery policies in response to COVID-19 to include community distribution and multi-month dispensation (MMD) of ART for stable and unstable PLHIV. There are limited data on the impact of COVID-19-associated disruptions and novel service strategies on HIV service access among key populations in low- and middle- income countries.

Methods: Between November-December 2020, we conducted focus groups with purposively sampled men who have sex with men (MSM), female sex workers (FSW), and transgender women (TGW) in Telangana and Maharashtra, Indian states with high HIV burdens. Seven focus groups were conducted; five by phone and two in-person with safety precautions. Discussion topics included service access experiences, medication adherence, and preferences to ensure service continuation. Inductive coding identified themes across topics.

Results: 44 individuals participated in focus groups (13 MSM; 16 FSW; 15 TGW) aged 20-49 years. 24 participants self-identified as living with HIV. HIV negative participants reported challenges to get HIV tests at hospitals due to lockdown travel restrictions and fear of contracting COVID-19. Some accessed HIV testing using transportation arranged by community-based organizations. Most PLHIV reported uninterrupted ART refills; however, some reported lapses in ART adherence and delayed viral load testing. Participants receiving MMD shared consistent appreciation for the service as it saved time, money and reduced exposure to COVID-19 and stigmatizing environments. PLHIV expressed gratitude for home deliveries which enabled access to ART, yet discouraged continuing home-based services due to the risk of a confidentiality breach to family/neighbors. Most suggested community dispensation points. Other themes included loss of livelihood and requests for economic support across groups, and concerns about telemedicine as a service option from FSW and TGW related to limited smartphone access.

Conclusions: COVID-19 had a greater impact on access to testing services (HIV testing, viral load) compared to treatment services. High acceptance of MMD and community-based services support the need for differentiated service delivery models to overcome COVID-19 disruptions. Varied preferences across key populations related to new service mechanisms and calls to address the impact of COVID-19 on livelihood options underscore the importance of tailoring HIV care to community needs.

OALD0702

VIBRA trial – Village-based refill of ART following home-based same-day ART initiation: a cluster-randomized clinical trial

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Background: Community-based based antiretroviral treatment (ART) delivery is an important component of differentiated service delivery models in sub-Sahara Africa. However, community-based delivery systematically excludes new patients during their first six or 12 months on ART. The pragmatic VIBRA (Village-based refill of ART) cluster-randomised trial in rural Lesotho compared the option of ART refill by lay village health workers (VHW) versus clinic-based refill after home-based same-day ART initiation during a door-to-door HIV testing campaign.

Methods: In village-clusters randomised to the intervention, individuals found HIV positive were offered ART refill by VHWs after same-day ART initiation. The trained VHWs dispensed drug supply for 1-3 months, scheduled a first clinic-based follow-up visit for blood draw at 6 months, and were supervised by a district ART nurse and the corresponding health facility. In control village-clusters, participants were referred to the clinic for ART refill and follow-up.

The primary outcome was viral suppression <20 copies/mL. Secondary endpoints comprised 3-month linkage and 12-month engagement in care, among others. Analyses were by intention-to-treat. Trial registration: NCT03630549.

Results: From August 15th, 2018, until May 28th, 2019, 139 individuals from 130 households in 60 clusters in control, and 118 individuals from 108 households in 57 clusters from intervention arm were enrolled. The majority were female (150 [58%]), with a median age of 36 years (interquartile range [IQR] 30-48), 200 [78%] were newly diagnosed. In the intervention arm, 48/118 (41%) opted for ART refill by the VHW, the remaining for clinic-based refill. At 12 months, 64/139 (46%) and 46/118 (39%) participants in the control and intervention arm, respectively, achieved viral suppression below 20 copies/mL (adjusted absolute difference -0.07 [95% confidence interval -0.20-0.06]; p=0.256). Linkage to care at 3 months did not differ between control versus intervention arm (65% versus 68%; p=0.630). 98/139 (71%) participants in control and 71/118 (60%) in intervention were active in care at 12 months (-0.12 [-0.23-0.003]; p=0.058). Zero deaths occurred in control and seven deaths in intervention arm.

Conclusions: The offer of village-based ART refill following home-based ART initiation was not able to increase linkage to care, engagement in care and viral suppression compared to standard clinic-based refill.

OALD0703

The Community HIV Epidemic Control Model: a community-based intervention to achieve 90-90-90 via comprehensive HIV differentiated service delivery in rural communities in Zambia

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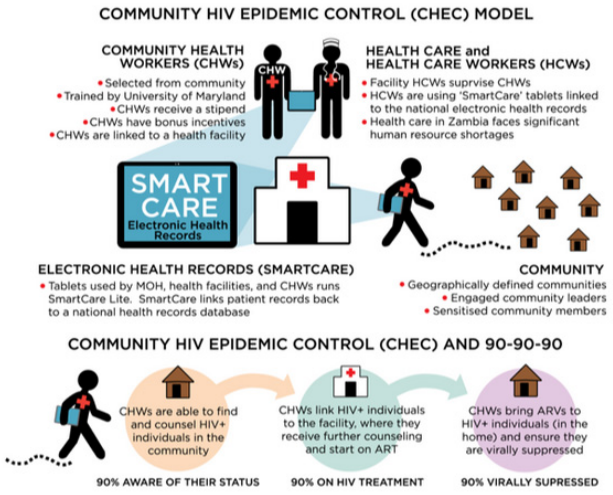
Background: Novel HIV differentiated service delivery models are needed to help Zambia achieve 90-90-90 epidemic control. University of Maryland Baltimore (UMB) designed and implemented the Community HIV Epidemic Control (CHEC) model to support HIV testing services (HTS), linkage to antiretroviral therapy (ART), and support viral load suppression (VLS).

Description: UMB implemented the CHEC model under the Stop Mother to Child HIV Transmission (SMACHT) project from 2015 to 2020 (Figure 1). Via health facilities, community health workers (CHW) were recruited and trained in HTS, and psychosocial and adherence counselling. CHWs conducted community HTS, escorted clients to initiate ART, and delivered ART to patients who were stable-on-care (SOC), defined as on ART for >12 months with a suppressed viral load and willing to receive ART at home.



Lessons learned: In the first year of CHEC implementation, HTS increased from 21,051 in 2015 to 71,289 clients in 2016; 29% were tested in the community by CHWs (up from 0%).

From 2015 to 2020, SMACHT provided HTS to 1,379,387 clients, of whom 46,138 were identified as HIV positive for a positivity yield of 3.3%. Of these, 41,366 were linked to ART, 90% linkage overall.

A February 2017 sub-study of all SOC patients found that of 1,091 clients, 97% were virally suppressed with near 100% retention in care. By 2020, 66,841 clients on ART had received a VL test and 60,694 were suppressed, 91% viral load suppression.

Conclusions/Next steps: By task-shifting HIV service delivery into the community, CHEC achieved 90% ART linkage and 91% VLS, with 97% VLS among SOC clients. Community-based programs can increase uptake of HTS and linkage to care. However positivity yields may be low, necessitating targeted strategies such as index testing. In home delivery of ART to SOC patients supports adherence and results in high levels of VLS.

OALD08 Building bigger and better together: Lessons in service delivery integration

OALD0801

Using multi-disease health screening campaigns to increase uptake of health and HIV testing services (HTS) in the Democratic Republic of the Congo (DRC)

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Background: In 2019, only 56% of estimated HIV-positive individuals in the DRC were diagnosed and enrolled on antiretroviral treatment (ART) indicating a need for new HTS strategies to reach undiagnosed PLHIV. PATH, through the USAID-funded Integrated HIV/AIDS Project, piloted use of a multi-disease screening campaign to improve uptake of HTS services.

Description: Under this campaign, health facilities offered free screenings during weekend and evening hours for hypertension, hyperglycemia, sexually transmitted infections (STI), pneumonia, dermatitis, and HIV. Community health volunteers disseminated information to raise awareness of the free consultations. At the consultation, clients completed an HIV risk assessment, then were screened for diseases based on eligibility and client preference; HIV testing was the last test. Clients who screened positive for any of the diseases were linked to care and treatment services, including same-day ART initiation if HIV-positive. PATH piloted this model at eight facilities in Haut-Katanga, using descriptive and inferential statistics to analyze data from September 2020 through January 2021.

Lessons learned: 2,860 clients (57% male) participated in the screenings, with highest representation among clients over 49 years (19%). Overall HIV prevalence was 12%, with higher prevalence among females (13%) than males (12%) and clients 25 years of age and older. 91% (192/210) of HIV-positive individuals were initiated on ART. Overall STI prevalence was 22%, and the HIV/STI co-infection rate was 14%, with higher co-infection among females than males (19% versus 10%; $p<0.05$), and highest HIV/STI co-infection prevalence among those in the 40-44 (26%) age band. More females than males had hypertension (11% versus 8%; $p<0.05$). Hyperglycemia was detected among 7% of clients. These results highlight our campaign's success in bringing individuals to facilities for multi-disease screenings, including HIV. The high HIV/STI co-infection rates reinforce the need to ensure provider-initiated HTS at STI entry points.

Conclusions/Next steps: Our results highlight the promise of using multi-disease screening campaigns to increase engagement in health services and improve HIV diagnosis among unreached PLHIV. We plan to continue testing this strategy, including investigating cost-effectiveness, to further optimize the model for potential expansion across DRC in support of epidemic control.

OALD0802

Combined interventions to accelerate delivery on outcomes for young children affected by HIV in southern Africa

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Background: Young children affected by HIV living in Africa face multiple vulnerabilities that hinder future success. The UNDP endorses "accelerator" interventions that drive success across multiple health and wellbeing outcomes as key for sustainable development. This study aimed to identify entry points for accelerator interventions relevant for children affected by HIV in southern Africa.

Methods: This study tracked child wellbeing outcomes among 989 children affected by HIV enrolled in community-based organizations in South Africa and Malawi. Data from participating children (4-13 years) and their caregivers were collected at baseline and at 12-15-month follow-up. We investigated five hypothesised protective factors: food security, cash grant, positive parenting, living in a safe community and community acceptance; and twelve child outcomes related to the Sustainable Development Goals (SDGs): health status, nutrition, education, cognitive development, and mental health. Protective factors were measured as consistent receipt at baseline and follow-up and had to be positively associated with several child outcomes across three or more SDGs. Associations were evaluated using multivariate multivariable logistic regression controlling for baseline covariates. Adjusted probabilities of experiencing each SDG aligned outcome conditional on receipt of single, combined or all identified accelerators were also calculated.

Results: Three protective factors that had impact on nine different child outcomes across three SDG aligned targets were identified. Household food security was positively associated with child education and cognitive development outcomes. Cash grant receipt was positively associated with nutrition and cognitive development outcomes. Living in a safe community was positively associated with all mental health outcomes. Experiencing a combination of two protective factors was associated with higher adjusted probability of positive child outcomes. Moreover, experiencing all three protective factors was associated with the highest probability of positive child outcomes (+10.4-28.4%points). Substantial improvements were noted in child education outcomes.

Conclusions: The accelerator model of combining protective factors yielded greater improvements in child outcomes across different developmental domains than single provisions. Household food security, cash grant receipt, and residence in a safe community may be key for success of children affected by HIV. Promoting services to support all three of these factors would yield the greatest improvement in child outcomes in similar settings.

OALD0803

Reduction trends in AIDS indicators (incidence, hospitalization and mortality rates) associated with conditional cash transfer measures in Brazil: an ecological study

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Background: Brazil has long been recognized for its strong response to the HIV/AIDS epidemic. Although the epidemic is classified as stable at the national level, AIDS incidence, hospitalizations and mortality rates vary geographically. Brazil is also one of the most unequal countries in the world, and it has implemented in the last two decades one of the largest Conditional Cash Transfer (CCT) programs, the *Bolsa Familia* Programme (BFP). BFP's target populations are poor households earning between US$35–70 per person per month. It is important to note that the BFP has two conditionalities: the beneficiary families are obliged to keep the children in school and to be accompanied in health units. We aimed to evaluate the impact of BFP coverage on trends in the rates of AIDS incidence, hospitalizations and mortality in Brazil.

Methods: An ecologic panel data study, with all 5,507 Brazilian municipalities over the 2004-2012 period, was performed. We employed a fixed-effects multivariate negative binomial model to estimate the association between BFP coverage - of the eligible poor population -, classified as low (0% to 29%); intermediate (30% to 69%); and high (≥70%), and AIDS indicators, adjusting for all relevant covariates.

Results: At the national level, a BFP coverage of 70% or more of the poorest population, in municipalities with the highest AIDS incidence, was associated with a 10.3% (95%CI:3.7-16.5) reduction in the incidence, with an even stronger effect among women (15%; 95%CI:6.6-22.6) and children under 14 years old (38.7%; 95%CI:20.9-52.5). Higher BFP coverage was also associated with a decline in AIDS-related hospitalizations (26.4%; 95%CI:18.0-34.0) and AIDS mortality rates (9.7%; 95%CI:1.8-17.0).

Conclusions: This is the first study to evaluate the association between BFP coverage and trends in AIDS indicators in all Brazilian municipalities over a long period. BFP contributed to reduce the incidence, hospitalizations and mortality by AIDS in Brazil, which could be explained by both its money allowances and conditionalities. These results have important implications for countries with social protection measures such as conditional cash transfers. They are evidence of the impact of a policy that can be adapted to other low- and middle-income countries with high socioeconomic inequalities.

E-POSTERS

Track A

Viral origins, evolution and diversity

PEA001

Unique molecular properties of reverse transcriptase conferring replication advantage on HIV-1C

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Background: HIV-1C appears to possess a unique ability to duplicate sequences of biological significance. Previous work from our laboratory identified two such hotspots of sequence duplication, one in the viral promoter and the other in p6-Gag. We sought to determine the *cis* (RNA secondary structures, sequence homologies, etc.) and *trans* (RT and associated proteins) elements regulating the ability of HIV-1C RT to duplicate sequence motifs. Comparative sequence analysis of RTs of diverse HIV-1 subtypes revealed the presence of signature amino acid residues at six different locations of HIV-1C. Among these residues, the substitution of glycine for threonine at position 359 in the connection domain of HIV-1C RT is vital due to the possibility of an additional hydrogen bond formation with the phosphate backbone of the nascent DNA.

Methods: We compared the specific activity of recombinant RTs of HIV-1B and C. We constructed panels of reporter and infectious molecular clones of HIV-1C and determined recombination frequency and replication kinetics.

Results: The specific activities of recombinant RTs of both subtypes are comparable. Threonine at position 359 seems to have a contrasting effect on two different properties of C-RT; while the specific activity reduced, the recombination frequency was enhanced significantly. We also observed a marginal reduction in viral replication of 359T viral strains of both subtypes.

Conclusions: A Threonine residue at position 359 has the potential to form an additional hydrogen bond between RT and the DNA, which we are evaluating experimentally. An additional hydrogen bond at the 3'-end of the nascent DNA may enhance recombination frequency during template-switch, as our data seems to indicate.

In contrast, the enhanced avidity between RT and the DNA may also be responsible for the reduction in the enzyme activity as our data suggests, since the extra hydrogen bond may slow down the rate of polymerization.

The reduced RT activity and increased recombination rate may help the virus escape immune surveillance more effectively, thus, influencing viral evolution. The direct implication of the G359T substitution on the high rate of sequence duplications observed in HIV-1C is currently under investigation.

PEA002

Genetic diversity of HIV-1 in a cross sectional study conducted in Teso, Western Kenya

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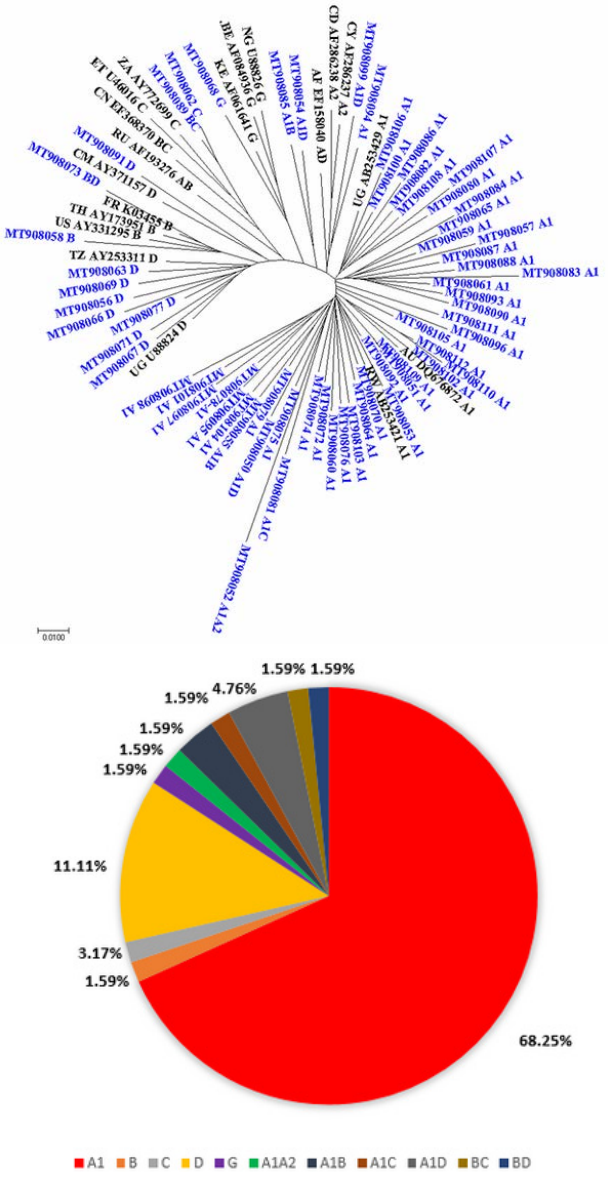
Background: High HIV-1 infection rates and genetic diversity especially in African population pose significant challenges in HIV-1 clinical management and vaccine development. HIV-1 is a major health challenge in Kenya and causes mortality and morbidity in the country as well as straining the healthcare system and the economy. This study sought to identify HIV-1 genetic subtypes circulating in Teso, Western Kenya which borders the Republic of Uganda.

Methods: A cross sectional study was conducted between Jan-Dec 2019 on HIV-1 positive individuals on antiretroviral therapy. Sequencing of the partial *pol* gene was conducted. Subtypes and recombinant forms were generated using the jumping profile Hidden Markov Model. Alignment of the sequences was done using ClustalW program and phylogenetic tree constructed using MEGA7 neighbor-joining method.



Results: 63 samples were successful sequenced. In the analysis of these sequences, we observed HIV-1 subtype A1 to be the most predominant 43 (68.25%) followed by D 8 (12.70%) and 1 (1.59%) each of C, G and B and inter-subtype recombinants A1-D 3 (4.76%), A1-B 2 (3.17%) and 1 (1.59%) each of A1-A2, A1-C, BC and BD. These findings are consistent with those from other parts of Kenya which indicated A1 to be the most common subtype.

Conclusions: Increased genetic diversity of HIV-1 subtypes was observed which not only pose a challenge in disease control and surveillance but also vaccine development. Therefore, there is need for continued surveillance to enhance future understanding of the geographical distribution and transmission patterns of the epidemic.

PEA003

Longitudinal alterations in O-linked glycosylation during chronic HIV-1 infection and its impact on V1/V2 & V3 targeting broadly neutralizing monoclonal antibodies

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Background: Preferential O-glycosylation at concentrated stretches of serines and threonines (S/T) in a protein sequence may modulate various biological functions such as cellular migration, cellular signaling, neutralizing antibody escape, and immunogenicity. Specifically, HIV-1 Env O-linked glycosylation has been linked and shown to reduce sensitivity to V3 targeting monoclonal antibodies but the evolution of O-linked glycosylation over the course of infection has not been fully characterized.

Methods: We *longitudinally* studied 14 antiretroviral-naïve individuals in the FRESH acute HIV-1 infection cohort based in Durban, South Africa. 1356 single genomes were analyzed at timepoints ranging from 1 to 1536 days post first detection of plasma viremia (median per participant = 97 sequences, median per timepoint = 16 sequences).

We characterized O-and N-linked glycosylation profiles of Env V1-domains. Phylogenetic relatedness of the sequences was assessed by the neighbor-joining method (MEGA-X). Based on NetOGlyc4.0 prediction scores and timepoints, selected *env* amplicons were cloned into the pcDNA™3.1 TOPO® vector. The TZM-bl assay was used to assess the neutralization profiles of four V1/V2 and V3 targeting bNAbs against the envelopes.

Results: The V1-domain phylogenetically diversified longitudinally in 100% of the participants. *V1-domain* length changes did not follow a generalizable direction longitudinally, but the total count of S/T residues *increased* in 57% of the participants. Furthermore, the S/T residue density within the V1-domain increased in 71% of the participants. The V1-domain showed an increase in the NetOGly4.0 sum score in 71% of the participants.

The sum of NetOGly4.0 score density within the V1-domain also increased in 71% of the participants. The total number of potential N-linked glycosylation sites remained unchanged in 57% of the participants. Interestingly, among the selected envelopes for TZM-bl neutralization assays, 71.4% showed a positive correlation between absolute changes in IC_{50} (against V1/V2 and V3 targeting mAbs) and fold change in NetOGly4.0 score density.

Conclusions: We demonstrate that O-linked glycosylation could be a mechanism through which HIV-1 progressively acquires resistance to V1/V2 and V3 targeting neutralizing antibodies. These findings inform better understanding of the longitudinal dynamics of Env glycan patterns thereby critical for decoding viral mechanisms of host immune system evasion and may aid rational immunogen design studies.

Viral fitness, persistence and resistance

PEA004

The frequency of HLA-I alleles could influence the level of post-transmission readaptation of HIV-1

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Background: The adaptive role of escape mutations transmitted and/or acquired post-infection is not fully elucidated. Using computational methods, our first objective was to classify the different escape polymorphisms to the cytotoxic immune (CTL) response in the viral gag protein in transmission events. Next, our objective was to evaluate the dynamics of escape after infection, and mainly, to analyze how these escape variables observed in the founder (transmitted) virus can influence viral readaptation and the course of infection.

Methods: A total of 17 adult patients were voluntarily enrolled during acute/early primary HIV infection (average of 43.7 days post-infection, SD: 24.3) during the period from 2009 to 2014 in the city of Buenos Aires. Blood samples were taken during the first year of infection. An average of 28.8 gag quasispecies per patient by NGS SMRT technology was sequenced. Genotyping of HLA class I A and B was performed using PCR-SSOP. NetMHC CBS prediction server for the 19 most prevalent HLA-A and B alleles and IEDB analysis resources was performed to epitope prediction. The frequency of both polymorphisms associated with transmitted escape (fTE, in the founder virus) and post-transmission escape (fPE) was measured.

Results: We observed a significant positive correlation of fTE as a function of the population frequency of HLA-I A/B alleles (Pearson, p: 0.005)(*), not so for fEE (p: 0.196). The figure shows how a higher fTE results in lower requirements for viral re-adaptation (fPE) especially for alleles of higher frequency (>13%). Interestingly, we also found that higher fTE values and lower fPE values are related to higher viral set-point values.

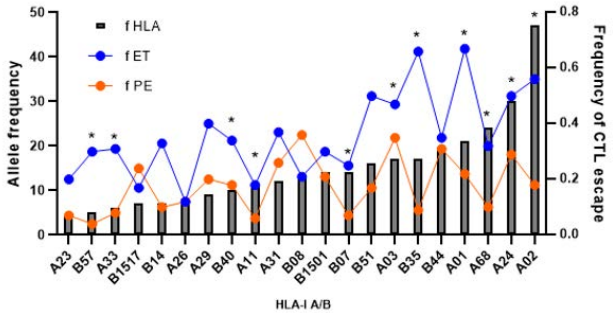

Figure.

Conclusions: We conclude that adaptation at the population level of HIV-1 occurs especially for the most frequent alleles. This seems to decrease the selection of new mutations that could reduce the replicative capacity, which negatively affects the course of the infection.

PEA005

Premutations could facilitate CTL escape in gag epitopes during early HIV-1 infection

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Background: Numerous studies demonstrated the relationship between escape mutations in the viral gag protein and monitoring values such as viral load and CD4 + T lymphocyte count. Our objective was to identify, through computational prediction, the post-transmission mutations associated with escape to the cytotoxic immune response and, on the other hand, to assess the incidence of pre-escape mutations within these immunodominant (ID) segments.

Methods: A total of 17 patients were voluntarily enrolled during acute/early primary HIV infection (average 43.7 days post-infection, SD: 24.3) during the period from 2009 to 2014 in the city of Buenos Aires, Argentina. Blood samples were taken during the first year of infection at three month intervals. An average of 28.8 gag quasispecies per patient by *NGS SMRT technology* was sequenced. Genotyping of HLA class I A and B was performed using PCR-SSOP. *NetMHC CBS prediction server* for the 19 most prevalent HLA-A and B alleles and *IEDB analysis resources* was performed to epitope prediction. The variability analysis (entropy) and the dN / dS ratio test were performed using the *Shannon algorithm* and the *SNAP v2.1.1* (Synonymous and Non-synonymous Analysis) software, respectively.

Results: Our results showed a greater entropy variation within ID segments compared to non-ID segments (t-test, p = 0.0485). Additionally, the results of the dN / dS test (selective pressure) did not show a variation in time for non-ID segments (Pearson, p = 0.4952 R2 = 0.1232), but a significant variation was observed in ID segments (Pearson, p=0.0072 R2 = 0.8650), consistent with the progressive increase of CTL escape during the first year of infection (Pearson, p = 0.0012 R2 = 0.9429).

Conclusions: Our results suggest that there is a progressive selection of certain mutations in ID segments, which, presumably, can gradually reduce the affinity of HLA-I or TCR molecules or act as compensatory mutations within the epitope and later facilitate the selection of the escape mutation itself. We believe that variability studies on specific genomic sequences could be useful for predicting regions susceptible to escape from the immune response or mutations associated with treatment failure for both HIV infection and other viral infections.

PEA006

Low-level HIV-1 viral load predicts virologic failure in antiretroviral experienced individuals in Botswana

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Background: A subset of people living with HIV (PLWHIV) experience low-level viremia (LLV) while on combination antiretroviral therapy (cART). Currently, not much data is available on the impact of LLV on virologic failure (VF). The aim of this study was to determine whether LLV predicts VF in individuals on cART in Botswana.

Methods: We conducted a longitudinal analysis of 1756 PLWHIV enrolled in the Botswana Combination Prevention Project (BCPP) from 2013-2018 residing in 30 communities in Botswana. HIV-1 viral loads(VL) were measured at baseline and after 2 years of follow-up. LLV was defined as any detectable baseline VL between 50-1000 copies/mL.

The primary outcome was virologic failure (VF), defined as any single detectable VL≥1000 copies/mL. Most of the participants were on Efavirenz-based first line regimens, before widespread dolutegravir rollout. Drug resistance mutations (DRMs) were assessed using the

Risk factor	Virologic failure Group (n=24) No. (%) or Median (IQR)	Non-virologic failure Group =1732 No. (%) or Median (IQR)	Univariate HR (95% CI)	p-value	Multivariate HR (95% CI)	p-value
Viral load group Suppressed (n=1700) low level viremia (56)	12(0.7) 12(21.4)	1688(99.3) 44(78.6)	1(ref) 22.5 (10.1-50.2)	<0.001	1(ref) 13.8(4.2-45.6)	<0.001
DRM at low level viremia Absence (n=34) Present(n=22)	5(14.7) 7(31.8)	29(85.3) 15(68.2)	1 2.57(0.81-7.09)	0.11	1 1.81(0.4-8.1)	0.77
SEX Female(n=1329) Male (n=20)	14(1.1) 10(50.0)	1315(98.9) 10(50.0)	1 1.78 (0.79-4.0)	0.17	1 1.49(0.5-4.3)	0.45
Age <25 years (n=77) 25-34 years(n=324) 35-44 years(n=661) 45-54 years(n=442)	4(5.2)) 6(1.9) 9(1.4) 5(1.1)	73(94.8) 318(98.1) 652(98.6) 437(98.9)	1 0.34(0.1-1.2) 0.26(0.08-0.84) 0.14(0.04-0.5)	 0.1 0.025 0.004	1 0.58(0.13-2.5) 0.66(0.2-2.3) 0.31(0.09-1.1)	 0.46 0.51 0.07
ART regimen First line(n=1596) Second line(n=91)	16(1.0) 5(5.5)	1580(99.0) 86(5.094.5)	1 5.75(2.3-14.1)	<0.001	1 3.0(1.1-8.0)	0.03
Duration on ART	5.84 (3.97-9.42)	6.70(3.30-9.53)	0.74(0.68-0.8)	<0.001	0.78(0.71-0.86)	<0.001

PEA006 Table 1. Predictive factors of virology failure.

baseline sample using the Stanford HIV drug resistance database. Predictors of VF were assessed using cox proportional hazard models, adjusting for clustering by community.

Results: A total of 1.4% (24/1756) participants experienced VF during follow-up period, among which 12 previously had LLV. LLV increased the risk of presenting VF [Hazard Ratio (HR)=22.5; 95%CI:10.1-50.2) compare to suppressed group (Table 1). Amongst 12 participants who experienced LLV, 7 (58.3%) had detectable DRMs. The presence of baseline DRMs among participants with LLV increased the chance of progressing to VF by 2.57 times. Participants on second line therapy were associated with a higher risk of presenting VF (p<0.001).

Conclusions: LLV was associated for higher risk of VF. Monitoring of individuals experiencing LLV may help prevent emergence of acquired DRMs.

PEA007

High resistance mutation to cART in HIV-1 exposed infected children and recent emergence of CRF02_AG variant in Bouar, a rural environment of Central African Republic

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Background: The emergence of HIV-1 recombinant forms and Drug combined antiretroviral therapy (cART) resistance are frequent in the therapeutic course of HIV-infected children in Low and Middle-Income Countries (LMIC) precisely in Central African Republic (CAR) as evidenced by studies carried out in the Bangui capital. Vertical transmission rate including during breastfeeding is 12.4.

The aim of study is to analyze retrospectively the molecular characterization of sequencing results and mutation detected in HIV infected children who have received cART initiated since infancy.

Methods: The 2019 retrospective review of the clinical, therapeutical, and immunological-molecular records of six children who were performed the genome sequencing, followed in Bouar, at the St Michel IST and HIV Center, in the north-west of the CAR. These children infected with HIV perinatally had their seropositive test performed at a median age of 6 years and initiated cARTs at an average age of 7 years as part of treatment regimens also used for the prevention of vertical transmission and the initiation of treatment for HIV infection in CAR.

Results: We analyzed results from viral RNA extracted amplification and sequencing of 6 children plasma samples collected under first line antiretroviral therapy. Persistent opportunist infections confirmed Immunosuppression in all patients. Sequencing of viral genomes revealed high level resistance mutations to NRTIs (ABC, FTC and 3TC) in five patients and to NNRTIs (EFV, NVP used locally and DOR, ETR and RPV unused) for all with ambiguous positions in amino-acids comparison and deletion. The HIV-1 group M found in these patients were sub-type A (1) and G-J (1), and CRF02_AG (4), respectively. Three CRF02_AG strains formed a variant cluster by strongly detaching from other CAR and worldwide strains with robust boostrap at 91. Retention and adherence were complicated by the cART limited number and laboratory tests, the irregular supply, and the remoteness of patients from the Center.

Conclusions: The genomes sequencing showed that resistance mutations made the treatment inefficient confirming the observed virological and immunological failure. The CRF02_AG genotype is an emerging variant, probably of foreign origin. This discovery clearly highlights the importance and the necessity of genetic resistance testing in the ART and personalized medicine.

HIV biology (entry, recplicative cycle, tanscitional expression and regulation)

PEA008

Implications of an interaction between HIV-1 Gag and the RNA interference pathway member Dicer

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Background: Viruses interfere with numerous host processes including the RNA interference (RNAi) pathway, a pathway important for gene regulation and RNA therapeutics. Although HIV-1 has no global effect on RNAi function, we show here that the viral polyprotein Gag interacts with Dicer, a key enzyme in the RNAi pathway. We propose that the formation of the Gag-Dicer complex post-transcriptionally regulates the function of specific microRNAs.

Methods: Immunofluorescence, Proximity Ligation Assay and immunoprecipitations were used to identify an interaction between Gag and Dicer. RNAs bound to Dicer were immunoprecipitated from cells in which HIV-1 Gag was present or absent. Immunoprecipitated microRNAs were identified in RNA-sequencing experiments and validated by reverse-transcription quantitative polymerase chain reaction (RT-qPCR). microRNA targets were identified from curated interaction databases and functional enrichments were scored using empirical sampling. TargetScan and miRDB were used for target site prediction and regulation scoring. Predicted targets were confirmed using microRNA mimics and antimiRNAs followed by RT-qPCRs, gene reporter assays with mRNA target sites and Western Blot assays (WB). RT-qPCR and WB were used to identify the effect of Gag (transfected alone or as part of the HIV-1 genome) on antiviral regulatory functions performed by a microRNA.

Results: Gag and Dicer were shown to co-localize and interact independently of RNA co-factors. Gag increased the occupancy of three microRNAs on Dicer without affecting their expression. These microRNAs targeted several gene sets including genes involved in viral processes and transcriptional regulation. One shared target was AF4/FMR2 Family Member 4 (*AFF4*), which encodes a scaffold for the host super elongation complex. A microRNA mimic knocked down AFF4 expression and regulated HIV-1 expression. In cells expressing the HIV-1 genome with or without Gag or in cells expressing Gag alone, Gag reduced the microRNA's effects on AFF4 and downstream HIV-1 expression.

Conclusions: We show that by interacting with Dicer, Gag regulates Dicer occupancy for specific microRNAs without affecting their expression. This in turn inhibits the effects of a specific microRNA on *AFF4*, augmenting HIV-1 expression. This regulation indicates a novel pathway by which HIV-1 regulates the cellular environment to favor viral expression and may be an important target in future therapies.

PEA009

HIV-1 infection elicits virus-MLOs for intranuclear viral steps

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Background: The key feature of lentiviruses consists in the ability to reverse transcribe their RNA genome into double-stranded DNA with subsequent integration into the host chromatin. Usually, HIV-1 integration step targets active host genes to ensure the release of its own progeny. So far, the reverse transcription (RT) activity has been considered a process that begins and ends in the cytoplasmic compartment of the host cell. Our recent study revisited the RT compartmentalization dogma highlighting that in macrophages, RT can occur in the host nucleus under NEV pressure. Nuclear RT generates functional viral DNA (vDNA), in fact, the ultimate goal of HIV-1 is integration into the host chromatin to optimize the release of high levels of viral progeny and discretely coexist with the host. Here, we asked whether nuclear RT also occurs in the absence of RT inhibitors.
Methods: To uncover intranuclear viral steps we directly tracked the vDNA and the viral RNA (vRNA) by coupling HIV-1 ANCHOR technology with RNA FISH or MCP-MS2 RNA-tagging bacterial system.
Results: Our computational imaging analysis revealed that proviral forms are early located in proximity of the nuclear periphery of mitotic and non-mitotic cells. We also observed that HIV-1 infection prompts clustering formation of the host factor CPSF6, restructuring nuclear membrane-less organelles, enriched in both viral proteins and speckle factors. Interestingly, we observed that integrase proteins are retained in CPSF6 clusters, while the late reverse transcribed DNA was excluded from HIV-induced membrane-less organelles (HIV-1 MLOs), indicating that those structures are not proviral integration sites, but orchestrate viral events prior to the integration step. In fact, we show that HIV-1 MLOs are physiological sites of nuclear RT. We also observed that HIV-1 MLOs are in the vicinity of pre-existing LEDGF clusters. Importantly, we identified that actively transcribing proviruses localize, outside HIV-1 MLOs, in LEDGF-abundant regions, known to be active chromatin sites. Finally, we computed the 3D distance of actively transcribed proviruses from HIV-1 MLOs.
Conclusions: This study highlights single functional host-proviral complexes in their nuclear landscape, which is markedly restructured by HIV-1 to favor viral replication.

Innate immunity

PEA010

Extracellular vehicles carrying HIV-1 Nef induce trained immunity in myeloid cells

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Background: HIV-1 protein Nef is the main viral pathogenic factor contributing to multiple HIV-associated pathological events, including persistent inflammation. Suppression of viral replication to undetectable levels by ART does not fully reverse this pathology. One possible explanation is that myeloid cells keep memory of encountering Nef even after its levels went down, a phenomenon called 'trained immunity'. In this study, we investigated whether treatment of maturing monocytes with Nef extracellular vesicles (exNef) induces a long-term pro-inflammatory status in these cells.
Methods: Human monocytes from several donors were treated during the first 24 h with exNef or exCont, in the presence or absence of fluvastatin, washed, and left to differentiate into MDM for 6 days. After differentiation, cells were analyzed by multi-parameter flow cytometry. Open chromatin regions were analyzed by ATAC-seq. Cells were stimulated with LPS for 24 h, RNA was analyzed by RNA-seq, and cytokines in the medium - by multiplex immune assay.
Results: The search identified 1829 non-duplicate records, of which 23 were included in the review. More than 80% (19/23) of included studies were conducted in 11 sub-Saharan African countries (SSA) and most were published in 2019–2020. Marked variations in initial VL monitoring coverage were reported across study settings (11–93%) and study populations (adults (25–93%), children and adolescents (2–94%), and pregnant women (32–67%)). Suboptimal uptake of follow-up VL monitoring and low regimen switching rates after confirmed treatment failure were observed.
Conclusions: Results of this study provide the first evidence that exNef can induce trained immunity in myeloid cells. The mechanisms of this activity seem to be similar to those described for beta-glucan and rely on cholesterol metabolism product mevalonate. Trained immunity may explain enhanced responses of monocytes/macrophages of HIV-infected individuals to inflammatory stimuli and sustained low-level inflammation even when viral load is reduced to undetectable levels. If these results extend to myeloid progenitor cells, even complete cure of HIV infection would still leave PLWH hyperresponsive to inflammatory stimuli and thus at risk for inflammation-associated diseases.

PEA011

Robust anti-viral immune responses at the placenta during early gestation limit *in utero* HIV infection and replication

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Background: Pediatric HIV-1 infection is still a major pandemic, despite substantial reductions (41%) in mother-to-child transmission (MTCT) achieved through scale-up of maternal antiretroviral therapy. In 2019, there were approximately 140,000 new infections among children globally and over 90% of these cases resulted from MTCT of HIV. Studies suggest that *in utero* transmission of HIV likely occurs in the third trimester, however there are a lack of mechanistic studies to explain this theory.

Methods: With written informed consent, early gestation and term placenta were collected from 20 HIV-1/Hep B/HCMV seronegative women (>18 years). Primary placental macrophages (Hofbauer cells [HCs]) were isolated and exposed to HIV-1BaL and/or IFN-α, IFN-β, IFN-λ, and RLR agonists. qPCR, FACS, ELISA, Luminex, and Western blot analysis determined the expression of activation markers, co-receptors, viral antigen, cytokines, antiviral genes, and host proteins.

Results: We found that early gestation HCs express higher levels of the HIV co-receptor, CCR5, compared to term HCs. Despite this up-regulation of CCR5, term HCs were more susceptible to HIV replication and displayed increased HIV gene expression compared to early gestation HCs. Early gestation HCs displayed a more activated phenotype than term and HIV exposure lead to the further up-regulation of T-cell co-stimulatory and MHC molecules. Limited HIV replication in early gestation HCs correlated with increased secretion of anti-inflammatory cytokines (IL-10 and IL-1RA) and a more robust antiviral immune response compare to the dampened or lack of antiviral response displayed by term HCs. In addition, treatment of early and term HCs with type I IFNs or RLR agonists completely blocked or significantly reduced HIV replication, emphasizing the importance of the RLR signaling pathway in inducing an antiviral state at the placental during viral infection.

Conclusions: Our findings show that viral recognition and robust antiviral immune responses at the placenta during early gestation may prevent *in utero* HIV-1 infection and diminished antiviral responses at term may promote viral transmission. Defining mechanisms and specific timing of vertical transmission are critical to understand for the development of specific vaccines and antiviral therapeutics to prevent new infections among children globally.

Humoral immunity (including broadly neutralizing antibodies)

PEA012

Isolation of SIVmac239 neutralizing antibodies with different specificities from infected rhesus macaques

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Background: SIV and SHIV have been widely used as model pathogens to facilitate HIV-1 vaccine development and evaluate protection efficacy of HIV-1 broadly neutralizing antibodies (bnAbs). In SHIV infected macaques and HIV-1 infected human, autologous serum neutralization responses develop quickly after acute infection. However, as a highly pathogenic virus, SIVmac239 elicits rather poor neutralizing antibodies (nAbs) from infected rhesus macaques. To this end, isolation of nAb against the well-characterized neutralization-resistant strain SIVmac239 will help to understand macaque humoral response to SIV and compare neutralizing epitopes with HIV-1 bnAbs.

Methods: SIVmac239 SOSIP.664-specific memory B cell population was single-cell sorted and expanded *in vitro* with feeder cells and cytokines. Culture supernatants containing secreted antibodies were harvested for high throughput SIVmac239 neutralization screening. Neutralization positive hits were cloned and expressed into IgG for functional characterization.

Results: 12 monoclonal SIVmac239 neutralizing antibodies (nAbs) were isolated from three infected rhesus macaques, with IC_{50} values ranging from 0.01 to 3.51 ug/mL. 10 of the nAbs target the immunodominant epitope on the SIVmac239 Env trimer in proximal to the subunit interface region that contains a glycan hole at 238 residue. These nAbs neutralized 7 of 15 SIV pseudoviruses with the glycan hole residue. Two antibodies that neutralized autologous SIVmac239 were trimer specific recognize V1V2 loop on SIVmac239 Env protein, with limited neutralization breadth.

Conclusions: Isolation of a collection of SIVmac239 nAbs suggest that the immunodominant bnAb specificity is gp120-gp41 interface rather than V3 glycan or CD4 binding site on HIV-1 Env. nAbs targeting V2 apex on SIVmac239 Env trimer display limited neutralization breadth. These nAbs help to solve high resolution structure of SIV Env trimer and study antibody-mediated protection from SIV infection.

PEA013

Immunogenicity of a 2-dose human papillomavirus vaccination schedule in HIV-infected adolescents with immune reconstitution

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Background: HIV-infected patients with HPV coinfections are at increased risk of HPV-associated diseases. A 3-dose schedule (3D) HPV vaccination is recommended. The 2-dose schedule (2D) may be sufficient for children and adolescents age 9-15 years with immune reconstitution following antiretroviral treatment.

Methods: Following informed consent, children and adolescents 9-24 years were stratified to receive 2D or 3D schedule: those aged 9-15 years who had CD4 cell counts > 500 cells/mm3 and HIV VL < 40 copies/mL for at least one year were assigned to the 2D, and the rest were given 3D. Pseudovirion based neutralization assay (PBNA) antibodies to HPV-16 and -18 were measured at pre-vaccination and 1 to 3 months after the last dose. Male adolescents received quadrivalent vaccine and female received bivalent vaccine according to the local guidelines.

Results: Of 96 subjects enrolled, 93 (96.9%) were perinatally infected, 58 (60.4%) were male, and 30 (31.3%) and 66 (68.7%) received 2D and 3D vaccination, respectively. In male participants, the neutralizing anti-HPV-16 antibody geometric mean titer (GMT) were 6859.3 (95% CI: 4394.3-10707.1) in 2D and 7011.1 (95% CI: 4648.8-10573.9) in 3D schedule (p=0.946), respectively; and the anti-HPV-18 antibody GMT were 2039.3 (95% CI: 1432.2-2903.8) in 2D and 2859.8 (95%CI: 1810.0-4518.4) in 3D schedule (p=0.313), respectively. In female participants, the anti-HPV-16 antibody GMT were 15758.7 (95% CI: 8868.0-28003.4) in 2D and 26241.6 (95% CI: 16972.7-40572.3) in 3D schedule (p=0.197), respectively; and the anti-HPV-18 antibody GMT were 5971.4 (95% CI: 3026.8-11780.6) in 2D and 9993.1 (95% CI: 5950.8-16781.1) in 3D schedule (p=0.271), respectively. GMT was generally higher in female than male receiving the same schedule. In males, the seroconversion rate for HPV-16 were 100% (20/20) and 100% (38/38) in 2D and 3D schedule, respectively; and for HPV-18 were 100% (20/20) and 97.4% (37/38) in 2D and 3D, respectively. In female, the seroconversion rate was found 100% for both HPV-16 and -18 in both the 2D and 3D.

Conclusions: 2D HPV vaccination was as immunogenic in children and adolescents 9-15 years old with immune reconstitution and could increase the accessibility. These findings support the further conduct of randomized controlled trials.

PEA014

Neutralizing antibody induction associated with a germline immunoglobulin gene polymorphism in rhesus macaques after neutralization-resistant SIVsmE543-3 infection

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Background: B cell receptor (BCR)/antibody repertoires induced by virus infection are different in individuals, while the underlying mechanism causing this difference remains largely unclear. We have recently found a potent neutralizing antibody (NAb) induction associated with a germline BCR immunoglobulin (Ig) gene polymorphism in rhesus macaques after neutralization-sensitive SIVsmH635FC infection (Matsuoka et al, J Virol 2020). The potent B404-class antibodies induced in macaques possessing a germline Ig VH3.33_38E allele can neutralize not only SIVsmH635FC but also neutralization-resistant SIVsmE543-3 and genetically-divergent SIVmac316.

In the present study, we investigated whether potent NAb induction associated with the germline Ig VH3.33_38E can be observed after neutralization-resistant SIVsmE543-3 infection.

Methods: Seven SIVsmE543-3-infected rhesus macaques were used in this study. Polymorphisms of the germline Ig VH3.33 in these seven animals were analyzed. Anti-SIVsmH635FC, anti-SIVmac316, and anti-SIVsmE543-3 NAb responses were examined from three months to two years after infection.

Results: Five of the seven macaques had the VH3.33_38E allele. Anti-SIVsmH635FC and anti-SIVmac316 NAb responses were induced in all the seven animals. In contrast, anti-SIVsmE543-3 NAb responses were induced only in the five macaques possessing the VH3.33_38E.

Conclusions: This study revealed that macaques possessing the germline Ig VH3.33_38E can induce anti-SIVsmE543-3 NAb responses after neutralization-resistant SIVsmE543-3 infection. Our results support a notion that germline BCR/antibody Ig gene polymorphisms can be a factor restricting effective antibody induction or responsiveness to vaccination.

Cellular immunity

PEA016

Impact of age on T cell exhaustion in children, adolescents and adults with vertically acquired HIV infection

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Background: In adults with chronic viral infections, including HIV/AIDS, persistent antigen exposure leads to progressive loss of T cell function and T cell exhaustion, which interferes with the efficacy and maintenance of virus-specific cell-mediated immunity. To determine whether the extent and dynamics of T cell exhaustion vary as a function of age, we characterized cell surface expression of immune checkpoint inhibitors that are associated with T cell exhaustion in children, adolescents and young adults who were infected with HIV by vertical transmission.
Methods: Multi-parameter flow cytometry was used to measure expression of cell-surface markers associated with T cell exhaustion (PD-1, CD160, CTLA-4, LAG-3, TIGIT, Tim-3) on peripheral blood mononuclear cells from study participants who were enrolled in the Early Pediatric Initiation, Canada Child Cure Cohort Study (EPIC[4]).
Results: Study participants (n=65; median age=14.82 years, IQR=10.23-18.02 years) were stratified based on their age (0-10, 10-18 and 18-26 years). Sex, viral load at the time of sample collection, and proportion of life under sustained viral suppression were not significantly different between the 3 groups. Frequencies of CD4+ central memory (CM), CD4+ effector memory (EM), and CD8+ CM cells were positively correlated with age of participants ($p<0.0001$, $p=0.0224$, $p=0.0022$), whereas frequencies of naïve (N) CD4+ and CD8+ T cells were negatively correlated with age ($p<0.0001$, $p=0.0313$). A significantly higher proportion of CD8+ CM and CD8+ EM expressing Tim-3 was observed in younger as compared to older participants ($p=0.0061$, $p=0.0006$). Negative correlations were found between age and frequencies of CD4+ CM ($p=0.0029$), CD4+ EM ($p=0.0478$), CD8+ CM ($p=0.0201$) and CD8+ EM ($p=0.0076$) cells co-expressing PD-1, TIGIT, and Tim-3. In younger participants, significantly higher proportions of cells co-expressing PD-1, CD160 and Tim-3 were observed in CD4+ CM, CD4+ EM, CD8+ CM, and CD8+ EM as compared to the 2 other groups (all p values <0.0384).
Conclusions: Higher proportions of CD4+ and CD8+ CM and EM T cells expressing combinations of exhaustion markers in younger children as compared to adolescents and adults suggest impairment of cell-mediated immunity that could contribute to the differential course of HIV infection observed between children and adults.

PEA017

Cross-reactivity to mutated viral immune targets can influence CD8⁺ T cell functionality: an alternative viral adaptation strategy

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Background: Loss of T cell immunogenicity due to mutations in virally encoded epitopes is a well-described adaptation strategy to limit host anti-viral immunity. However, the relevance of mutations within epitopes that retain immune recognition and are beneficial for the virus is a less understood adaptation strategy.
Methods: To understand this adaptation strategy, we utilized a single cell transcriptome approach to identify features of the HIV-specific T cell responses targeting non-adapted (NAE) and adapted (AE) forms of epitopes. T cell receptor (TCR) repertoire and transcriptome were obtained from antigen-specific CD8⁺ T cells of chronically (n=8) and acutely (n=4) HIV-infected subjects identified by HLA-I (class I) tetramers loaded with either form of the epitope or by upregulation of activation markers following stimulation with peptides representing these forms.
Results: CD8⁺ T cells were predominantly dual tetramer⁺, confirming a large proportion of cross-reactive TCR clonotypes among NAE- and AE-only activated T cells. The transcriptomic profile of CD8⁺ T cells was dependent on the autologous virus. Subjects whose virus encoded the NAE form of the epitope (and who transitioned to the AE form at a later timepoint) exhibited an 'effective' immune response, as indicated by expression of transcripts associated with polyfunctionality, cytotoxicity and apoptosis (largely driven by the genes GZMB, IFNγ, CCL3, CCL4 and CCL5).
Conclusions: These data suggest that viral adaptation at a single amino acid residue can provide an alternative strategy for viral survival by modulating the transcriptome of CD8⁺ T cells and potentially selecting for less effective T cell clones from the acute to chronic phase.

Mucosal immunity

PEA018

Retinoic acid boosts HIV-1 replication in monocyte-derived macrophages

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Background: Background: While the persistence of viral reservoirs (VR) in long-lived CD4+ T-cells of people living with HIV (PLWH) receiving viral-suppressive antiretroviral therapy (ART) is well-established, the contribution of myeloid cells, such as tissue resident macrophages (MFs), remains a subject of debate. Our previous studies demonstrated that, in the colon of ART-treated PLWH, CD4+ T-cells carry high levels of integrated HIV-DNA, while integrative infection in MFs is rarely observed. Noteworthy, the intestinal environment is rich in retinoic acid (RA), a booster of HIV replication in CD4+ T-cells. Thus, we investigated the impact of RA on HIV replication in monocyte-derived MFs (MDMs).

Methods: Methods: Monocytes, isolated from the blood of HIV-uninfected individuals by negative selection using magnetic beads (Miltenyi), were differentiated into MDMs by culture in the presence of M-CSF for 6 days, in the presence or the absence of *all-trans* RA (ATRA, 10 nM). MDMs were infected with replication competent CCR5-tropic (NL4.3BaL, transmitted/founder (T/F) THRO) and CXCR4-tropic (NL4.3), or single-round VSV-G-pseudotyped HIV ($HIV_{V\text{-}SVG}$). Morphology was observed by light microscopy. Phenotyping was performed by flow cytometry. Levels of early (RU5) and late (Gag) reverse transcripts and integrated (Alu/LTR) HIV-DNA levels were quantified by nested real-time PCR. HIV replication was measured by HIV-p24 ELISA.

Results: Results: ATRA significantly increased CCR5 but not CXCR4 expression in MDMs. ATRA increased replication of $HIV_{NL4.3BaL}$, HIV_{THRO}, and $HIV_{NL4.3}$ strains, with T/F HIV_{THRO} replication in ATRA-treated MDMs being the most efficient. Single-round infection with $HIV_{V\text{-}SVG}$ demonstrated that ATRA-treated MDMs exhibit an increased permissiveness to HIV infection at post-entry levels, between reverse transcription and integration.

Conclusions: Conclusions: These results demonstrate that ATRA significantly boosts HIV permissiveness in MDMs by mechanisms involving an increased CCR5-mediated HIV entry, but also an increased replicative capacity at post-entry levels. Therefore, the rarity of VR persistence in colon-infiltrating MDMs of ART-treated PLWH is not due to their resistance to infection but may be rather explained by their rapid turn-over *in vivo*. These results support a model in which MΦs in a RA rich environment, such as the intestine, are important HIV infection targets in the absence of ART, especially when exposed to highly virulent T/F HIV strains.

Systemic immune activation and inflammation

PEA019

Changes in inflammation scores among people living with HIV (PLWH) under different antiretroviral treatment (ART) regimes

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Background: Despite the advances in antiretroviral treatment (ART), persistent inflammation remained a challenge. We determined inflammatory-score changes through 2-years in PLWH treated with different antiretroviral regimes.

Methods: This study was conducted in Hacettepe University HIV/AIDS Treatment and Research Center. PLWH diagnosed between 2014-2020 were included. Inflammatory and metabolic markers (CD4/CD8 ratio, Systemic Inflammatory Index (SSI), Neutrophil-Lymphocyte Ratio (NLR), Mean Platelet Volume (MPV), Platecrite (PCT), and Low-Density Lipoprotein/High-Density Lipoprotein (LDL/HDL)) and ARTs were captured from database through 2-years from the diagnosis. The 2-year change (Δ) in markers was calculated and compared by ART type (backbone and 3rd agent). Mann-Whitney-U test was used for statistical analysis.

Results: This study included 205 PLWH; 175 were male (85.4%), and the mean age was 38.98±10.88 years. The number of patients with suppression of viremia was 164 (80%) (<40 HIV-RNA copies/ml) at the end of the second year. An increase in MPV was significantly higher among PLWH receiving ABC/3TC compared to PLWH receiving TDF/FTC (p<0.05). The CD4:CD8 ratio increased, and SII, NLR, LDL/HDL ratios decreased significantly among PLWH treated with integrase inhibitors compared with protease inhibitors and Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) (p<0.05) (Table 1).

Marker	Backbone regimen		p	3rd agent			p
	TDF+FTC	*ABC+3TC*		*Integrase inhibitors*	*Protease inhibitor*	*NNRTI*	
ΔCD4/CD8	+0.36 (-0.48, +2.64)	+0.34 (-0.32, +0.62)	0.828	+0.38 (-0.35, +2.64)	+0.28 (-0.36, 0.94)	+0.19 (-0.48, +0.93)	0.007
ΔSII	+5.16 (-1196.43, +801.33)	-20.24 (-175.15, +686.97)	0.322	-24.32 (-1196.43, +724.25)	+54.97 (-477.38, +801.33)	+55.47 (-258.66, +379.11)	0.033
ΔNLR	-0.08 (-3.58, +3.53)	-0.34 (-1.10, +0.47)	0.407	-0.26 (-3.58, 2.84)	+0.04 (-3.48, +3.53)	+0.12 (-1.72, +1.26)	0.033
ΔMPV	+0.10 (-3.30, +2.40)	+0.35 (-0.40, +1.20)	0.013	+0.20 (-1.80, +2.30)	-0.20 (-3.30, +2.40)	+0.15 (-1.30, +1.40)	0.005
ΔPCT	+0.02 (-0.18, +0.19)	+0.03 (-0.01, +0.09)	0.817	+0.02 (-0.18, +0.19)	+0.03 (-0.02, +0.11)	+0.03 (-0.08, +0.10)	0.041
ΔLDL/HDL	+0.04 (-5.78, 1.43)	+0.03 (-1.39, 1.09)	0.966	-0.10 (-5.78, +1.09)	+0.46 (-0.86, +1.38)	+0.32 (-0.62, +1.43)	0.039

Table 1. Change in inflammation-related markers in the 24th month from baseline, median (minimum, maximum)

Conclusions: Integrase inhibitor treatment is related to favorable inflammatory marker profile among PLWH in the 2-year follow-up. A favorable inflammatory profile may, in turn, contribute to the prevention of non-AIDS conditions among PLWH.

PEA020

Maternal HIV infection is associated with distinct systemic cytokine profiles throughout pregnancy

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Background: Maternal HIV infection is associated with adverse pregnancy outcomes, but the mechanisms remain unknown. The course of pregnancy is regulated by immunological processes and HIV infection and antiretroviral therapy (ART) impact key immune mechanisms, which may disrupt the immune programme of pregnancy.
Methods: HIV positive women on cART (n = 56) and HIV negative women (n = 68) were enrolled in a prospective pregnancy cohort study at Chris Hani Baragwanath Academic Hospital in Soweto, South Africa. Women were enrolled in early pregnancy and gestational age was accurately determined by first trimester ultrasound scan. Maternal blood samples were obtained in each trimester of pregnancy and a broad range of systemic cytokines were evaluated at each trimester.
Results: The pro-inflammatory cytokine IP-10 was detected in each trimester in all HIV-positive women, which was significantly more than in HIV-negative women. The anti-viral cytokine IFNλ1 was detected more frequently in HIV-positive women, whereas IFNα2 and IFNβ were detected more frequently in HIV-negative women. Th1 cytokines IL-12 and IL-12p70, Th2 cytokine IL-5, and Th17 cytokine IL-17A were detected more frequently in HIV-positive women throughout pregnancy. Il-6, IL-9, and IL-10 were more commonly detected in HIV-positive women in the first trimester. Trends of increased detection of Th1 (IL-2, IL-12p70), Th2 (IL-4, Il-5, Il-13) and Th17 (IL-17A, Il-17F, IL-21, IL-22) cytokines were associated with small-for-gestational-age babies.
Conclusions: Our findings indicate that maternal HIV/ART is associated with distinct systemic cytokine profiles throughout pregnancy, which may provide a mechanistic link to adverse pregnancy outcomes.

PEA021

Control of SIV replication in animals co-infected with *M. tuberculosis* does not eliminate high bacterial burden or dysregulated immunity present in SIV/Mtb co-infected animals

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Background: Individuals infected with HIV, including those who are virally suppressed, are at an increased risk of developing severe tuberculosis disease. Here, we used a nonhuman primate model of SIV and *Mycobacterium tuberculosis* (Mtb) co-infection to understand the relationship between SIV replication, mycobacterial growth, and immunological function in Mtb-affected tissues during the early phase of infection.
Methods: Mauritian cynomolgus macaques (MCM) were either infected with SIVmac239 (n=8) or left SIV-naïve (n=8) for six months, then infected with a low dose (3-19 colony forming units, CFU) of a molecularly barcoded Mtb Erdman strain for six weeks. We found that 3 SIV-infected MCM had viral load set points <10^3 viral copies/mL (SIV controllers), whereas the remaining 5 had plasma viral loads of >10^3 (SIV non-controllers). Following necropsy, thoracic lymph nodes (LN) and lung granulomas were excised and the bacterial load (CFU) and viral burden (SIV copies per cell) were measured. Genomic DNA was extracted from Mtb colonies and their unique molecular barcode was sequenced in order to understand mycobacterial dissemination. *Ex vivo* flow cytometry was also conducted to determine the frequency of CD4+ and CD8+ T cells expressing IFNg, TNFa, PD1, and TIGIT.
Results: SIV non-controllers (n=5) had more Mtb bacilli in both thoracic LN and lung granulomas when compared to SIV controllers (n=3) or SIV-naïve MCM. Additionally, fewer T cells in SIV+ MCM produced cytokines, but more T cells expressed PD1 and TIGIT compared to SIV-naïve MCM, and that this was often associated with the level of peripheral SIV replication and tissue site. There was significantly higher barcode diversity present in the LN when compared to the lung granulomas across SIV controllers, SIV non-controllers, and SIV-naïve MCM, consistent with frequent bacterial dissemination in MCM, independent of SIV status.
Conclusions: Regardless of plasma viremia, CD4+ and CD8+ T cells present in SIV-infected tissues from SIV/Mtb co-infected MCM have diminished capacity to control Mtb infection, suggesting that the immunologic impairment as a result of acute SIV infection is not easily repaired when the virus is later contained.

PEA022

Unique peripheral blood cell gene expression profiles in youth with long-term human immunodeficiency viral suppression

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Background: Antiretroviral therapy (ART) suppress HIV replication and disease progression. In long-term suppressors on ART, host peripheral blood cell (PBC) gene expression may offer insights into the molecular interactions leading to viral control. PBC transcriptional profiles unique to youth with HIV (YWH) on long-term suppressive ART were assessed in comparison with YWH non-suppressive on ART and with HIV uninfected youth.
Methods: PBC mRNA was profiled by Affymetrix HG-U133 Plus 2.0 Arrays for 52 individuals (27 HIV^+ and 25 HIV^-) balanced for age, gender, and race. Among 27 YWH (ages 18 to 23 years) who initiated ART prior to CD4 T-cell decline, 19 achieved viral suppression (< 50 RNA copies per ml), while 8 had breakthrough viral replication. Differentially expressed genes (DEGs) (FC ≥ 1.3 and FDR ≤ 0.05), identified by comparison between youth with viral suppression and uninfected youth (Group I) or youth with continued viral replication (Group II), were analyzed using Significance Analysis of Microarrays (SAM). Database for Annotation, Visualization and Integrated Discovery (DAVID) and Panther program were used for pathway enrichment analysis of DEGs.
Results: Unsupervised principal component and hierarchical clustering analyses distinguished gene expression profiles between YWH and uninfected youth. 367 DEGs were expressed in Group I whereas 131 DEGs were expressed in Group II. Disease interactions were inferred for the DEGs based on molecular function or associations in related

biological processes or pathways for both the groups. 89 DEGs from Group I and 27 DEGs from Group II interact with HIV. DEGs, including TAFs, DCAF16, and DHX9, which play a central role in gene regulation and RNA metabolism, were expressed in both groups. Enrichment analysis identified DEGs in Group I that were primarily associated with platelet activation, apoptotic signaling, and positive regulation of serine/threonine protein kinase pathways, indicating persistent pro-inflammatory and systemic immune activation. DEGs in Group II were involved in DNA repair, RNA processing, and negative regulation of RNA polymerase II transcription pathways, indicating mechanisms of viral control.

Conclusions: Unique gene expression profiles in long term viral suppressors on ART are distinct from YWH with chronic viral replication or uninfected individuals.

Microbiomes and microbial translocation

PEA024

SIV infection induces CD4+ T cell loss, dysbiosis, and inflammation in the oral mucosa that is only partially inhibited by probiotic therapy

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Background: During HIV and SIV infections the mucosal microenvironment is characterized by global CD4+ T cell loss, potential microbial dysbiosis, microbial translocation and overt inflammation. One of the most understudied of mucosal microenvironments, the oral cavity, is known to exhibit HIV-induced immunosuppression and local co-morbidities contribute to distal disease complications, but specific measures of immunopathology remain poorly described.
In this study we evaluated the impact of acute SIV infection on the oral mucosae and tested the hypothesis that oral probiotic supplementation (Pbx), which can stimulate and augment inflammatory or anti-inflammatory pathways, could dampen SIV-induced disease.
Methods: Indian-origin rhesus macaques were treated for a total of 42 days receiving Visbiome orally, while control animals received oral vehicle alone. Macaques were challenged with SIVmac251 on day 28 and evaluated longitudinally. Blood, colorectal, lymph node, and buccal biopsies were collected throughout the treatment and infection periods. Viral loads were quantified by standard measures, while T cells and innate lymphoid cells (ILC) were quantified and analyzed phenotypically by flow cytometry. SIV-specific T cells were quantified by IFN-γ ELISPOT, and soluble mediators of inflammation were quantified by Luminex. 16S rRNA gene sequencing was performed for microbiome analyses.
Results: All oral CD4+ T cells, but particularly central memory CD4+ T cells, were rapidly depleted similar to the GI, and as one of the first comprehensive analyses of the oral microflora in SIV infection, we also observed significant modulation among two genera, *Porphyromonas* and *Actinobacillus,* early after infection. ILC type 3 frequencies were modulated concomitant with viremia similar to previous findings. Finally, although Pbx therapy did not impact virus loads, substantially protect against oral dysbiosis, or ameliorate cell loss, it did dampen T cell responses and overall T cell activation. Pbx therapy also down-modulated systemic inflammatory mediators including IFN-alpha, IFN-gamma, IP-10, and IL-6.
Conclusions: Collectively, these data provide one of the most comprehensive evaluations of SIV-induced changes in oral microbiome and CD4+ T cell populations and suggest that oral Pbx could be a simple therapy to improve anti-inflammatory states in addition to more traditional antivirals.

Correlates of HIV susceptibility and disease progression (Aiomarkers and genetics)

PEA025

Marijuana modulates interferon-induced inflammation in youth with HIV (YWH) receiving antiretroviral therapy (ART)

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Background: HIV can induce chronic inflammation through interferon-induced upregulation of chemokine production. Effects of recreational marijuana, or marijuana used in combination with tobacco on these inflammatory pathways is unknown.
In this study, we examined the effect of marijuana used with and without tobacco on interferon-mediated inflammation in youth with HIV (YWH).
Methods: Plasma chemokines associated with interferon-induced inflammation, including CCL4, CCL5, CXCL9, CXCL10 were assessed in 98 YWH on ART, ages 20 to 28 using ELISA/multiplex assays. Blood samples were collected in PaxGene tubes, and RNA was amplified and hybridized to Human Genome U133 Plus 2.0 Arrays. Marijuana and/or tobacco use was validated by self-report and plasma toxicology. Participants were sub-divided into non-substance using YWH with detectable virus (≥ 50 copies/ml) and three groups of YWH with suppressed virus (< 50 copies/ml): those using no substance, marijuana only, or marijuana plus tobacco.
Non-substance using youth without HIV (N = 38) balanced for age, gender, and race were included as a reference group.
Differentially expressed genes (DEG) of chemokines were compared across groups. CCL4, CCL5, CXCL9, and CXCL10 $\log_2$ gene expression values and plasma protein levels were compared across groups using unpaired nonparametric t test.
Results: Compared to youth without HIV, median CXCL9 and CXCL10 gene expression values and protein levels were higher among non-substance using YWH with or without viral suppression and virally suppressed YWH using marijuana plus tobacco. In contrast, median gene expression values and protein levels of CXCL9 and CXCL10 among virally suppressed YWH using marijuana alone were similar to youth without HIV. Analysis of DEGs revealed upregulation of CXCL9 and CCL5 in all groups except YWH using only marijuana. Gene expression values for CXCL9 and CXCL10 correlated with plasma protein levels across groups (CXCL10; $r = 0.52$, $p < 0.0001$, CXCL9; $r = 0.35$, $p = 0.0011$), although a similar relationship was not apparent for CCL4 or CCL5.

Conclusions: Recreational marijuana use is associated with lower CXCL9 gene expression and plasma protein levels suggesting an anti-inflammatory effect through interferon-mediated signaling via CXCR3. Concomitant use of tobacco with marijuana abrogated the anti-inflammatory profile of marijuana alone.

PEA026

Elevated levels of CCR5+ tissue resident CD4 T cells in female genital tract during follicular phase of HIV seronegative women

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Background: Female sex hormones are known to regulate the adaptive and innate immune functions of the female genital tract (FGT). While the majority of immune cells found in the FGT are T lymphocytes, however very few studies have focused on tissue resident CD4 T cells in the FGT.

Methods: Here, we characterized the distribution, phenotype and function of tissue resident CD4 T cells in FGT of HIV seronegative women using different mucosal sampling methods; cervicovaginal lavage (CVL), endocervical cytobrush (CB), and cervicovaginal biopsy and compared them to blood counterparts. We isolated cells from blood and FGT of 33 healthy women and performed multi-color flow cytometry to characterize the CCR5+ target cells with tissue resident memory (TRM) phenotypes between luteal and follicular phase.

Results: First, we looked at the distribution of TRM CD4 T cells across the samples and found that TRM CD4 T cells are significantly higher in the tissue samples studied. Between the subsets present in the CD69 and CD103 axis, only CD69+CD103+ population was significantly increased (Mann-Whiteny, p=0.01) in the cytobrush during the follicular phase compared to the luteal phase. This CD69+CD103+ population expresses significantly higher levels of HIV target cells CCR5 but not a4b7 in follicular phase (p=0.02) compared to luteal phase. In addition, the lymph node homing molecule CCR7 was significantly lower in these cells (p=0.04). Within the follicular phase, cervicovaginal biopsy had significantly higher levels (p=0.04) of CCR5+CD69+CD103+ target cells when compared to cytobrush samples.

Conclusions: Altogether, these data demonstrate that FGT is enriched with tissue resident CD4 T cells with higher CCR5 expression, these data suggest that CCR5+ TRM cells could be more susceptible to HIV infection during follicular phase.

Virology of CNS compartment

PEA027

Chronic morphine administration alters gut-brain homeostasis in SHIV infected rhesus macaques

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Background: Commonly used opioids such as morphine have been implicated in augmented central nervous system (CNS) pathology. Recently, we have shown that morphine increases replication-competent viral reservoirs in CNS-microglia. However, the extent of myeloid cell polarization and viral persistence in different brain regions remains unclear. To address this, we profiled myeloid cell polarization and viral persistence within diverse brain regions and evaluated the role of morphine dysregulation of gut-brain systems crosstalk.

Methods: Eight rhesus macaques were ramped-up, and a daily injection of either morphine (n=4) or saline (n=4) for a total of 9 weeks and infected with SHIVAD8EO variants. During necropsy, isolated mononuclear cells from different regions of the brain (frontal lobe, cerebellum, medulla, putamen, hippocampus (HIP) and subventricular zone (SVZ)) and gut (lamina propria (LP) and muscularis (MUSC) of ascending colon, duodenum, and ileum) were profiled for myeloid cell polarity/ activation. Levels of SHIV DNA were evaluated using the digital droplet PCR assay. Luminex platform to quantify soluble plasma/ CSF biomarkers and changes in the fecal microbiome was investigated using the Illumina NovaSeq platform.

Results: There were no significant differences in the plasma and CSF viral loads between the two groups. Morphine exposure led to exacerbated M1(CD14/ CD16)/ M2 (CD163/ CD206) polarization in activated microglia that spanned across diverse brain regions. This was accompanied by elevated SHIV DNA enriched in sites of neurogenesis (HIP/SVZ). HIP/SVZ CD16+ activated microglia positively correlated with SHIV DNA levels in the brain ($r = 0.548$, $p = 0.042$). Simultaneously, morphine depleted butyrate-producing bacteria such as *ruminococcus* ($p = 0.05$), *lachnospira* ($p = 0.068$) genera and *roseburia* species ($p = 0.008$) and enriched CD163+ cells in MUSC macrophages. Morphine also altered the regulation of inflammation in the CNS by reducing levels of CSF IL1Ra.

Conclusions: These data indicate that morphine 1) elevates CNS inflammation by altering receptor regulation and selective enhancement of SHIV persistence in sites of neurogenesis; 2) depletes crucial genera that support optimal brain function; 3) Increases macrophage activation in sites enriched with enteric neurons (MUSC), warranting further investigation into mechanisms involved in morphine enhanced alternation of the gut-brain axis during SHIV infection.

HIV and Ageing (molecular and cellular pathogenesis, biomarkers)

PEA028

The role of oxidative stress markers in predicting frailty in HIV-infected individuals

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Background: PLWH are challenged by comorbidities frequently and earlier than their uninfected counterparts because of persistent immune activation under suppressive ART. Frailty is the total sum of comorbidities along with chronic HIV infection. Here, we determined the role of oxidative damage markers in predicting the risk of adverse health outcomes including, frailty, sarcopenia, increased mortality risk, neurocognitive impairment, and increased cardiovascular disease among PLWH.

Methods: This cross-sectional study carried-out at Hacettepe HIV/AIDS Treatment and Research Center between September 2019 and May 2020. We included PLWH over 40, under stable-suppressive ART for at least 3-months, and HIV RNA <200 copies/ml. PLWH with active co-infection excluded. Frailty determined by Fried Frailty Phenotype and the Edmonton Frailty Scale. We determined sarcopenia by Bioelectricity-impedance analysis, hand-grip strength test, and gastrocnemius muscle ultrasound. Neurocognitive impairment defined with Mini-Mental State Test (MMT). The data collection on adverse events of Anti-HIV drugs (D: A: D) scoring, and the Veterans Aging Cohort Study (VACS) were calculated. Malondialdehyde (MDA) and total antioxidant capacity (TAC) levels were examined in order to determine the oxidative stress state.

Results: A total of 71 PLWH were recruited. 57 of these patients were male and 14 were female. Three patients were found to be frail and 32 patients found to be pre-frail. Median CD4 levels were found as 733, 687, 583 in the frail, pre-frail and non-frail groups respectively; and median MDA found as 1,26 nmol/ml, 1,32 nmol/ml, 0,91 nmol/ml in frail, pre-frail and non-frail groups respectively. While MDA levels were found to be significantly lower in non-frail patients (p <0.001); decreased muscle strength, low MMT score and high VACS score were found to be associated with MDA level and frailty (p-values of the relationship between decreased muscle strength, VACS, MMT with MDA respectively: 0.029, 0.031, 0.004). No relationship between TAC level and frailty was found.

Conclusions: A result of the study, it was found that MDA can be used to predict frailty and mortality in individuals living with HIV, and executions of similar studies with additional markers related to oxidative stress will be useful in a wider patient population.

Host cellular factors and latency

PEA029

Role of cellular immune activation in enrichment of deleted HIV proviruses during antiretroviral therapy

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Background: Antiretroviral therapy (ART) does not cure HIV infection due to a reservoir of proviruses integrated into the DNA of host immune cells. Provirus levels modestly decline during ART, while the frequency of proviruses with gene deletions increases in most HIV-infected individuals. Elucidation of the mechanisms shaping proviral populations will identify new strategies to treat or cure HIV. HIV *gag* encodes structural proteins and its deletion renders a provirus non-replication competent. We previously demonstrated that enrichment in the proportion of proviruses deleted in *gag* occurs after 1-2 years on ART, but the forces driving delayed deletion of *gag* remain uncertain. To investigate the relationship between host immune factors and enrichment of deleted proviruses, we analyzed HIV DNA and cellular immune parameters in HIV-infected individuals on long-term suppressive ART.

Methods: Samples from individuals undergoing uninterrupted ART for over 3 years were collected under multi-site studies of HIV-infected adults. Flow cytometry was used for immunophenotyping a panel of CD4 and CD8 subsets, including HLA-DR, CD27, CD38, and CD45RO. Levels of cell-associated HIV long terminal repeat and *gag* DNA were quantified using multiplexed digital droplet PCR as previously described (Anderson, et al., 2020). Data were analyzed using Pearson correlations; all p-values were Bonferroni-adjusted.

Results: Study participants (N= 74) had a median age of 50 years and a median CD4 count of 655 cells/µl on ART (range 4.8-26.1 years). Median log LTR and *gag* DNA on ART were 3.38 and 2.79 copies/million CD4 cells, respectively. Despite years of continuous ART, 8% of participants did not undergo *gag* deletion. Levels of LTR and *gag* DNA correlated positively with percent CD8+CD45RO+ cells (LTR: r=0.43, p=0.003; *gag*: r=0.49, p=0.0002). Despite prolonged ART, there was a persistent negative correlation between *gag* levels and nadir CD4 (r=0.37, p=0.023).

Conclusions: The proportion of *gag*-deleted proviruses increases during ART, in most, but not all individuals, suggesting complex counterbalancing forces. Individuals with higher copy numbers of LTR and *gag* have higher levels of CD8 memory cell subsets, suggesting ongoing cellular immune activation during ART may shape the proviral landscape. Markers of the HIV reservoir should be correlated with clinical outcomes, such as development of comorbidities.

PEA030

Role of multiple NF-κB motifs in HIV-1 LTR in modulating gene expression noise and fate-switch

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Background: Stochasticity in gene expression can influence fate-specification in HIV-1. The presence of multiple, tandemly arranged, and overlapping transcription factor binding sites makes gene expression from HIV-1 LTR inherently noisy. This inherent noise is further amplified by the Tat positive-feedback loop, greatly influencing active versus latent viral transcription fate decision. The LTR of HIV-1 subtype C (HIV-1C) contains three or four NF-κB binding sites that confer stronger Tat positive-feedback hence enhanced transcriptional strength. How multiple NF-κB motifs modulate gene expression noise and subsequently influence HIV-1C latency establishment, reversal, and maintenance is the primary aim of the study.

Methods: We engineered a panel of sub-genomic or full-length HIV-1C reporter viral strains with a varying number of NF-κB motifs (0 to 4) in the LTR. Stable Jurkat T-cells cell pools, single-cell clones, or primary CD4+ cells expressing d2EGFP under LTR were generated after sorting. Single-cell analyses were performed using flow cytometry and time-lapse live-cell imaging. Gene expression noise was determined as the Mid: On ratio at the population level and coefficient of variance (CV) at the clonal level. Statistical evaluation was performed using one-way ANOVA, two-way ANOVA, and the Student *t*-test.

Results: We found a negative correlation between gene expression noise and the copy number of NF-κB motifs in the LTR. In a range of experiments, gene expression noise of a viral promoter containing fewer NF-κB motif copies (0 and 1) was found to be significantly higher during latency establishment or reversal. Gene expression noise enhanced significantly following the perturbation of the NF-κB signaling pathway using siRNA or chemical interference. Additionally, a positive correlation was observed between the copy number of NF-κB elements and stable viral latency.

Conclusions: Our data are suggestive of a critical role the NF-κB motifs play in modulating gene expression noise in HIV-1C LTR, hence in viral fate decisions. The minimization of transcriptional noise with the increasing copy number of NF-κB motif is indicative of some level of cooperativity at the promoter between these motifs and other TFBS. The mechanism of noise modulation may provide novel directions for drug discovery and superior disease control measures.

Cellular and tissue reservoirs of HIV/SIV

PEA031

The role of *nef* in promoting persistent HIV in effector memory CD4+ T cells from individuals on long-term ART

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Background: We recently reported that genetically intact HIV proviruses are unequally distributed between naive and memory CD4+T-cell subsets. Moreover, we showed that effector memory (T_{EM}) cells harbour the highest number of intact proviruses. Here, we evaluated the contribution of cytotoxic T-lymphocyte (CTL) escape mutations and the presence of the immunomodulatory gene *nef* upon the persistence of HIV within T_{EM} cells.

Methods: Full-Length Individual Proviral Sequencing (FLIPS) was performed on naive (T_N), central (T_{CM}), transitional (T_{TM}), and T_{EM} memory CD4+T-cells sorted from 26 HIV+ donors on antiretroviral therapy (ART) (2-21 years). Bioinformatic tools were used to characterize genetically-intact proviruses, genetically-intact HIV genes, and CTL escape mutations in the *gag* gene.

To evaluate the role of *nef* in HIV persistence, CD4+T-cells from 3 HIV+ donors were infected with HIV-NL4-3 and co-cultured with autologous CD8+T-cells previously expanded with Gag peptides. Effects of CD8+ clearance on the proviral landscape was determined by FLIPS.

Results: After long-term ART (>15 years), the proportion of genetically intact HIV proviruses was significatively higher in T_{EM} cells ($p<0.01$) compared to the other subsets. Since Gag is one of the main immunogenic HIV proteins, we hypothesized that the proportion of sequences with intact *gag* gene would decrease overtime in all subsets. Surprisingly, the proportion of sequences with intact *gag* remained stable overtime in T_N, T_{CM} and T_{TM}, but increased in T_{EM} cells ($p=0.004$). The proportion of proviruses with CTL escape mutations within *gag* did not differ between subsets.

Remarkably, the proportion of sequences with both intact *gag* and *nef* genes increased overtime in T_{EM} cells ($p<0.05$). To assess the role of *nef* in promoting HIV persistence, HIV-infected cells were co-cultured with autologous *gag*-specific CD8+T-cells. Interestingly, the proportion of sequences with intact *gag* and *nef* genes increased after CD8+ clearance ($p<0.05$).

Conclusions: We observed T_{EM} cells are preferentially enriched for genetically intact HIV proviruses after long-term ART. However, CTL escape does not contribute to HIV persistence within these cells. Instead, we provide evidence that *nef* contributes to the persistence of HIV proviruses expressing immunogenic proteins such as Gag. This indicates that cellular expression of the viral Nef protein supports the maintenance of the latent HIV reservoir.

PEA032

HIV DNA genome levels and sequence profiles before and after flu vaccination

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Background: HIV persistence is driven at least partially through antigen-driven clonal proliferation of infected cells. Here, we examine the impact of influenza vaccination on the proportions and clonality of HIV DNA genomes in blood.

Methods: PBMC samples were collected from three chronically HIV-infected ART- suppressed individuals immediately before, and two weeks after receiving the FLULAVAL-TETRA (GSK) quadrivalent influenza vaccine. Prevalence of influenza-specific CD4+ T cells within total $CD4^+$ T cells were measured by AIM assay using flow cytometry (CD3+CD4+CD69+CD137+) after *ex vivo* stimulation by FLULAVAL. Total and intact HIV proviruses were quantified using droplet digital PCR based intact proviral DNA assay (IPDA). Extracts were limiting diluted, subjected to PCR amplification (HXB2 623-9632) and Illumina sequencing. Genome-intactness was defined as the lack of large truncations, hypermutations and frame-shifting mutations. Neighbor-joining algorithm was used for phylogenetic analyses.

Results: Vaccination was associated with detectable increases in proportions of influenza-specific $CD4^+$ T-cells in two donors, from 0.3% to 4.0% (Donor 1), 1.0% to 4.1% (Donor 2), while this remained stable at 3.3% and 3.0% (Donor 3). By IPDA, no significant differences were observed pre and post vaccination in total nor genome-intact HIV DNA concentrations (p=0.3-0.7, paired t-tests). Proportions of proviral sequences that were genome-intact, hypermutated, or contained large truncations were not significantly different pre- and post- vaccination (p=0.6-1.0, Fisher's Exact tests). Vaccination was not associated with detectable clonal expansion of infected cells: only one hypermutation clonal cluster had a marginally statistically significant increase in proportions pre- versus post-vaccination in Donor 3 (p=0.05; Fisher Exact tests 2-tailed). Pre and post vaccine HIV sequences intermingled in phylogenetic trees, indicating the lack of strong selection of specific lineages.

Conclusions: A single round of influenza vaccination did not measurably impact HIV DNA genome sequence landscape, levels nor clonality profiles, suggesting a lack of appreciable impact on the overall reservoir in blood in these three study participants. Since influenza-specific cells comprise a fraction of total $CD4^+$ T-cell, our result does not preclude changes in the proviral landscape within this population, which is a topic for future study.

PEA033

Dynamics of the prostratin-inducible HIV-1 peripheral reservoir in vertically infected children and adolescents

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Background: HIV-1 remains incurable due to its ability to hide out of reach in cellular reservoirs. However, studies in adults and children have shown that early initiation of combination antiretroviral therapy (cART) can limit the size of the reservoir and can lead to sustained viral suppression (SVS) following treatment interruption. Here we examine how the size and dynamics of the cellular reservoir in children and adolescents with vertically acquired HIV infection are influenced by age, maintenance of SVS, and early initiation of cART.

Methods: Our study group included 55 children from the Early Pediatric Initiation, Canada Child Cure Cohort Study (EPIC4) who were followed prospectively for an average of 18 months and were stratified according to their age (<6, 6-10, and >10 years) and control of viral replication (30 with SVS; 18 with « blips » in viremia, and 7 without SVS). Inducible cell-free HIV-1 RNA (ICF) was measured following ex vivo stimulation of purified CD4+ T cells with the SUW013 PKC agonist.

Results: ICF levels were highest in participants without SVS (median=5.00, IQR= 3.709-5.00 log10 RNA copies/106 CD4+ T cells; p<0.0001) regardless of age, when compared to « blippers » (median=0.99, IQR=0.27-2.90; p<0.0001) and participants with SVS (median=0.00, IQR=0.00-0.62; p<0.0001). Reservoir size was stable in participants with SVS with a median slope of 0.00 (IQR=-0.23-0.03) and was most variable in « blippers » (median slope=-0.44, IQR=-0.85-0.00). ICF levels were negatively correlated with the cumulative proportion of life under SVS (cPLUS, p<0.0001) and positively correlated with age at initiation of treatment (p=0.0004).

Finally, cART was initiated before 8.4 months of age in 6/7 (86%) of participants in whom ICF levels were below the limit of detection at every time point.

Conclusions: Results indicate that the size of the inducible viral reservoir is reduced in vertically infected children and adolescents in whom cART was initiated earlier and who achieved SVS. Results also indicate that the presence of « blips » influences the trajectory of reservoir size over time, thereby confirming the biological and potentially clinical significance of these isolated peaks in viral production.

PEA034

Impact of early antiretroviral therapy on tissue resident myeloid cells in the liver and lung of SIV-infected rhesus macaques

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Background: Viral dissemination occurs early after infection targeting CD4 T cells and monocytes/macrophages. Monocytes derived from bone marrow and tissue resident macrophages (TRMs) derived from yolk sac, are short-lived and long-lived cells, respectively. Whereas we demonstrated that early antiretroviral therapy (ART) efficiently prevents infection of monocytes in the blood, spleen and intestine of SIV-treated rhesus macaques (RMs) [1], little is known so far about the role of TRMs, and whether these cells may represent VRs in SIV-infected RMs after early ART.

Methods: RMs were infected with SIVmac251 and treated at day 4 with a cocktail of antiretroviral drugs. Cells from liver and lung were mechanically isolated. The phenotype of TRMs was analyzed by flow cytometry using specific antibodies including antibodies against CD14, CD16, CD44, TIM-4, CD117, CD206, MERKT, and LYVE (these markers were previously defined in mice). The levels of viral DNA and RNA were quantified by qPCR for each tissue. In situ hybridization was used to detect vRNA in tissues.

Results: Our results revealed that myeloid cells from liver and lung of SIV-infected RMs expressed mostly CD44, CD117, CD206 and LYVE markers, but represent a small proportion of liver and lung cells. Concomitantly, our data revealed that liver and lung of non-treated SIV-infected RMs both contain viral RNA and DNA that are positively correlated with the viremia. Furthermore, treated-RMs have no viral RNA and DNA both in the liver and lung.

Conclusions: Herein, we characterized the phenotypes of long-lived TRMs that colonize lung and liver of SIV-infected RMs. We also showed that early ART efficiently prevents early viral seeding both in the liver and lung. These results highlight the crucial importance of early treatment by decreasing anatomical VRs.

1. Rabezanahary, H., et al., Early antiretroviral therapy prevents viral infection of monocytes and inflammation in SIV-infected rhesus macaques. Journal of Virology, 2020: p. JVI.01478-20.

Characterizing HIV/SIV reservoirs and rebounding virus

PEA035

Exploring proviral evolutionary dynamics in the Women's Interagency HIV Study

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Background: Understanding proviral evolutionary dynamics is key to HIV cure efforts, but women with HIV-1 subtype B are understudied. Towards addressing this, we reconstructed within-host HIV evolution in three seroconverters from the Women's Interagency HIV Study to infer proviral ages and temporal stability during cART, and to compare ages of rebound viruses to the overall proviral pool.

Methods: Participants 1, 2 and 3 (P1, P2, P3) initiated cART in chronic infection; total follow-up was 14-22 years. Pre-cART longitudinal single-genome-amplified (SGA) plasma HIV RNA env-gp120 sequences were previously published; we now used SGA (env-gp120) to characterize plasma HIV emerging after initial suppression (P1), and proviruses sampled on-cART (P1: 4 times over 5yrs; P2: thrice over 4yrs; P3: once). After excluding defective, hypermutated and recombinant sequences, maximum-likelihood within-host phylogenies were inferred from unique sequences, from which rebound virus and proviral ages were estimated by root-to-tip regression.

Results: We recovered 340, 176 and 231 total intact env sequences for P1, P2 and P3, respectively, where proviruses were 80%, 80% and 55% unique. All within-host phylogenies had strong molecular clocks. For P1, unique proviruses initially sampled on cART were 8yrs old on average (oldest 16yrs) with most dating to the chronic phase. Inferred proviral integration date distributions remained stable over 5yrs on cART ($p=0.68$) but rebound viruses that emerged after 1yr of suppressive cART were younger than the persisting proviral pool ($p<0.0001$). P2's unique proviruses were 5yrs old on average (oldest 8yrs) at initial sampling, with most dating to the chronic phase; inferred proviral integration dates remained stable over 9yrs ($p=0.55$). P3's unique proviruses were an estimated 7yrs old on average (oldest 13yrs) with many dating to early infection.

Conclusions: Proviral age distributions support ongoing archiving and persistence of diverse proviral lineages pre-cART. Modest skewing towards chronic-phase deposition in two participants is consistent with reports in HIV-1 subtype C and among men. The stability of proviral integration dates on cART supports negligible decay of the persisting proviral pool that is predominantly genetically defective.

Younger rebound virus ages suggest these emerged from a replication-competent reservoir that is younger than the overall persisting proviral pool.

PEA036

In-depth single-cell analysis of translation-competent HIV-1 reservoirs identifies cellular sources of residual viremia and rebound viruses

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Background: Clonal expansion of HIV-infected cells is a well-known driver of the long-term persistence of the HIV-1 reservoir in ART-suppressed individuals, though the contribution of cell clones to plasma viremia under ART and upon analytical treatment interruption (ATI) is poorly understood. We developed a single cell assay to simultaneously sequence the proviral genome, matched integration site (IS), and TCR from cells harboring inducible proviruses, called STIP-Seq.

Methods: Peripheral blood CD4 T cells from 8 ART-treated individuals were stimulated with PMA/ionomycin. Following methanol permeabilization and p24 staining, p24+ cells were single cell sorted. Whole genome amplification allowed for sequencing of the near full-length (NFL) proviral genomes by a 2- or 5-amplicon non-multiplexed PCR, IS analysis by Integration Site Loop Amplification and TCRβ sequencing by a multiplexed PCR. Three out of eight participants underwent an ATI, and phylogenetic analyses were performed to compare plasma-derived *env* (V1-V3) sequences to STIP-Seq proviral sequences.

Results: A large proportion of p24+ cells stemmed from clonally expanded infected cells (78%, 135/173). NFL sequencing yielded a total of 42 distinct genomes. While only 14% of the genomes were intact and 2% had a large deletion, 83% displayed a small deletion at the 5' end of the genome (<500bp), consistently removing the major splice donor site. In two participants, STIP-Seq identified a clone with a genome-intact provirus matching low-level viremia (LLV) under ART, one of which had a predicted specificity towards *M. tuberculosis* and an IS in *KCNA3*, a gene involved in cell proliferation. The other clone (IS in *SMG1P2*) also matched plasma sequences retrieved during the ATI, suggesting that this clone was already producing LLV during ART before contributing to rebound upon ATI. Finally, we found a match between a plasma sequence under ART and a STIP-Seq sequence with a 5bp deletion covering the MSD, suggesting that MSD-defective proviruses could contribute to LLV.

Conclusions: This study provides one of the most comprehensive characterizations of the translation-competent HIV reservoir to date. By applying STIP-Seq in the context of an ATI, we identified cellular sources of plasma viremia, showing the relevance of the assay in HIV reservoir studies.

PEA037

Proviral turnover pre-ART is dynamic and variable between hosts, impacting reservoir composition

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Background: While proviral variants integrate continually into the HIV reservoir, their subsequent turnover rates shape reservoir composition over the long-term. Despite their relevance to HIV cure strategies, however, these rates remain incompletely understood. We estimate *in vivo* proviral turnover rates by applying mathematical models to host-specific HIV reservoir sequences.

Methods: Proviral *env* sequences were sampled a median of 6.3 months after ART in 12 Zambian individuals who started treatment during chronic HIV infection. An integration date into the reservoir was inferred for each proviral variant using a phylogenetic method that leveraged pre-ART within-host HIV evolutionary rates, providing an age distribution of the reservoir composition.

We then estimated proviral turnover until ART initiation by applying a mathematical model that assumes proviruses enter the reservoir at a rate proportional to viral abundance in pre-ART plasma, after which they decay at a constant rate. Each individual's pre-ART infection was modeled two ways: first with an idealized curve of HIV viremia throughout infection, and second using a piecewise linear function coupling typical acute-phase infection dynamics to the participant's own longitudinal plasma viral loads. The likelihood of each participant's observed proviral age distribution was then calculated based on a multinomial distribution, and the decay rate (half-life) was estimated via maximum likelihood.

Results: When idealized pre-ART viremia curves were used, estimated within-host proviral half-lives ranged from 150 (95% CI 0-415) to 570 (95% CI 0-2110) days, with an overall median of 210 days. Substituting the participants' pre-ART viremia data yielded highly consistent (Spearman rho=0.91; p<0.0001), albeit 25% higher on average, proviral half-lives (median 255 days). Repeat sampling in four participants yielded proviral half-life estimates whose 95% CI overlapped the first estimate in all cases.

Conclusions: An average *in vivo* inferred proviral decay rate of <1 year during active HIV infection is considerably shorter than historic on-ART cellular decay estimates (44 to 140 months). Results are consistent with the idea that proviral turnover pre-ART is dynamic, and considerably faster than on-ART. This in turn helps explain frequent skewing of the reservoir towards proviruses seeded near ART initiation.

PEA038

Subtype D HIV-1 reservoir levels and viral sequence profiles in Rakai, Uganda

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Background: Reservoir profiles of non-B-subtype HIV-1 remain a major knowledge gap in cure research. Here, we validate proviral sequencing and quantification methods, as well as describe reservoir profiles of subtype D HIV-1 and its associated recombinant forms observed in Rakai, Uganda, where subtype D is the most prevalent subtype.

Methods: Blood samples were collected from six male and nine female (n=15) virologically-suppressed individuals at >1-year post-therapy initiation who were chronically subtype D or A1/D recombinant HIV-1 infected, as determined by viral RNA sequencing of reverse transcriptase/gp41. Resting CD4+ cells were negatively selected from total PBMC ($CD69^-/CD25^-/HLA\text{-}DR^-$) and extracted for DNA.

Total HIV-1 DNA levels were quantified via *gag*-specific droplet digital PCR, followed by limiting dilution, nested near-full-viral-genome PCR (HXB2 623-9632) and Illumina sequencing. Viral genome-intactness was defined as the lack of large truncations, hypermutations and frame-shifting mutations. Mann-Whitney tests were used in all statistical comparisons.

Results: We obtained 368 near-full-genome HIV-1 DNA sequences after sampling ~two million cells per individual (median 21 viral-genomes/donor). Among the 15 individuals, proviral subtype distribution was 1 A1, 9 D, and 5 A1/D.

Total HIV-1 DNA copies per million CD4 cells did not differ between sexes nor between subtype D versus A1/D (median 4791 male 3642 female, p=0.9; median 2554 D 2642 A1D, p=1.0). Clonal expansion of infected-cells was observed in 11 individuals; relative proportions within the total HIV DNA pool did not differ by sexes nor between D versus A1/D (median 21% male 23% female, p=0.5; median 23% D 21% A1/D, p=0.6). Intact genomes were observed in three subtype-D-infected individuals at 5%, 8% and 20% intra-host prevalence. APOBEC-3G/F-associated hypermutated genomes were observed in 10 individuals; relative proportions did not differ by sexes nor between D versus A1/D (median 2% male 5% female, p=0.4; median 2% D 5% A1/D, p=0.5).

Large deletions were significantly less frequently observed in *gag* relative to integrase, *vif, vpr, vpu,* and *env* (intra-host median 55% *gag-deleted* versus 80-86% other genes, p=0.0008-0.0055).

Conclusions: Our study shows that, similar to subtype B reports in the literature, a high proportion of subtype D and A1/D recombinant HIV-1 reservoirs contain defective viral genomes and/or have undergone clonal expansion.

PEA039

Translation-competent expanded HIV clones are phenotypically diverse

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Background: Identifying the phenotype of the cells harboring persistent and inducible HIV have been hampered by the limited throughput offered by flow cytometry cell sorting and the challenge of amplifying full length genomes from bulk sorted populations. Here, we developed a single cell approach to identify biomarkers of cells harboring near full length HIV genomes in samples from individuals on ART.

Methods: p24+ single HIV-infected cells from 6 participants on suppressive ART were sorted following 24h stimulation with PMA/ionomycin. Levels of expressions of CD45RA, CCR7, PD-1, TIGIT, ICOS, HLA-DR, integrins α4 and β1 were simultaneously measured. Individual proviruses from single-sorted cells were amplified by a modified FLIPS PCR. Near full-length HIV genomes were sequenced by PacBio. Proviruses integrity and clonality were further associated with the expression levels of each cellular marker.

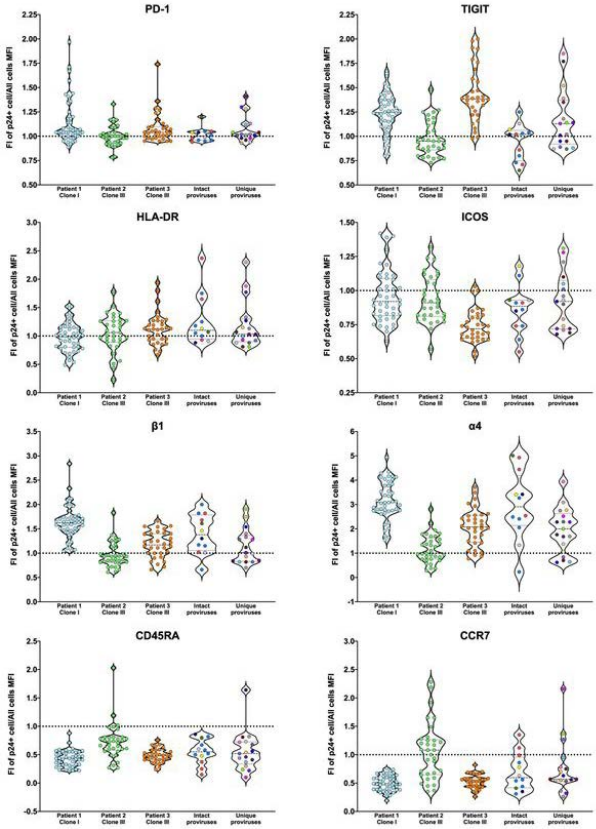

Figure 1. Levels of expression of 8 phenotypic markers at the surface of p24+ cells in 3 representative clones, in cells harboring intact proviruses and in cells harboring unique proviruses. Cells harboring identical sequences are depicted by a similar color.

Results: We obtained a total of 308 proviral sequences from single-sorted p24+ cells (41-59 per participant). Clonal expansions of translationally competent proviruses (defined by cells sharing the exact

same HIV genome) were observed in all individuals (between 2-7 clones, composed of 2-44 individual cells) and accounted for the majority of p24+ cells (mean = 81%, range 61-92%). Within a given clone, levels of expression of cellular makers greatly varied (Figure 1), revealing the plasticity in the phenotype of the expanded clones.
Despite their ability to produce p24, the majority of these viral genomes were defective, particularly in the packaging signal (61% of all defects). Intact genomes were found in 3 participants (4% of all p24+ proviruses) and did not display a specific phenotypic signature.
Conclusions: The translation-competent HIV reservoir is highly clonally expanded and encompass only a small fraction of intact proviruses. Identical proviruses are found in cells displaying diverse phenotypes, suggesting that clonal expansion contributes to the phenotypic diversification of the pool of HIV reservoir cells.

Eliminating and silencing latency

PEA040

XPB degradation by Spironolactone prevents HIV-1 reactivation from latency

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Background: HIV transcriptional inhibitors have immense potential in block-and-lock functional cure approaches. The block-and-lock approach aims at the transcriptional and epigenetic silencing of integrated proviruses, blocking viral reactivation in the absence of therapy, preventing disease progression and transmission. Despite their great potential, there are still no HIV transcriptional inhibitors in the clinic. HIV transcription requires assembly of cellular transcription factors at the HIV promoter. The TFIIH general transcription factor facilitates transcription initiation by opening the DNA strands around the transcription start site and phosphorylating the C-terminal domain for RNA polymerase II (RNAPII) activation. Spironolactone (SP), an FDA approved aldosterone antagonist, triggers proteasomal degradation of the XPB subunit of TFIIH, and concurrently blocks HIV transcription *in vitro*. Here we investigated the repurposing of SP as a block-and-lock agent in primary and cell line models of HIV-1 latency.
Methods: Cell line models of HIV latency and primary CD4+T cells isolated from people living with HIV (PLWH), were treated with 10 µM SP that leads to maximal XPB degradation. We investigated the effects on residual viral transcription under ART, recruitment of RNAPII to the HIV genome, reactivation from latency, and global effects on cellular transcription.
Results: SP rapidly and selectively inhibits HIV-1 transcription by reducing RNAPII recruitment to the HIV-1 genome. shRNA knockdown of XPB confirmed that XPB degradation is the mechanism of action of SP. While SP strongly suppresses HIV transcription as a single drug, long-term pre-treatment with SP does not result in epigenetic suppression of HIV upon SP treatment interruption, since virus rapidly rebounds when XPB reemerges. Importantly, SP inhibits HIV reactivation from latency in both cell line models and resting CD4+ T cells isolated from aviremic PLWH upon cell stimulation with latency reversing agents.
Conclusions: XPB plays a key role in HIV transcriptional regulation and is a novel block-and-lock target. SP has immense potential for use alongside other latency promoting agents (LPAs) to reduce residual viral transcription from the latent reservoir under ART and allow permanent epigenetic silencing of the reservoir. Repurposing a clinically approved drug provides a unique opportunity to accelerate block-and-lock studies in animal models and human trials.

PEA041

Dasatinib inhibits provirus reactivation in patients co-infected with HIV and HCV

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Background: Previously, our group demonstrated that patients co-infected with HIV and HCV have a larger HIV reservoir than HIV-monoinfected individuals. We also determined that the tyrosine kinase inhibitor dasatinib affects significatively the formation and reactivation of HIV provirus in monoinfected patients. Besides, dasatinib increases the activity of cytotoxic cells. Here, we assessed whether these antiviral effects of dasatinib may be extensive to viral reservoir in HIV/HCV co-infected patients.
Methods: Forty-four individuals HIV+ (n=32) or HIV+/HCV+ (n=12) (without HCV clearance) were recruited. Provirus reactivation and SAMHD1 phosphorylation were analyzed by flow cytometry after TCR-mediated stimulation. Cell populations were analyzed by flow cytometry. Direct cytotoxic activity was analyzed using K562 cell line as target.
Results:
1) Most individuals were males (78.1% HIV+ and 100% HIV+/HCV+). Median age of HIV diagnosis was 35.0 years (IQR 27.0-40.0y) and 26.0y (IQR 14.5-29.0y), respectively.
2) Co-infected individuals showed 1.4-fold increase of the provirus reactivation compared to monoinfected subjects, although SAMHD1 phosphorylation was reduced 1.5-fold in response to TCR-mediated activating stimuli
3) The presence of dasatinib efficiently reduced proviral reactivation in both monoinfected (3.3-fold) and co-infected (4.3-fold) individuals and decreased SAMHD1 phosphorylation 44.8-fold and 17.1-fold, respectively.
4) CD8+ T cells were increased 1.4-fold in coinfected patients ($p<0.05$), but CD8+TCRγδ+ cells were reduced 2.2-fold.
5) Although levels of CD56+ NK cells were similar in both groups, co-infected patients showed the expression of activating receptor NKG2D reduced 1.6-fold ($p<0.05$), in comparison with monoinfected patients.
6) Treatment in vitro with dasatinib increased 1.4-fold the cytotoxic activity against K562 of PBMCs from monoinfected individuals (1.4-fold), but not from co-infected patients.
Conclusions: HCV co-infection induces an increase in HIV reservoir size and the reactivation of latent provirus. Dasatinib induced a potent cytostatic effect able to interfere very efficiently with the reactivation of latent provirus, and it preserved SAMHD1 antiviral activity in

both groups. However, the immunomodulatory activity of dasatinib against HIV was more efficient in monoinfected individuals, likely due to an impaired cytotoxic response in co-infected individuals. These data support the notion that HIV provirus may be more difficult to eliminate in the presence of HCV co-infection.

Gene therapy

PEA042

Novel vector systems towards a cure for HIV/AIDS

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Background: Many potent antiviral drugs are available to treat HIV infection and combination therapy has saved many lives. However, antiviral therapy has to be continued life-long because HIV rebounds from an established reservoir when therapy is interrupted. HIV DNA in the reservoir can be targeted by the CRISPR-Cas genome-editing tool. This system consists of the Cas nuclease that cuts double-stranded DNA and a guide RNA (gRNA) that directs Cas to a complementary sequence in the DNA. Our laboratory demonstrated potent and durable HIV inhibition in a combinatorial attack with two gRNAs. Although remarkable, the large size of CRISPR-spCas9 transgene cassettes impedes their implementation in gene therapy applications with vectors that have a limited packaging capacity, including lentiviral vectors. There is a serious need for more simple/smaller CRISPR-Cas vector designs.

Methods: We propose to minimize the size of the lentiviral vector by:
a) adopting the small H1 Pol-III promoter that we found to exhibit both Pol-III and Pol-II promoter activity for the production of both the gRNA and Cas9-encoding mRNA and
b) incorporating a smaller saCas9 or cjCas9 nuclease. These measures will reduce the vector size and likely increase the vector titer.

Results: We have compared the different CRISPR-Cas systems for their antiviral activity and viral titer. Virus inhibition was tested in HIV replication studies which allow us to test for viral escape (in long-term cultures) and a potential CURE of the infected cells. The viral gRNA-targets were sequenced to elucidate the mechanism of viral escape or the means of provirus inactivation in case of a CURE. Superior antiviral activity is reported for saCas9 compared to cjCas9, which can achieve full HIV inactivation in cell culture with only a single gRNA. We also disclose that DNA cleavage by the saCas9 and cjCas9 endonucleases and subsequent DNA repair cause mutations with a sequence profile similar to spCas9.

Conclusions: We demonstrated that reduction of the vector size (smaller Cas9 nuclease and dual-polymerase active H1 promoter) increases the vector titer. This greatly facilitates the use of viral vectors with a limited packaging capacity. These results are important in the path towards formulation of a highly effective cure strategy.

PEA043

Using the CRISPR-Cas9 system to cure cells from HIV and at the same time prevent super-infection by new HIV strains

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Background: HIV continues to pose a major public health burden worldwide. Although combination antiretroviral therapy suppresses the infection, it has to be taken lifelong and it does not result in a cure. Therefore, the search for a HIV-cure remains an important area of research. Gene editing-based antiviral approaches offer an attractive alternative to target DNA or retroviruses. CRISPR-Cas-based gene editing enables sequence-specific gene-editing, providing a mean to inactivate viral genomes, including the integrated HIV proviral DNA.
In this study, we aimed at designing a CRISPR-Cas-based approach which leads to the HIV-inactivation, but at the same time prevents super-infection of these cured cells by new HIV strains.
The approach is based on targeting of the Rev gene, which encodes the protein responsible for the switch from spliced HIV transcripts to partially spliced and unspliced transcripts. Rev-inactivation by means of CRISPR-induced mutations will restrict HIV gene expression to the early Tat and Nef proteins that are transcribed from the fully spliced viral transcript. Rev-Inactivation will thus not only block HIV expression, but ongoing expression of the Nef protein will induce the "state of superinfection resistance" (SIR) by CD4 down-modulation at cell surface of infected cells.

Methods: Anti-Rev gRNAs were designed and their HIV-inhibition efficiency was measured in transfection with a molecular HIV clone and quantitated by CA-p24 ELISA assay. Lentiviral vectors were used to deliver Cas9 mRNA and the different Rev-targeting gRNAs in T cells which were subsequently infected with HIV. Viral replication was monitored to study virus inhibition and a possible cure.

Results: We describe a set of gRNAs targeting highly conserved Rev sequences. A strong reduction of virus production was measured for most gRNAs compared to the negative control. We now plan to perform a second viral challenge with a GFP-encoding HIV variant to study if the SIR mechanism was activated in some of these cured cells. Flow cytometry and Western Blot will subsequently be used to confirm the SIR mechanism.

Conclusions: Overall, our preliminary data shows potent targeting of HIV Rev sequences by CRISPR-Cas9 within the context of the designed gene-editing platform.

PEA044

Extinction of all infectious HIV in cell culture by the CRISPR-Cas12a and b systems

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Background: The CRISPR-Cas9 system has been used successfully for genome editing of various organisms. We previously reported inhibition of HIV in cell culture infections and subsequent viral escape when a single guide RNA (gRNA) was used, but complete inactivation of all infectious HIV with certain combinations of two gRNAs. Although this is a remarkable result, the large size of CRISPR-spCas9 transgene cassettes impedes their implementation in gene therapy applications with vectors that have a limited packaging capacity, including lentiviral vectors (LV).

Methods: There is a serious need for more simple/smaller CRISPR-Cas vector designs, for which the Cas12a and Cas12b nucleases are attractive candidates. CRISPR-Cas12 offers several unique features. For instance, Cas12 targets a T-rich PAM sequence, thus expanding the potential target sequences compared to Cas9. Cas12 produces a sticky DNA end that is potentially useful for HIV inactivation as the cleaved and subsequently repaired DNA sequence is likely re-cleaved by Cas12 as the critical recognition motifs are maintained. Such subsequent round(s) of DNA cleavage and repair will yield more dramatic mutations at the cleavage site, thereby increasing the chance of HIV-inactivation. We compared Cas12a and CaS12b to the original Cas9 system for inactivation of the integrated HIV DNA genome.
Results: Superior antiviral activity is observed for Cas12a which can achieve full HIV inactivation in cell culture with only a single gRNA (called crRNA). We disclose that DNA cleavage by the Cas12 endonuclease and subsequent DNA repair causes mutations with a sequence profile that is distinct from that of Cas9. Both CRISPR systems can induce the typical small deletions, but Cas12 does not induce the pure DNA insertions that are routinely observed for Cas9.
Conclusions: We demonstrated that Cas12a and b can achieve full HIV inactivation in cell culture with only a single gRNA by "hypermutation" at the target site as a result of DNA cleavage and subsequent error-prone DNA repair. We propose that the different architecture and kinetics of the Cas9 and Cas12a nucleases can explain this differential outcome.

PEA045

A novel design algorithm to predict the silencing activity of siRNA

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Background: The COVID-19 pandemic, caused by SARS-CoV-2, has renewed efforts to develop safe and effective antiviral treatments. RNAi, mediated by siRNA, is one avenue under development for gene therapy, whereby target gene expression is suppressed based on siRNA sequence homology. Although siRNAs that target mRNA via post-transcriptional gene silencing (PTGS) have established design principles that allow some predictability of antiviral silencing effect, siRNA that target the gene promoter via transcriptional gene silencing (TGS) do not have a specific design algorithm that predicts silencing efficiency.
Methods: We performed a comprehensive analysis of known TGS-inducing siRNA sequence features, compared to PTGS-inducing siRNA sequences, and determined whether siRNA sequences complied with conventional PTGS design principles.
Results: We found that comparing the PTGS Reynolds rational design principles to known PTGS- or TGS-inducing siRNA sequences provided a poor indication of siRNA antiviral activity, with only 3/8 criteria reported in >75% of known antiviral siRNAs. Further analysis of the TGS siRNA sequences discovered 7 features that were conserved between 77-100% of TGS siRNA sequences. This enabled the creation of a new set of guiding principles for a TGS siRNA design algorithm. This newly formulated criteria also successfully predicted 3/4 novel siRNA from a pool of 16 siRNAs targeting SARS-CoV-2 with unknown antiviral silencing activity in a live SARS-CoV-2 infection cell survival assay.
Conclusions: This study has developed the first unique design algorithm to accurately predict the silencing activity of siRNA sequences, prior to experimental testing, and will facilitate rapid development and implementation of TGS siRNA therapeutics.

HIV-1 controllers (including post-treatment controllers) and long-term non-progressors

PEA046

Increased platelet activation and inflammation markers associated to cardiovascular risk in HIV controllers

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Background: HIV controllers (HICs) present spontaneous control of viral replication and preservation of immune response, but some studies indicated persistent inflammation and higher rates of atherosclerosis/hospitalization in HICs compared to the uninfected population. Since immune activation and inflammation drive the development of cardiovascular diseases (CVD), HICs could be at higher risk for CVD despite viremia control.
Methods: We evaluated clinical data and inflammation markers associated to CVD in two groups of HICs: Elite controllers (EC; Viral load <50 copies/mL; n=8) and Viremic controllers (VC; Viral load <2000 copies/mL; n=5). Individual under HIV therapy (cART; >2 years of effective cART; n=18) and HIV-negative individuals (HIVneg; n=18) were evaluated as control groups. Frequency of activated platelets, monocyte-platelet aggregates (MPA), and the balance of classical (CM), intermediate (IM) and non-classical monocytes (NCM) were evaluated by Flow cytometry. Serum levels of inflammation markers was measured by Luminex. All data obtained were adjusted for the variables age, sex, hypertension, dyslipidemia, diabetes, smoking, body mass index, and cholesterol levels.
Results: Both HICs groups presented higher expression of CD62P in platelets ($p<0.007$ for VC; $p<0,03$ for EC) when compared to HIVneg, but MPA frequencies were similar among all groups. Monocytes analyses showed no differences for IM, lower CM frequencies in VC ($p<0,00001$ vs HIVneg; $p<0,00002$ vs cART; $p<0,004$ vs EC) and higher frequencies of NCM for VC ($p<0,00001$ vs HIVneg; $p<0,0002$ vs cART; $p<0,02$ vs EC) and ECs ($p< 0,04$ vs HIVneg). Among serum markers, VC had higher levels of D-dimer ($p<0,01$ vs HIVneg; $p<0,002$ vs cART; $p<0,03$ vs EC), ST2 ($p<0,03$ vs cART), VCAM-1 ($p<0,005$ vs HIVneg) and ICAM-1 ($p<0,02$ vs HIVneg). EC had higher levels of VCAM-1 ($p<0,00001$) and ICAM-1 ($p<0,05$) than cART and of VCAM-1 ($p<0,0001$) compared to HIVneg. MCP-1 levels differed among groups only in unadjusted analyses, while concentrations of CD40L, IL-6, IL-10, and TNF-α were below detection limit for most patients.
Conclusions: Our data showed that VC display increased levels of inflammation markers associated with CVD development. Meanwhile, EC show signals of lower, but persistent inflammation, comparable to the cART group, indicating the potential benefits of alternative therapies to decrease inflammation in both HICs groups.

Mechanism of transmission (mucosal, vertical, blood-borne)

PEA047

Vaginal proteome signatures of unprotected sex

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Background: Unprotected sex is associated with seminal fluid, an influx of leukocytes, and minor epithelial trauma in the vagina. It is also the main source of HIV transmission in women. Characterization of sex-associated changes at the molecular level in the vaginal mucosa may be useful for HIV prevention studies by identifying signatures of recent sexual activity.

Methods: Self-collected vaginal secretions from 10 Canadian women from the THRIVE study were collected via swab 1 day before, 1 day after, and 3 days after reported unprotected sex, and were analyzed by label-free tandem mass spectrometry, where human proteins were identified using the SwissProt database. Ingenuity pathway analysis and ConsensusPathDB were used to infer protein functions. Longitudinal effects were analyzed using Friedman tests.

Results: Proteomic analysis identified 686 human proteins in the vaginal mucosal samples. Forty-nine (7.1%) proteins were differentially abundant between all 3 time points ($p<0.05$). Functional annotation analysis identified the migration of cells pathway to be transiently activated 1 day post-unprotected sex, while the organization of cytoskeleton and granulocyte activation pathways were upregulated at days 1 and 3 post-unprotected sex ($z>=1.5$, $p<0.0001$). Certain granulocyte activation biomarkers (PSMC2, VAMP8, PDAP1, FABP5) remained elevated 3 days post-sex. To limit contributions from the seminal proteome, a sub-analysis of participants (n=5) that did not have a spike (>5 $\log_2$(abundance)) in seminal protein abundance (PSA, SEMG1, SEMG2) 1 day post-unprotected sex was performed. This identified 62 (9%) differentially abundant proteins, including additional granulocyte activation proteins (n=15), and factors involved in epidermis development (n=7). Eighteen proteins remained elevated 3 days post-sex including epidermis development proteins, CALML5, FABP5 and SCEL.

Conclusions: Granulocyte activation and epidermal barrier proteins are increased after unprotected sex. Certain proteins remain elevated up to 3 days post-sex, which may represent ongoing processes to re-establish vaginal homeostasis. These proteins may be novel biomarkers of recent sexual activity, which extend beyond the measurement of biomarkers measured from semen and may be useful for HIV prevention studies. A larger study is required to validate how well these biomarkers classify recent unprotected vaginal sex.

PEA048

Impact of acute sexual assault on female genital tract inflammation, psychological distress, and the association of increased risk of HIV

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Background: An increased inflammatory response is associated with risk of HIV acquisition. The objective of this study was to evaluate genital tract biomarkers longitudinally in women exposed to acute sexual assault.

Methods: Nineteen cervical vaginal lavage (CVL) samples were collected from non-pregnant, HIV negative women >18 years presenting within 5 days of sexual assault with reported penile/vaginal contact, with follow-up visits at 4-6 weeks and 12 weeks after assault. Cases were compared to controls from a previous study without history of sexual assault. ELISA was used to detect biomarkers associated with HIV acquisition and pathogenesis and the results were analyzed using GraphPad Prism. Nucleic acid amplification testing for gonorrhea, chlamydia, and trichomonas and Nugent score for bacterial vaginosis was performed at each visit. Psychological assessment tools were scored at baseline and follow up visits. The Acute Stress Disorder Scale (ASDS) was administered at baseline, and the Center for Epidemiologic Studies-Depression (CES-D), and the Kessler Psychological Distress (K-10) scales were administered at both follow up visits.

Results: The population was 63% white, 37% Hispanic, and 16% Black/African American. Eighty-four % was pre-menopausal, and 53% used hormonal contraception. There were no STIs detected at the baseline exam, however 31% of the population had a Nugent score >6, consistent with bacterial vaginosis. In CVL, there was significant upregulation in levels of pro-inflammatory cytokines IL-1α ($p=0.0168$), IL-1β ($p=0.0387$) but downregulation of TNF-α ($p=0.0064$) at initial visit. We observed an upregulation of IL-1α and IL-6 between 0-12 hours after assault compared to 13-24 hours and 25-72 hours. Using a cut-off of 56 on the ASDS, 85% scored >56 (mean score 68) at presentation. From the 4-6 week to 12 week visits, the K-10 score (a measure of global distress) decreased from a mean of 25 (mild mental disorder) to 15 (likely well).

Conclusions: We observed significant changes in pro-inflammatory cytokines and acute stress during the initial visit with a decrease in mean scores measuring global distress over the subsequent study visits. Our data points to increased risk of HIV acquisition immediately following sexual assault.

Immune responses during acute HIV infection

PEA049

Dysregulation of IFN-γ, TNF-α, IL-12 and IL-18 secretion in newly diagnosed individuals with HIV/TB co-infection

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Background: Tuberculosis (TB) and HIV have profound effects on the immune system, which can lead to the activation of viral replication and negatively regulate the activation of T cells. Understanding immune interactions in patients with dual HIV/TB infection is critical for effective antiretroviral and anti-TB therapy. The objective of the study was to evaluate the expression of proinflammatory cytokines in dual infection HIV/TB.

Methods: The cytokines plasma levels were determined by enzyme immunoassay (Vector-Best kit, sensitivity 0-5 pg/ml). Each sample was run in duplicate. Mann-Whitney test was performed for the significance differences.

Results: A total of 176 individuals were enrolled in the study (newly diagnosed with HIV/TB, HIV and TB): 50 patients with HIV/TB co-infection, 44 patients with HIV, 42 patients with TB, and 40 healthy donors(HD). The median CD4+ were for HIV/TB group, HIV, TB, and HD: 165, 274, 592, and 989 cells/ml^3, respectively. Patients with HIV/TB showed an increase in IL-18 expression compared to: HIV-infected patients by 4.6 times; to TB patients by 3.3 times and to HD by 22.4 times: 3146.7±1950.9pg/ml vs 691.1±313.6pg/ml; vs 964±460.8pg/ml; vs 140.5±63.5pg/ml, respectively (p<0.001).

Also, IL-12/p70 expression was increased 1.6-fold in HIV-infected patients, 4.4-fold in TB patients, and 12.8-fold in HD: 42.4±18.7 pg/ml vs 25.8±3.5 pg/ml; vs 9.7±1.6 g/ml; vs 3.3±0.5pg/ml, respectively (p<0.001). At the same time, the group of patients with HIV/TB showed a decrease in the secretion of IFN-γ and TNF-α compared to the patients with HIV and TB. There was a 1.6-fold decrease in the level of IFN-γ in HIV/TB patients compared to HIV patients: 11.5±3.7pg/ml vs 18.5±2.6pg/ml, p<0.002 and 2.2-fold compared to TB patients: 25.5±10.3pg/ml; HD 0.1±0.5pg/ml, p <0.002. There was a 1.9-fold decrease in TNF-α secretion in HIV/TB patients compared to the TB group: 13.25±9.6pg/ml vs 25.5±8.2pg/ml, HD 0.5±pg/ml,p<0.002.

Conclusions: IL-12 and IL-18 hypersecretion is observed in patients with HIV/TB co-infection. Enhanced levels of these cytokines, especially with reduced production of IFN-γ and TNF-α, presumably contributes to increased viral replication. Also, IL-12 hypersecretion alongside with low levels of IFN-γ can cause deep inflammation in the lungs.

Novel vectors and strategies

PEA050

Reactivity of plasma from HIV-infected pregnant women with recombinant Q β phages displaying the membrane proximal external region of HIV-1 envelope

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Background: The Membrane Proximal External Region (MPER) of HIV-1 envelope glycoprotein-41 (gp41) bears conserved linear epitopes that are promising markers for an HIV vaccine design. However, it remains challenging to design and deliver MPER based immunogen that can efficiently induce HIV-1 specific broadly neutralizing antibodies (bnAbs). Our research group has previously demonstrated the ability of MPER derived immunogens displayed upon recombinant coliphage Qβ (QβMPER) to detect MPER targeted antibodies in antiretroviral naive HIV infected people.

Methods: In this study we have assessed the reactivity of this novel recombinant immunogen with plasma of HIV-1 infected pregnant and non-pregnant women. This comparative cross-sectional study was conducted from September 2018 to March 2019 at Gyneco-Obstetric and pediatric hospital of Yaounde (HGOPY), and the Chantal Biya International Reference Center for research on the prevention and management of HIV/AIDS (CIRCB).

A total of 94 samples were collected at the hospital including 29 HIV infected pregnant women (HIPW), 22 infected non-pregnant (HINPW), 20 uninfected non- pregnant (HUNPW) and 23 uninfected pregnant women(HUPW). The HIV status of participants was confirmed using the rapid diagnostic test, and the CD4 count was determined by PIMA™ CD4 analyser.

Results: The plasma levels of IgM and IgG antibodies specific to recombinant QβMPER were measured using an indirect ELISA assay. Data were analysed with Graph pad Prism 7.04 and expressed as median and compared using Mann-Whitney test. Spearman's correlation (r_s) coefficient was used to assess possible associations between variables.

The results show a significant increase in recombinant QβMPER-specific IgM antibody responses in both HIPW (p=0.0081) and HINPW (p=0.0022) compared to the uninfected women. There was a significant reduction in both IgM (p=0.01605) and IgG (p<0.0001) antibody responses specific to MPER in HIPW compared to HINPW. The profile of IgG antibody responses specific to recombinant QβMPER phages in HIPW correlates inversely with increasing gestational ages of the pregnant women (r_s=-0.4302, P=0.0198) with the lowest amount of IgG levels observed during the 3rd trimester.

Conclusions: These findings suggest that the recombinant QβMPER phages could be used to monitor MPER targeted antibody responses of HIV infected pregnant women and could eventually be optimized as a therapeutic vaccine for people living with HIV.

Co-infection: Viral hepatitis

PEA052

T cell maturation and senescence evolution after HCV elimination in HIV-HCV patients

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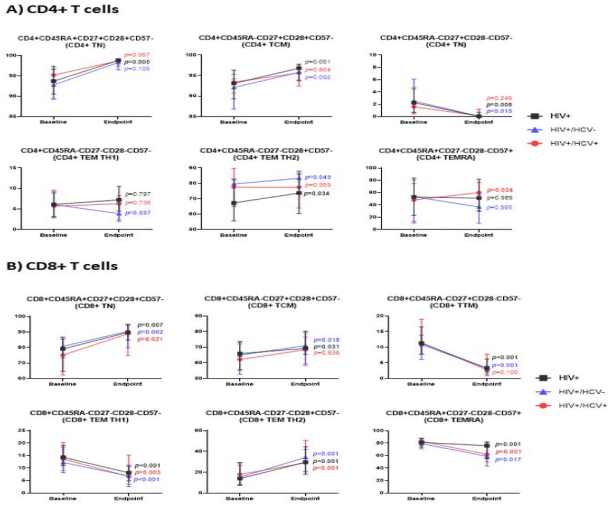
Background: Previously, our group studied the effect of HCV elimination with DAAs or spontaneous clearance (SC) on the size of the HIV reservoir. A stabilization of the reservoir size was found in HIV+ monoinfected and HIV+/HCV+ coinfected patients, as well as a decrease in HIV reservoir size in HIV+/HCV- SC. However, variations in different memory T cell populations, the main component of the viral reservoir, are unknown and could broaden the understanding of the evolution of its size.

Methods: Longitudinal study (52 weeks follow-up) in 146 patients: 49 HIV+/HCV+, 38 HIV+/HCV- and 59 HIV+, all aviremic. Flow cytometry study of the expression of maturation (CD45RA, CD27) and senescence (CD28, CD57) markers in CD8+ and CD4+ T-cells. Paired samples were analysed using a beta-inflated mixed model.



Results: Patients had a median age of 49 years. 63.7% were men. The most frequent ART was based on integrase inhibitors (35.6%, n=52). All HIV+/HCV+ patients achieved sustained virological response with DAAs. No differences were observed in CD4+ and CD8+ T-cell counts between time points nor among study groups.

A generalized increase in expression of CD28 and decrease in CD57 was observed for CD8+ T cells. The evolution of the expression of these markers was similar in CD4+ cells but only in those CD27+. CD27-CD28- cells decreased significantly in HIV+/HCV- patients as CD27-CD28+ cells increased.

Conclusions: The general decline in cell senescence of cytotoxic lymphocytes may be due to reduced antigenic stimulation of both HIV-specific and HCV-specific lymphocytes. A similar evolution in CD4+CD27+ lymphocytes could be due to the effect of HIV viral proteins Nef and Vpu. In addition, the evolution of HIV viral reservoir in HIV+/HCV- patients matches the evolution of CD4+ cells with a TH1 phenotype, which could mean a decrease in the number of circulating TFH1 lymphocytes after an improvement in the state of generalized inflammation.

PEA053

Epidemiological history of hepatitis B virus in Portugal and the Portuguese role in its spreading across the world

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Background: In 2015, 257 million people lived with chronic hepatitis B infection. Portugal, where 1.4% of the population is chronically infected with hepatitis B virus, is a country with a long term history of high connectivity with several world regions, that started through its desire to explore, via the oceans, other lands and cultures in Africa, Asia, and South America in the XV-XVI centuries and continued with Portuguese colonies until the XX century. In this study, we aimed to investigate the epidemic history and transmission dynamics of HBV genotypes that are endemic in Portugal.

Methods: HBV *pol* gene was sequenced from viral genomes of 130 patients followed in Lisbon, between 2005 and 2012. Spatio-temporal evolutionary dynamics were reconstructed using a Bayesian Markov Chain Monte Carlo method, as implemented in BEAST v1.10.4, with a GTR nucleotide substitution model, an uncorrelated lognormal relaxed molecular clock model under a Bayesian skyline plot, and a continuous diffusion model.

Results: Our results indicate that HBV/D4 was the first subgenotype to be introduced in Portugal by the end of the XIX century, around 1857 (HPD 95% 1699 - 1931) followed by subgenotypes D3 and A2 a few decades later. Genotype E and subgenotype A1 were introduced in Portugal later, almost simultaneously. Our results also indicate a very important role of Portugal in the exportation of HBV subgenotypes D4 and A2 to Brazil and Cape Verde, respectively, at the beginning of the XX century.

Conclusions: This work clarifies the epidemiological history of HBV in Portugal and responds to some gaps in the epidemiological history of HBV in former Portuguese colonies, illustrating the important role of Portugal in the global spread of this and eventually other viruses.

Co-infection: STIs, including HPV

PEA054

High prevalence of bacterial sexually transmitted infections among Brazilian adolescents' men who have sex with men in Northeast Brazil

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Background: Bacterial sexually transmitted infections (b-STI) among adolescents' men who have sex with men (aMSM) has been a growing concern in the era of PrEP rollout. However, data on the prevalence of b-STI and sexual behaviors among aMSM are still scarce. We aimed to estimate b-STI prevalence and associated factors among aMSM in Salvador, Brazil.

Methods: Baseline data from one of the sites (Salvador city) of the first demonstration PrEP cohort study among aMSM 15 to 19 years old ongoing in Brazil (PrEP1519). Eligible participants (177) were enrolled between March 2019-August 2020 answered a sociodemographic/sexual behavior questionnaire. Swabs samples were collected from pharyngeal, urethral and rectal sites to test for *Neisseria gonorrhoeae* (NG), *Chlamydia trachomatis* (CT) and *Mycoplasma genitalium* (MG) using qPCR. Positivity was defined by detection in at least one site. Serological rapid test was used for *Treponema pallidum* (TP) detection. The outcome variable was b-STI dichotomized in "yes" (at least one infection) and "no". Adjusted prevalence ratio (aPR) using Poisson regression with robust variance and 95% confidence intervals (95%CI) were estimated.

Results: The prevalence of b-STI were high among aMSM specifically NG (18.1%) and TP (11.0%) (Table 1). Factors associated with any b-STI were lower education (aPR=1.92, 95%CI: 1.22-3.01), receptive anal sex with casual partners (aPR=1.77, 95%CI: 1.14-2.77), drug use interfering with condom use (aPR=1.74, 95%CI: 1.07-2.83) and clinical suspicion of a b-STI (aPR=2.08, 95%CI: 1.30-3.34).

Sexually Transmitted Infection	n	Prevalence (%)	95%CI
Neisseria gonorrhoeae	32	18.1	13.0-24.5
Chlamydia trachomatis	6	3.4	1.5-7.4
Mycoplasma genitalium	11	6.2	3.5-10.9
Treponema pallidum	19	11.0	7.1-16.7
Any b-STI	45	32.2	25.7-39.5

Table 1. Baseline prevalence of b-STI among aMSM. PrEP1519 study-Salvador site

Conclusions: We observed worrisome rates of b-STIs among aMSM. A comprehensive approach for STI prevention is essential for aMSM, not only in terms of point of care protocols/screening tests but also service delivery that includes LGBT friendly environments, counselling, follow-up and linkage to health services.

PEA055

Bacterial STI rates by pharyngeal, urethral and rectal sites among adolescents' men who have sex with men in Northeast Brazil: the importance of comprehensive sample collection sites

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Background: Comprehensive and timely detection of bacterial sexually transmitted infections (b-STI) is crucial to prevent transmission and sequelae of untreated infection. However, for adolescents' men who have sex with men (aMSM) the diagnosis of b-STI is still a challenge because they have little access to b-STI prevention, detection, and treatment services. Additionally, most infections are asymptomatic, especially when it occurs at rectal or pharyngeal sites. We aimed to estimate the rate of detection loss when using results from one collection site only (pharyngeal, urethral, or rectal) compared with results combining the three sites.

Methods: Baseline data from the first PrEP demonstration cohort study among aMSM aged 15-19 years old going on in Brazil (PrEP1519). Eligible participants were enrolled between March 2019-August 2020 at Salvador site, Northeast Brazil. Swabs samples were collected from pharyngeal, urethral, and rectal sites and tested with qPCR for *Neisseria gonorrhoeae* (NG), *Chlamydia trachomatis* (CT) and *Mycoplasma genitalium* (MG). Proportions were estimated by collection site and in combination.

Results: For NG the rate of detection loss was 34.2% (11 participants), 50.8% (18), and 89.5% (29) when only the pharyngeal site, the rectal site, the urethral site was analyzed respectively. For CT the loss rates were 67.6% for the pharyngeal site, 61.8% for the rectal site and 64,7% for the urethral site. For MG the loss rates were 36.4%, 63.64%, 81.84% when only rectal, pharyngeal, and urethral samples were analyzed, respectively. There were significant differences in the detection of NG using rectal and urethral samples and in the detection of MG using urethral samples.

STI	Three sites combined (n =177) n (%)	Only pharyngeal (n =177) n (%)	Detection loss (%)	p-value	Only rectal (n =158) n (%)	Detection loss (%)	p-value	Only urethral (n =160) n (%)	Detection loss (%)	p-value
NG	32 (18.1)	21 (11.9)	34.2	0.13	14 (8.9)	50.8	0.02	3 (1.9)	89.5	0.001
CT	6 (3.4)	2 (1.1)	67.6	0.17	2 (1.3)	61.8	0.29	2 (1.2)	64,7	0.28
MG	11 (6.2)	7 (3.9)	37.1	0.47	4 (2.5)	59,7	0.12	2 (1.2)	80.6	0.02

Table 1. b- STI prevalence and detection loss rates by collection site and combined sites

Conclusions: Our data shows that comprehensive and timely detection of b-STI is quite important and can lead to early treatment of existing and prevention of new infections especially in young MSM. This measure, associated with an effective prevention policy, can contribute to better control of the spread of b-STI.

Co-infection: SARS-Co-V2

PEA056

Systematic review: COVID-19 and HIV, risk of hospitalization/ICU admission and mortality

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Background: In December 2019, a new coronavirus (SARS-CoV-2) strain brought about yet another outbreak that was first seen in China as an epidemic and quickly declared a pandemic by WHO on March 11, 2020. The primary objective was to assess the risk of hospitalization, Intensive Care Unit (ICU) admission, and mortality of PLWH with COVID-19. The secondary objective was to correlate the variations in CD4+ count to the outcome of COVID-19 in the HIV population and to deduce if they are more protected due to Antiretroviral therapy (ART). The third objective was to evaluate the typical clinical presentation of COVID-19 in Persons Living with HIV (PLWH).

Methods: Literature review by searching databases such as Cochrane, PubMed, and Google Scholar with keywords were used: "COVID-19," "SARS-CoV-2," and "HIV." was done. We included case reports, case series, and cohort studies. We excluded clinical trials and review articles. 23 articles met the inclusion criteria.

Results: A total of 651 PLWH with confirmed COVID-19 were studied. Risk of hospital admission was 69.13% (450/651), ICU admission was 12.90% (84/651) in total infected patients, and 18.67% (84/450) among hospitalized patients. The case fatality rate was 11.21 (73/651).A weak positive correlation was found between CD4+ counts and hospital admissions in case series and case reports , while the weak negative correlation was found in cohorts.

Author (mortality data)	Age (mean) Gender	Comorbidities	ART	CD4+ counts
Viscarr et al (no= 2)	N/A	N/A	N/A	1st pt.: 137 2nd pt.: 636
Del Amo et al (no= 20)	N/A 16 m, 4 f	N/A	-10 pt. on TAF/FTC -8 pt. on ABC/3TC	N/A
Ho et al (no= 19)	62 (55-68) 13 m, 6 f	13 obesity	-10 pt. on TDF -3 pt. on PI	686 (466-800)
Sigel et al (no= 18)	62 (57-67) 13 m, 5 f	4 DM, 6 HTN, 2 COPD, 6 CKD, 3 organ transplant, 1 liver cirrhosis, 1 obesity	-13 pt. on Integrase -5 pt. on PI -16 pt. on NRT	1 pt. < 50 6 pt. 50-200 6 p.t 201-500 1 pt. >500
Meyerowitz et al (no= 2)	59, 63 1 m, 1 f	1st pt.: CHF, CKD, DM, HLD, HTN, prior stroke, 40 BMI 2nd pt.: HTN, prior stroke, CKD	-1st pt.: CTG+ABC/ ETG+DRT/r+ETR -2nd pt.: DTG+TAF/FTC	426
Gervasoni et al (no= 2)	47, N/A 2 m	-1st pt.: obesity -2nd pt.: CVD, lung cancer	N/A	N/A
Harter et al (no= 3)	59, 55, 82 3 m	-1 pt.: HTN, COPD, DM -other 2: N/A	-1st pt.: DOR/TDF/FTC -2nd pt.: BIC/TAF/FTC -3rd pt.: DRV/RTV/RGV	388.7 (718, 69, 379)
Byrd et al (no= 1)	59 m	ESRD, cancer	EFV, ABC	936

Table 1. Mortality data of all studies

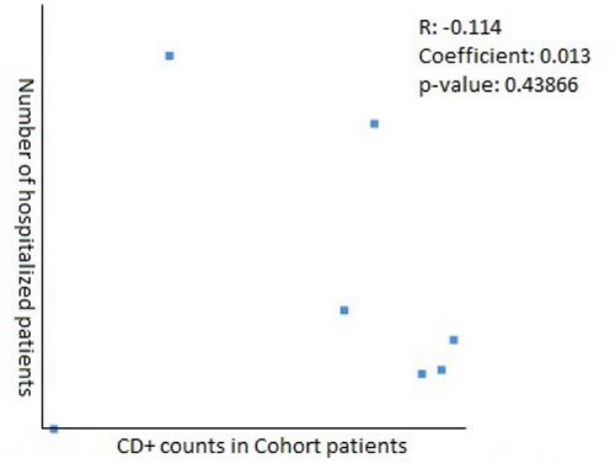

Figure 1. Correlation of CD4+ counts & hospitalization in cohorts patients

Conclusions: There was a high rate of hospitalization, ICU admission, and mortality among patients living with HIV and COVID-19. We recommend that PLWH be closely monitored and strictly adhere to antiretroviral therapy and universal COVID-19 precautions

PEA057

Sars-COV-2 and HIV in Brazil: a dangerous combination

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Background: Although people living with HIV (PLHIV) are among the conditions considered at risk for the complication of COVID-19, the way the infection affects this population involves a learning process that is still under construction and it needs to be better understood. We aim to describe clinical and epidemiological aspects of severe acute respiratory syndrome (SARS) caused by COVID-19 in PLHIV in Brazil.

Methods: Descriptive and cross-sectional study carried out through a non-deterministic relationship of the COVID-19 and HIV/AIDS database from January to August 2020. Data came from Severe Acute Respiratory Syndrome System, Information System of Notifiable Diseases (SINAN), Laboratory Examination Control System (SISCEL), Drug Logistics Control System (SICLOM) and Mortality Information System (SIM). Demographic, clinical and epidemiological characteristics were analyzed, in addition of elaborating thematic maps of cases proportion and lethality.

Results: Of 1,840 cases of SARS due to COVID-19 in PLHIV, 1,524 (82.8%) had already been reported as AIDS, 69.8% were male, 29.1% represented those over 60 and 57.8% declared themselves to be black/brown. São Paulo state recorded the majority of cases (37.6%). Cough, dyspnea, fever, respiratory distress and O2 saturation <95% were frequent signs and symptoms. The most frequent comorbidities: immunosuppression (858 cases) followed by cardiovascular diseases (425) and diabetes mellitus (394). The lethality was 32.6 deaths per 100 cases and the mortality from HIV/COVID-19 co-infection was 45.9 deaths per 100,000 inhabitants.

Conclusions: Clinical and epidemiological characteristics of PLHIV with COVID-19 are similar to those described in general population. Older age and comorbidities are important aspects to be considered in the mortality of coinfected patients. These results reinforce the

need to strengthen the epidemiological surveillance of co-infected people. Also, they show the importance of the political commitment for strategies implementation to allow the continuity of care, especially in the face of the pandemic. of COVID-19.

Co-morbidities: Non-communicable diseases

PEA058

Overt expression of IL-32 isoforms in the colon of ART-treated PLWH: negative regulation by IL-17A

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Background: The interplay between intestinal epithelial cells (IEC) and Th17 cells is key for mucosal immunity homeostasis. HIV infection is associated with an impairment of intestinal barrier functions leading to chronic immune activation, which is not normalized by antiretroviral therapy (ART). Such alterations coincide with the overexpression of interleukin (IL)-32, a novel family of cytokines composed of multiple isoforms. IL-32 overexpression was associated with the loss of HIV virological control in individuals with a history of natural control of viral replication and was causally implicated in non-AIDS co-morbidities such as cardiovascular disease (CVD). The involvement of specific IL-32 isoforms in HIV gut pathogenesis remains poorly investigated.
Methods: Sigmoid colon biopsies (SCB) and blood were collected from ART-treated PLWH (HIV+ART; n=17; median age: 55 years; CD4 counts: 679 cells/ml; time on ART: 72 months) and age-matched HIV-uninfected controls (HIVneg; n=5). Cells were isolated by enzymatic digestion and gradient centrifugation. The HT-29 cell line was used as IEC model. HT-29 cells were exposed to TLR1-9 agonists, TNF-α, IL-17A, and HIV. IL-32α/β/γ/d/ε/θ and IL-17A mRNA levels were quantified by real-time RT-PCR. IL-32 protein levels were quantified by ELISA.
Results: The IL-32β/γ/ε mRNA was predominantly expressed in blood and SCB, with IL-32β mRNA levels being significantly higher in HIV+ART compared to HIVneg participants. IL-17A mRNA was detectable in SCB only, with IL-17A levels being superior in HIVneg compared to HIV+ART and negatively correlated with IL-32β mRNA levels. The same IL-32β/γ/ε isoforms were detected in HT-29 cells upon exposure to TNF-α, Poly I:C (TLR3 agonist), Flagellin from *Salmonella thiphymurium* (TLR-5 agonist) and HIV. Noteworthy, IL-17A significantly decreased IL-32 β/γ/ε mRNA and cell-associated total IL-32 protein expression induced by TNF-α and Poly I:C.
Conclusions: Our results provide a cartography of IL-32 isoform expression in the colon and blood of ART-treated PLWH and reveal the capacity of the Th17 hallmark cytokine IL-17A to attenuate overt IL-32 expression in inflamed IEC. Our results support a model in which inflamed IEC are an important source of IL-32, with the paucity of IL-17A, caused in part by Th17 depletion, fuelling overt IL-32 expression at intestinal level during HIV infection.

PEA059

Baricitinib reduces macrophage-mediated inflammation in HIV infection

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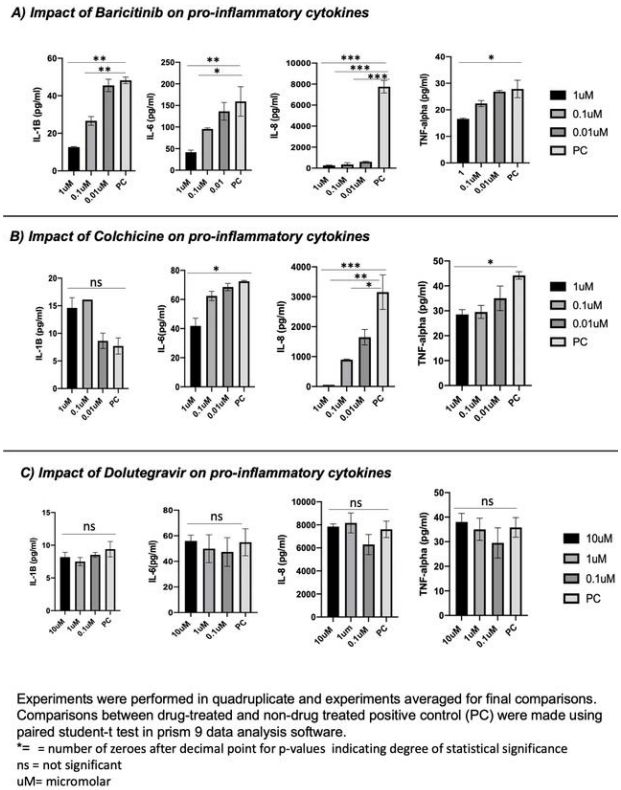
Background: Macrophages (MΦ) contribute to chronic inflammation during HIV-infection. They play a central role in the pathogenesis of chronic inflammatory conditions such as cardiovascular disease (CVD), neurocognitive disorders and accelerated aging. These conditions disproportionately affect people with HIV (PWH). Anti-inflammatory therapy could reduce risk of these chronic conditions. We explored the impact of anti-inflammatory agents and antiretrovirals to reduce HIV-induced MΦ-mediated cytokine production in-vitro.
Methods: Human monocyte-derived MΦ isolated from buffy coats were pretreated with baricitinib (JAK1/2 inhibitor),colchicine, or dolutegravir (DTG). Drug-treated cultures were infected with dual-tropic HIVP89.6. 5 days post-infection, MΦ supernatants were collected. Experiments were performed in quadruplicates across multiple experiments. p24 was quantified by ELISA. Multiplex cytokine profiling was performed using flow cytometry-based microbeads for IL-1β, IFN-α2, IFN-γ, TNF-α, MCP-1, IL-6, IL-8, IL-10, IL-12p70, IL-17A, IL-18, IL-23, and IL-33. Comparisons between drug-treated and non-drug treated positive control (PC) were made (paired student-t test; Prism 9).



Experiments were performed in quadruplicate and experiments averaged for final comparisons.
Comparisons between drug-treated and non-drug treated positive control (PC) were made using paired student-t test in prism 9 data analysis software.
*= = number of zeroes after decimal point for p-values indicating degree of statistical significance
ns = not significant
uM= micromolar

Figure. Impact of Baricitini B, Colchicine and Dolutegravir on cytokine production in iHIV-infected macrophages

Results: Baricitinib significantly reduced HIV-infection in MΦ (EC50 = 0.013 μM) and inhibited production of key pro-inflammatory cytokines IL-6, TNF-α, IL-1β and IL-8. Colchicine also reduced HIV-infection in MΦ (EC50 = 0.04μM), but demonstrated less broad activity in inhibiting pro-inflammatory cytokines compared to baricitinib, and instead

showed inhibition only towards IL-6, TNF-α and IL-8 production. DTG did not inhibit production of pro-inflammatory cytokines in HIV-infected MΦ.

Conclusions: There are no targeted pharmacologic approaches to reduce inflammation for PWH. Repurposing anti-inflammatory agents presents an opportunity to identify useful drugs to address this need. JAK-inhibitors, like baricitinib with both antiviral and immunomodulatory effects, are attractive candidates for this purpose. Colchicine, an older anti-inflammatory drug, is emerging as a strategy to reduce CVD risk in non-HIV cohorts; its use in PWH remains to be defined. Primary human MΦ systems may provide mechanistic insights towards identifying safe, specific, clinically relevant agents to mitigate chronic inflammation that drives co-morbidities in PWH.

PEA060

BMI as a predictor of high fasting blood glucose among people living with HIV in the Asia-Pacific region

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Background: Non-Asian body mass index (BMI) classifications are commonly used as a risk factor for high fasting blood glucose (FBG). We investigated the incidence and factors associated with high FBG among people living with HIV (PLHIV) in the Asia-Pacific region utilizing a different WHO classification of BMI specific for Asian population.

Methods: PLHIV enrolled in a longitudinal cohort study from 2003 to 2019, receiving antiretroviral therapy (ART) without prior tuberculosis (TB) were included. BMI at ART initiation was categorized using Asian BMI classifications: underweight (<18.5 kg/m^2), normal (18.5-22.9 kg/m^2), overweight (23-24.9 kg/m^2), obese (≥25 kg/m^2). High FBG was defined as a single post-ART fasting plasma glucose measurement ≥126mg/dl. Factors associated with high FBG was analysed using Cox regression model stratified by site.

Results: A total of 3939 patients (63% male) were included. Heterosexual contact was the most common mode of HIV exposure (69%), and the median age at ART initiation was 34 years (interquartile range [IQR] 29-41). Half had a BMI in the normal weight range, 23% were underweight, 13% and 14% were overweight and obese respectively.

Overall, 313 (8%) had a high FBG, with incidence rate of 1.14 per 100 person-years. Factors associated with increased hazard of high FBG included being obese compared to normal weight (HR=1.79, 95%CI: 1.31-2.44, p<0.001), and older age compared to those aged ≤30 years (31-40 years: HR=1.47, 95%CI: 1.08-2.01, p=0.014; 41-50 years: HR=2.03, 95%CI: 1.42-2.90, p<0.001; ≥51 years: HR=3.19, 95%CI: 2.17-4.69, p<0.001). The probability of not having high FBG 5 years from ART initiation, was 96% for underweight, 94% for normal weight, 93% for overweight, and 92% for obese individuals (Figure 1).

Conclusions: Higher BMI was linearly associated with an increased risk of high FBG, even at BMIs that are considered normal in non-Asian classifications.

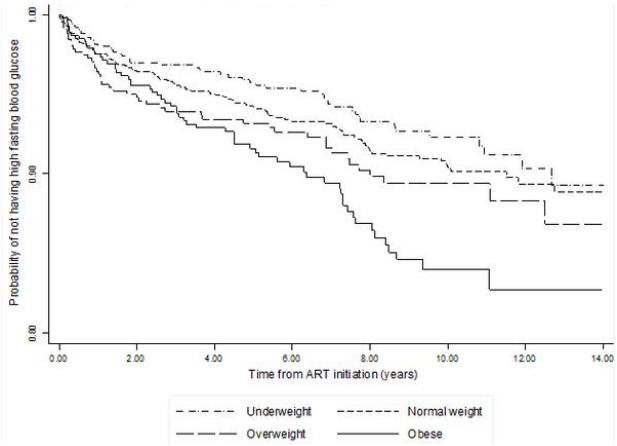

Figure 1. Kaplan-Meier curves of patients by Asian BMI classifications

Novel assays to measure immune responses

PEA061

Correlation between serum and salivary HIV antibodies in a cohort of well-controlled children living with perinatal HIV/AIDS

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Background: In 2018, 21% out of 37.9 million people living with HIV were unaware that they had contracted the virus. In this scenario, early detection of the HIV infection is of paramount importance to prevent further transmission. There is often a higher preference for less invasive specimen collection techniques, such as saliva. Recent studies showed that HIV antibodies detected from the oral cavity had a similar sensitivity (99.21%) and specificity (100%) to tests with serum. When the protocols are appropriately modified, the use of saliva in reference methods can become equally feasible. The aim of our study was to correlate the presence of salivary and serum anti-HIV I and II antibodies among well-controlled children living with perinatal HIV/AIDS (CLWPHA).

Methods: A cross sectional study was conducted with convenience sampling of 20 HIV-positive adolescents from an institutional setup at Tiruvallur (February, 2020). Both male and female participants were included. Salivary antibody presence was assessed using HIV Oral Mucosal Transudate HIV antibody detection kit. The findings were correlated with serum antibody presence, which was assessed using the gold standard serum antibody test (Spearman correlation). Additional information such as their CD4 count, viral load, etc. were also collected.

Results: The mean age of the 20 participants (Male-8, Female-12) was 15.75±2.14. Salivary antibody presence had a strong positive correlation of 1.0 with serum antibody presence. All patients (100%) were agreeable to being tested using oral fluid, while only 80% of the patients were comfortable with the serum test. The remaining 20% of patients were apprehensive of the blood test as it involved being pricked with a needle.

Conclusions: A perfect positive correlation was observed between saliva and serum antibodies providing evidence that both testing methods can be used interchangeably. Thus, this salivary kit can be used as an effective screening device for HIV antibody detection and can be introduced in hospitals and clinics as a routine screening procedure. This study proves the efficacy of oral cavity testing, which is also easily acceptable by children. This would encourage early testing among children, hence enabling early detection of HIV.

Novel animal models to test interventions (vaccines, cure, antiretrovirals)

PEA062

Antibody responses of cows immunized with HIV V2-apex focusing immunogens

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Background: We have previously reported on the elicitation of broadly neutralizing serum antibody responses in cows following homologous prime and boosting immunization with the BG505 SOSIP.664 gp140 trimer. These responses were rapidly elicited in as little as one month and the responses were reliably detected in all four cows. Broadly neutralizing antibodies (bnAbs) isolated from these animals target the CD4bs epitope.

Here, we report the immunization of cows with V2-apex targeting trimers to determine if similar broadly neutralizing serum response would develop against the V2-apex epitope given the high frequency of long (>28 amino acids) and ultralong (>50 amino acids) antibodies present in the cow antibody repertoire.

Methods: Two groups of two cows were immunized six times in total. Group 1 cows were immunized three times with a simian immunodeficiency virus (SIV)-Env trimer called MT145K SOSIP, which contains a mutation that enhances binding and neutralization by HIV V2-apex bnAbs. This immunization was followed by two doses of HIV Env C108 SOSIP and a final boost with a cocktail of HIV Env trimer derived from four different strains. The second group of cows was immunized five times with the HIV Env C108 SOSIP trimer followed by a final boost with the same cocktail of the four HIV Env SOSIP trimers.

Results: Broadly neutralizing serum responses were detected in one cow from group 1 and one cow from group 2. A total of 20 bnAbs were isolated with eight and 12 bnAbs from cows in group 1 and 2, respectively. All antibodies harbor ultralong CDRH3s (>50 aa) and target the V2-apex epitope based on epitope competition, epitope mapping, and electron microscopy data.

Conclusions: Compared to the previous cow experiment, neutralization breadth was not elicited with a single trimer immunogen, only a subset of cows developed broad responses, and robust responses were only observed later in the immunization sequence. These results indicate that availability of a high frequency of long HCDR3s was insufficient alone to elicit a robust V2apex bnAbs but that a prime-boost strategy could be successful.

Track B

Morbidity, mortality and life expectancy

PEB063

The VACS index predicts five year mortality among people living with HIV In Thailand

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Background: The Veterans Aging Cohort Study (VACS) index score predicts mortality in people living with HIV (PLHIV), better than indices restricted to CD4 count, HIV RNA and age. This study aimed to evaluate and validate the VACS score in a longitudinal cohort from Thailand, and explore differences by sex, since the VACS equation does not include sex.

Methods: All PLHIV enrolled in the HIV- Netherlands, Australia and Thailand Collaboration (HIV-NAT) cohort, from January 1991 to November 2020 were analyzed. The primary outcome was AIDS- or non-AIDS related mortality after starting ART. VACS score (possible range 0-164 points) was calculated at the clinic visit which preceded death or the most recent clinic visit by 5 years ('baseline'). We calculated odds ratios (OR) for death by VACS score, and OR adjusted (aOR) for other known confounders. Models were developed separately by sex; model discrimination was assessed by the area under the receiver operating characteristics curve (AROC).

Results: Of 2,646 patients (67% male, median (IQR) age at antiretroviral therapy (ART) initiation 31 (26 -37)), 150 (5.7%) patients died; 41/150 (27%) were females and 109/150 (73%) were male. Duration of ART before death or censoring was 8 (IQR = 2.2 – 16.7) years.

The median (min-max) VACS score was 24 (0-99) and 13 (0-92) in the patients who died or were alive at 5 years, respectively. Separated by sex, median (IQR) VACS score was higher in females than males by mortality group: 28 (16-44; max=99) and 22 (10-28; max=92) in females, and 24 (13-42; max=81) and 12 (6-20; max=92) in males, who died and

alive, respectively. After adjustment for whether patients were ART naïve or experienced at baseline, CDC class C and age at ART initiation, the aOR per 20 point increase in VACS score was 1.85 (95%CI 1.26 – 2.72); <0.001, AROC 0.71 (95%CI 0.63-0.78) in females, and 2.31 (1.81-2.93); P<0.001, AROC 0.78 (95%CI 0.73-0.82) in males.

Conclusions: In this Asian cohort, VACS index performed well in predicting of 5 year mortality for both males and females. Higher VACS scores observed in females versus males were partly due to lower hemoglobin levels.

PEB065

High-dimensional polychromatic flow cytometry reveals mucosal-homing as a putative biomarker of natural killer cells in persons aging with or without HIV

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Background: Natural killer (NK) cells are critical modulators of HIV transmission and disease. While recent evidence suggests the loss of NK cell cytotoxicity during aging, a compound analyses of NK cell biology and aging in persons with HIV (PWH) are lacking.

Methods: We performed a cross-sectional analysis on HIV uninfected donors (HD) [n=49; age 32.47 – 73.48], PWH on antiretroviral therapy (ART) [n=61; age 26.66 – 73.33], and off ART [n=25; age 27.28 – 78.07] in the Hawaii-HIV-Aging Cohort. The study group was 81% male and 45% Caucasian. High-dimensional polychromatic flow cytometry was used to quantify surface expression on peripheral blood mononuclear cells of 28 proteins relevant to NK cell biology: (i) trafficking, (ii) activation/inhibition, (iii) adaptive/memory, and (iv) immune exhaustion. Additionally, anti-CMV IgG titers were quantified in plasma. Spearman correlations and generalized linear models (GLM) with bootstrapping were conducted.

Results: In HD, the frequency of NK cells positively correlated with age, and with NK cell subsets expressing CD85j, Tim-3, and CD8a, markers which have been linked to aging.

Interestingly, expression of gut-homing α4β7 on NK cells positively correlated with age (R = 0.41; p =0.0085), whereas the lymph-node homing receptor, CCR7 declined with age (R = -0.52; p = 0.0005).

NK cell phenotypes in PWH, either on or off ART, demonstrated a negative correlation between age and α4β7 expression and increased expression of inhibitory NKG2A with advancing age. GLM with bootstrapping revealed no significant predictors of infection status for people under 45, but for persons over 50: CD2, α4β7, CCR5, CCR7, and CD85j were all predictors of PWH compared to HD.

Furthermore, CMV status was the predictive co-factor for several markers such as CD2 and CCR5, but not α4β7. However, duration of known HIV infection negatively correlated with α4β7 expression, while plasma viral load positively correlated with α4β7 expression (all p<0.05).

Conclusions: NK cell phenotypes are dynamic across aging, but are significantly altered in HIV and ART and with co-factors such as CMV. Specifically, HIV may significantly impact mucosal homing and surveillance by perturbing the α4β7 on NK cells.

Determinants of HIV progression and disease control

PEB066

Preservation of lymphocyte functional fitness in perinatally-infected HIV+ pediatric patients with sub-optimal viral control

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Background: In this study we interrogated the functional fitness of the immune response in two US based cohorts of perinatally infected HIV+ patients with early anti-retroviral therapy (ART) initiation but divergent patterns of virologic control. We hypothesized that sub-optimal viral control in perinatally-infected HIV+ patients on ART will compromise their immune functional fitness.

Methods: This study was carried out over a two-year period starting in 2018 in collaboration with the Special Infectious Diseases Clinic at the Ann and Robert H. Lurie Children's Hospital of Chicago. The immune responses in six study subjects in each of the two HIV+ cohorts were benchmarked against the responses measured in eleven age-range matched, uninfected healthy control subjects. Lymphocyte responses were examined by intra-cellular cytokine secretion and degranulation assays following mitogenic and Gag potential T cell epitope peptide pool stimulation. A subset of these data were further queried by automated dimensionality reduction [t-Distributed Stochastic Neighbor Embedding (t-SNE)] and clustering [Cluster Identification, Characterization, and Regression (CITRUS)] algorithms. Additionally, lymphocyte signaling properties were evaluated by phosflow in response to treatment with immunomodulatory cytokines and anti-CD3 stimulation. Finally, we evaluated the humoral immune responses to childhood vaccines (Tetanus toxoid, VZV, Measles and Hemophilus influenzae b) in all three cohorts.

Results: Our results demonstrated that contrary to expectations, pediatric HIV+ patients with sub-optimal viral control displayed no significant deficits in immune functional fitness. In fact, the patients that displayed better virologic control lacked functional Gag-specific T cell responses and compared to healthy controls they also displayed signaling deficits and an enrichment of mitogen-stimulated CD3 negative and positive lymphocyte clusters with suppressed IFNγ and TNFα secretion.

Conclusions: These results highlight the immune resilience in HIV+ children on ART with sub-optimal viral control. With respect to HIV+ children on ART with superior viral control, our findings suggest that periodic administration of a vaccine engineered to selectively stimulate HIV (including low-fitness variants)-specific CD8 T cells, could be considered to reverse the functional quiescence. Such an approach could potentially contribute to immune-mediated "block and lock" strategies that might also eventually maintain viral suppression without ART, similar to what is observed in aviremic, adult "elite-controllers".

HIV testing and retesting

PEB067

Increased ability of the new lateral flow point-of-care HIV-Combo test to detect acute HIV infection in Eswatini

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Background: The diagnosis of acute HIV infection (AHI) is hardly performed in resource-limited settings. Barriers include high costs of viral load (VL) based diagnostic testing algorithms and unavailability of reliable point-of-care (POC) tests. We assessed the performance of a new POC tests for the detection of AHI in Eswatini.

Methods: Adult outpatients testing HIV-negative on Alere™ Determine through finger-prick testing by lay counsellors, or with discordant result (Alere™ Determine positive and Uni-Gold™ negative) were tested with the quantitative Xpert HIV-1 VL assay (gold standard) for AHI at Nhlangano Health Centre, from March 2019 to March 2020. AHI was defined as a VL test result ≥40 copies/mL. Leftover paired venous whole blood and plasma specimens were tested with the lateral flow fourth-generation antibody/p24 POC Alere™ HIV-Combo. Both Xpert and HIV-Combo tests were performed in the laboratory by a laboratory technician. AHI-positivity according to the HIV-Combo was defined as reactivity on the p24 antigen and/or antibodies bars. Diagnostic test characteristics were evaluated for plasma (HIV-Combo-plasma) and whole blood (HIV-Combo-wb) when compared with Xpert testing.

Results: A total of 745 (HIV-Combo-plasma/Xpert) and 429 (HIV-Combo-wb/Xpert) paired test results were available. According to Xpert, 29/745 (3.9%) and 19/429 (4.4%) were AHI-positive. 26/745 (3.5%) were reactive on HIV-Combo-plasma and 16 (3.7%) on HIV-Combo-wb. Most positive test results with the HIV-Combo showed reactivity to antibodies only (76.9% HIV-Combo-plasma; 75.0% HIV-Combo-wb), and the remainder to p24 antigen (15.4%, 18.8%) only, or both p24 antigen and antibodies (7.7%, 6.3%). The receiver operating characteristic area was 0.93 and 0.89 for HIV-Combo-plasma and HIV-Combo-wb. The sensitivity tended to be slightly higher for HIV-Combo-plasma (86.2% vs 78.9%), and specificity was high for both tests (≥99.8%). The negative predictive value was above 99.0% for both tests, and the positive predictive values were 93.8% for HIV-Combo-wb and 96.2% for HIV-Combo-plasma.

Conclusions: The lateral flow POC HIV-Combo had the ability to diagnose most cases of AHI. It has potential for use in routine settings due to reduced costs and ease of use. However, further studies are needed to evaluate its performance when used in a routine outpatient care setting by lay counsellors on finger-prick samples.

PEB068

Establishment of a predictor risk score for the prioritization of patients for testing for Acute HIV Infection

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Background: Resource-poor settings hardly screen for acute HIV infection (AHI). One barrier is the lack of contextualized screening algorithms that would allow prioritization of patients for resource intensive diagnostic viral load (VL) testing. We developed a predictors risk score (PRS) algorithm that may assist health workers to select patients for AHI testing in Eswatini.

Methods: Adult outpatients with a HIV-negative or discordant test result according to the serial Alere™ Determine and Uni-Gold™ testing algorithm underwent VL testing (Xpert®) for the diagnosis of AHI at Nhlangano Health Centre, from March 2019 to March 2020. We defined AHI as a VL above 40 copies/mL. A nurse performed a physical examination and administered a questionnaire assessing risk factors of AHI. We used the least absolute shrinkage and selection operator (Lasso) method to determine factors for the prediction of AHI. Their beta-coefficients were rounded to the nearest integer to obtain predictor scores for each patient. Test characteristics of the PRS of the entire cohort for identification of AHI were described in comparison with Xpert testing results. Finally, the performance of four external PRS reported from Africa was assessed with receiver operating characteristic (ROC) curves statistics.

Results: Of 795 patients enrolled, 30 (3.8%) presented with AHI. The final PRS comprised the following factors with rounded beta-coefficients/risk scores: discordant rapid-diagnostic test result (4), women (1), feeling at risk of HIV (1), self-reported swollen glands (1), and fatigue (1). Two main cut-off points of the PRS were identified. At the cut-off of ≥2 points, sensitivity and specificity were 86.7% and 62.1%. At the cut-off of ≥3 points, sensitivity decreased to 50.0% and specificity increased to 91.8%. While NPV was ≥97.9% for both cut-off points, the PPV remained at ≤19.2%. Based on ROC statistics, the study-specific PRS (ROC 0.83) had the highest ability to correctly classify AHI cases while ROC statistics for external PRS ranged from 0.50 to 0.74.

Conclusions: PRS can identify patients at risk of AHI that would allow prioritization for diagnostic VL testing. Further studies should evaluate the routine use of PRS in public sector settings and validate external PRS before local use.

PEB069

Decline in HIV testing and changes in positivity rates during the COVID-19 pandemic

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Background: Patient visits to ambulatory care centers declined during the COVID-19 pandemic, which may affect HIV screening rates and hinder progress toward 90-90-90 targets. We assessed if HIV diagnostic test volume and positivity rates have changed compared to the pre-pandemic period.

Methods: The volume of the HIV diagnostic test, 4th generation HIV-1/2 antigen/antibody with nucleic acid confirmation, ordered in the United States and Puerto Rico Mar-Oct 2020 was compared to test volume ordered Mar-Oct 2019. Valid test results were interpreted per CDC guidelines. HIV positivity and acute infection rates were assessed by geography, and patient sex and age, and compared between the two time periods using the Z test for two population proportions; two-tailed p<0.05 was considered significant.

Results: HIV diagnostic test volume decreased 17.5% from 3.36 million in the period from March-October 2020 compared to the same period in 2019. HIV positivity rates also decreased (0.677% to 0.662%, p=.023), along with the proportion of positive tests that showed acute HIV infection (1.154% to 0.910%, p=.016).

Regional and state-level variability was seen in changes of positivity, with significant declines in the Southeast (0.849% to 0.764%, p<0.0001) and South Central regions (0.948% to 0.889%, p=.004), and a significant increase in the West (0.574% to 0.664%, p<0.0001).

Positivity increased in males (1.406% to 1.479%, p<.0001), specifically those aged <25 years (0.820% to 0.971%, p<.0001) and 25-40 years (1.504% to 1.600%, p=.0002). Males aged 25-40 years also experienced a significant decrease in the proportion of positive tests showing acute infection (1.271% to 0.897%, p=0.035).

In contrast, positivity decreased in females (0.256% to 0.229%, p<.0001), specifically those aged 25-40 years (0.164% to 0.148%, p=0.003). Females aged <25 years experienced a significant increase in the proportion of positive tests showing acute infection (2.105% to 5.611%, p=.028).

Conclusions: Diagnostic HIV test volume, positivity, and acute infection rates declined during the COVID-19 pandemic, but regional and sex-based differences were noted. State-specific restrictions and SARS-CoV-2 transmission concerns may affect healthcare engagement among those at high risk for HIV infection.

PEB070

The impact of COVID-19 on UNAIDS 90–90–90 targets calls for new HIV care models

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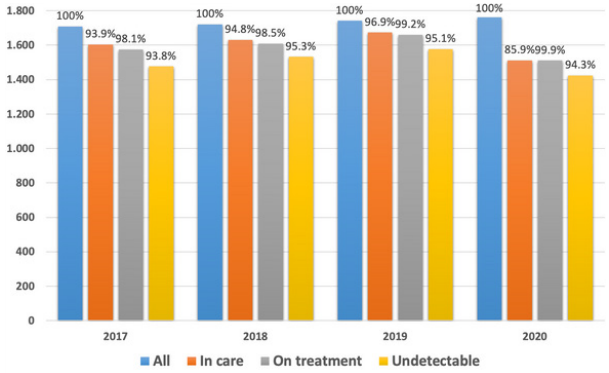
Background: The objective of the study was to compare the 2020 cascade of care during COVID-19 crisis with the trends observed in the 90–90–90 targets across the period 2017-2019 in people living with HIV (PLWH).

Methods: This observational study compared data of the period January-September across 2017-2020 in HIV outpatient Clinic of Modena, Italy. The first 90 was estimated using the formula: PLWH in care for the current year + PLWH who entered the care in the subsequent year – PLWH who died in the current year. The second 90 was calculated as a ratio of PLWH receiving antiretroviral therapy (ART) and PLWH who had a confirmed diagnosis of HIV infection. The third 90 was defined as a ratio of PLWH with undetectable HIV RNA and PLWH receiving ART for at least 6 months.

Results: 116 new HIV diagnoses were observed with no change of AIDS presenters. 67 deaths were also observed. The median age in 2020 was 54 (IQR: 45-59), 69.6% were males and median CD4 was 697 (IQR: 511-935). A significant loss in the 90-90-90 target objectives in 2020 when compared to 2017-2019 (p<0.01). The first 90% target was reduced from 96.9% to 85.9% (Figure 1). In 2020, 249 PLWH were lost to care. Predictors of loss to care were migrant status OR=1.5 (95%CI:1.04-2.14) and being resident outside Emilia-Romagna region OR=3.1 (95%CI: 3.1-2.2) after correction for sex OR=0.99 (95%CI:0.71-1.38) and age OR=0.98 (95%CI: 0.97-1.0).



Conclusions: We observed a reverse trend in HIV cascade that might be attributable to COVID-19 crisis. Understanding the impact of COVID-19 crisis in PLWH provides a meaningful and robust paradigm to re-design health services for PLWH in light of the COVID-19 era.

Viral load and CD4 measurement

PEB071

Expanding HIV-1 VL PT programs using a simple innovative technology

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Background: Proficiency testing (PT) is an essential part of quality assurance to assess the performance of laboratories conducting HIV-1 viral load (VL) testing. The number of conventional laboratories and point of care testing (POCT) sites needing VL PT continue to increase in support of the UNAIDS's goals of ending the AIDS epidemic by 2030. To address these gaps, we developed a simple technology to produce PT and transfer to low- and middle-income countries (LMIC).

Methods: Lyophilized HIV-1 virus preparations were evaluated by comparing VL values in dried tube specimen (DTS) samples prepared from virus stocks pretreated four ways: frozen-thawed; frozen-thawed-inactivated; frozen-thawed-lyophilized; or frozen-thawed-inactivated-lyophilized. DTS were prepared from lyophilized virus stock with two stabilizing matrixes, 3% bovine serum albumin (BSA) and 3% silk, stored at different temperatures and durations (4°C at eight weeks and one year and 45°C at two weeks) were evaluated. Two freeze/thaw cycles of four batches of lyophilized viruses were tested for reproducibility. This program was transferred to five countries (Ethiopia, India, Kenya, Senegal, and South Africa) and performance between 2015 and 2019 was verified.

Results: Results were comparable (±0.5 $\log_{10}$ copies/mL) for DTS samples prepared from different pretreated viruses. The frozen-thawed-inactivated-lyophilized virus was chosen because of its high temperature stability for DTS. DTS prepared from lyophilized virus with 3% silk showed consistent results across different storage temperatures and

durations while with 3% BSA showed inconsistent results. DTS results were comparable for all four batches of lyophilized virus up to two freeze/thaw cycles at -20°C storage. Results from PT Programs providers in five countries were within acceptable criteria.

Conclusions: Results demonstrate that the use of lyophilized virus for PT panel production is a simple, stable, transferable, adaptable, and sustainable approach to address the needs for expansion of HIV-1 VL PT programs in LMIC. Results indicate successful expansion of PT programs to LMIC through Ministries of Health for country ownership and sustainability. This technology will enable further program expansion, which includes rapid VL scale-up for conventional laboratories and POCT in pediatric, pregnant and breastfeeding women.

PEB073

A multipronged strategy to improve viral load testing coverage in Liberia

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Background: Liberia has an estimated 40,000 persons living with HIV (PLHIV), 16,000 of whom are on antiretroviral therapy (ART). The national viral load (VL) testing coverage rate was below 35% in 2019, and the viral suppression rate among those tested was only 66%. To improve VL monitoring, the USAID/PEPFAR-funded EpiC project introduced a VL coverage acceleration plan across 17 ART facilities where 70% of the country's PLHIV receive ART services.

Description: From February to March 2020, EpiC engaged government, and civil society partners to introduce specific strategies to address VL testing supply and demand issues. A hub-and-spoke system to link facilities to the 20 GeneXpert machines available in the country for processing VL samples was designed to better distribute testing volume according to lab capacity. In addition, volunteers from a network of PLHIV with physician and nursing assistance qualification were selected and equipped to facilitate pre-clinic health talks and adherence counseling with VL-focused information, education, and communication (IEC) materials; conduct VL sample collection and transport to VL labs for processing; return results for quick clinical decision making; track and provide intensive support to PLHIV with non-suppressed VL through home visits and phone calls.

Lessons learned: National VL testing coverage increased from 1,314 tests in the quarter preceding the intervention (October–December 2019) to 3,057 in the quarter afterwards (April–June 2020). The increase in testing coverage also corresponded with an improved viral suppression rate during the same timeframe, from 66% to 75%. Demand for VL testing increased among PLHIV and, with better VL coverage and results utilization, more PLHIV have been transitioned to more convenient differentiated ART services.

Conclusions/Next steps: PLHIV who are health workers can play a critical role in improving VL monitoring by bridging logistical gaps between the ART clinic and VL labs, providing effective adherence counseling, and offering targeted, client-centered support for those who are virally unsuppressed. A hub-and-spoke system helped distribute VL workload between limited labs to ensure effective coverage. Pre-clinic adherence counseling and VL-focused IEC materials generated demand for VL testing among PLHIV. These strategies will be scaled to other facilities to optimize and sustain national VL monitoring in Liberia.

PEB074

Monitoring for advanced disease in the UTT era: trends in CD4 count testing volumes among patients presenting for HIV care in South Africa

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Background: South Africa eliminated CD4 criteria for ART eligibility in 2016 under its Universal Test and Treat (UTT) policy. However, CD4 count at entry into care remains an important marker of disease progression, and national guidelines specify patients should still have a CD4 count at presentation. We quantified first CD4 count testing volumes in Ekurhuleni District, as captured in two databases used for capturing patient-level clinical data.

Methods: We analyzed data on all CD4 counts recorded within the Three Interlinked Electronic Registers (Tier.net) database and National Health Laboratory Services (NHLS) National HIV Cohort. We defined "CD4 count at presentation" as the first CD4 test for each patient within each database. We assessed volumes and compared trends of tests conducted within Ekurhuleni district, Gauteng, between January 2004 and March 2018. Changes in volumes with the implementation of UTT in September 2016 and Same-Day Initiation (SDI) of treatment in September 2017 were also assessed.

Results: A total of 850,672 (NHLS) and 527,835 (Tier.net) individuals with a first CD4 count from 92 facilities were analyzed. First CD4 count testing volumes increased from 2004 reaching over 84,000 in 2011 within NHLS. Decreasing trends were observed starting in 2011 and persisted during the UTT era (Figure 1).

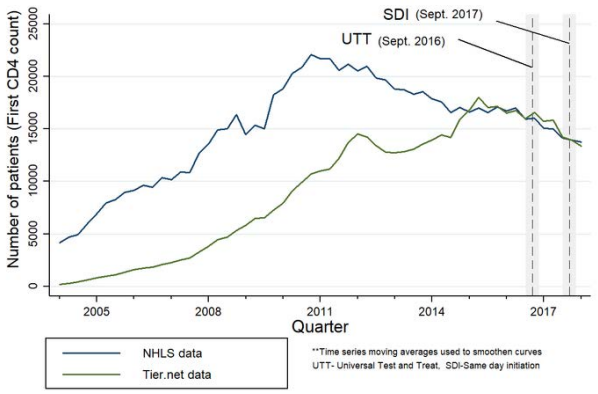

Figure 1. Number of patients with first CD4 count by quarterly calendar period from January 2004 - March 2018 in NHLS and Tier.Net

Tier.net data which were back-captured in the early years of the treatment program lagged behind until 2015, after which similar trends were observed. First CD4 test volumes fell by about 26% from August 2016, a month before UTT, to March 2018 in both databases. However, we detected no immediate drop following UTT and SDI policies.

Conclusions: Since the treatment expansion of eligibility with UTT, first CD4 test volumes have declined. However, as these modest declines continue, a trend of falling test volumes since 2011 may reflect falling numbers of people entering HIV care over time, rather than changes in clinical practice.

PEB075

Viral load in adults switching to DTG-BASED first-line ART in Malawi and Zambia

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Background: Switching patients to Dolutegravir-based ART despite detectable viral load could increase the risk of emerging resistance. We studied people living with HIV (PLHIV) who were switched to a DTG-based regimen in Southern Africa.

Methods: The SWITCH Study is a prospective cohort of 2818 PLHIV on first-line ART who switched to a DTG-based ART in routine care in two ART programs in Malawi and Zambia. In Malawi, PLHIV are switched irrespective of viral load (VL) whereas only those with a previous VL <1000 copies/mL are switched in Zambia. Adult PLHIV on ART for at least 6 months were recruited. At switch, and after 48 and 96 weeks, participants provide a blood sample for VL and drug resistance testing. Here we calculated the percentage of PLHIV who switched with VL >400 copies/mL by sex, age, ART program, and ART duration and examined differences in logistic models.

Results: Viral load at switch was available for 2,712 (96.2%) PLHIV; 1,306 (93.3%) in Malawi and 1,406 (99.2%) in Zambia (Table). The median age was 37 years (IQR 31–43), and 90.7% (2,460) were women. 112 PLHIV (4.1%) switched to a DTG-based regimen with VL >400 copies/mL. The proportion was higher in Malawi (5.4%) than in Zambia (3.0%; P=0.002) and higher in younger (8.0% in 18-29 year-olds) and older PLHIV (4.5% in 50+ year-olds) than in middle-aged PLHIV (1.9% in 40-49 year-olds; P<0.001). It decreased with ART duration, from 7.7% for <1 year to 2.1% for >8 years (P=0.002). It was higher in those with a last VL ≥1000 (46.7%) than in those with a VL <1000 copies/mL (3.4%; P<0.001). In the multivariable model adjusted for sex, age, ART program, years on ART and last viral load, a last VL >1000 copies/mL was strongly associated with switching with >400 copies/mL (aOR 19.5; 95%CI 6.5-58.4). The difference between the two countries was attenuated (aOR 1.58; 95%CI 0.97-2.57).

Conclusions: Given that NNRTI drug resistance in Malawi and Zambia is estimated at 5-10% or higher, the proportion of PLHIV switching with >400 copies/mL is lower than expected. The Zambia policy to switch PLHIV with a VL <1000 copies/mL appears to be effective.

ART adherence measurement

PEB076

No difference in urine tenofovir levels in patients living with HIV on unboosted vs dose-adjusted boosted tenofovir alafenamide

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Background: Tenofovir alafenamide (TAF) is increasingly used in HIV treatment, with or without agents that require pharmacologic boosters like ritonavir/cobicistat. Boosters increase TAF levels, so the TAF dose is lowered in single pill combinations. We hypothesized that individuals on dose adjusted boosted TAF would have similar urine tenofovir (TFV) concentrations to those on unboosted TAF.

Methods: We collected urine samples from patients with HIV on TAF with evidence of virologic suppression (most recent HIV RNA <200 copies/ml) who reported daily adherence at two San Francisco clinics from June 2019-January 2020. We measured urine TFV levels by liquid chromatography/tandem mass spectrometry (LC-MS/MS) and used linear regression to compare natural log-transformed urine TFV levels for patients on TAF plus a booster to those on unboosted TAF.

Results: Our analysis included 30 patients on unboosted TAF (25mg daily) and 15 on boosted TAF (12 on 10mg daily TAF, 3 on 25mg). Patients on unboosted vs. boosted TAF were similar in baseline median age (56 vs 54 yrs), weight (84 vs 80 kg), gender (83% and 80% male), and creatinine (1.1 vs 1.0 mg/dL). The median (IQR) urine TFV levels were 4.14 (2.03, 6.56) and 4.27 µg/mL (2.73, 5.51) respectively**.** In unadjusted univariate linear regression, there were no statistically significant differences in urine TFV levels based on presence/absence of a booster following TAF dose-reduction to 10mg [geometric mean ratio (GMR) 1.07; 95% CI: 0.53-2.16]. This finding was unchanged in adjusted analysis accounting for gender, age, creatinine, and weight (GMR 1.10; 95% CI: 0.53-2.28, Table 1).

Variable	Geometric mean ratio	Standard Error	95% Confidence Interval	P-value
TAF dose				
Unboosted TAF (25 mg)	reference	--	--	--
Boosted TAF (10 mg)	1.10	0.36	0.53- 2.28	0.80
Boosted TAF (25 mg)	1.46	0.62	0.41- 5.12	0.55
Creatinine	1.32	0.61	0.38-4.56	0.65
Age per ten years	0.82	0.14	0.62- 1.08	0.16
Gender	1.35	0.34	0.68- 2.70	0.38
Natural log-transformed weight in kilograms	0.57	0.73	0.13- 2.51	0.45

Table 1: Adjusted Linear Regression Analysis for Boosted vs. Unboosted Tenofovir Alafenamide (TAF) and Urine Tenofovir Levels by LC-MS/MS in People Living with HIV with Virologic Suppression on TAF-based Antiretroviral Therapy

Conclusions: No significant differences in urine TFV levels were seen for patients on unboosted vs. boosted dose reduced TAF. These results have important implications for our forthcoming point-of-care urine immunoassay for TAF, implying that separate adherence cut-offs will not be necessary for patients on boosters and dose-reduced TAF. A single POC TAF immunoassay will thus support monitoring on most TAF-based antiretroviral therapy.

PEB077

Effect of digital adherence tools on adherence to antiretroviral treatment among adults living with HIV in Kilimanjaro, Tanzania: a randomised controlled trial

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Background: Lifelong adherence to antiretroviral treatment (ART) remains challenging for people living with HIV (PLHIV). Interventions should target multiple barriers to adherence. The aim of this study was to investigate whether any of two digital adherence tools (DAT) could improve adherence compared to standard card among PLHIV in Kilimanjaro, Tanzania.

Methods: We performed a parallel three-arm non-blinded randomized controlled trial with 1:1:1 allocation. We included adults aged between 18 and 65 years, living in Kilimanjaro Region, on ART for at least six months. Importantly, their adherence, as judged by the study nurses, had to be suboptimal. They also had to be able to read and understand SMS. In one arm, participants received reminder short message service (SMS)-texts followed by a question-SMS. In the second arm, participants received a real-time medication monitoring (RTMM) device (Wisepill®). If intake was not on time, participants received an SMS-reminder. In the third arm, participants received standard care only. The primary outcome of mean adherence over 48 weeks based on pharmacy refill data and self-report was compared between arms using between-group t-tests in a modified intention-to-treat analysis.

Results: In each arm, we randomized on 83 participants; Eighty-two participants in the RTMM arm, 80 in the SMS-arm and 81 in the standard care arm were part of analysis. Mean average (over 48 weeks) adherence in the SMS, RTMM and control arm was 89.6%, 90.6% and 87.9% for pharmacy refill; 95.9%, 95.0% and 95.2% for self-report in the past week; and in the past month 97.5%, 96.6% and 96.9% (p-values all not statistically significant).

Conclusions: DATs did not improve adherence to treatment and treatment outcome in PLHIV. A Hawthorne effect leading to improved adherence in the control group as compared to actual standard care and limited intervention coherence may have led to this finding.

Drug resistance testing

PEB079

HIV-1 drug resistance mutations in proviruses of early treated infants in Botswana

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Background: Despite early infant ART, reservoirs may harbour transmitted drug resistance mutations (DRMs) but their respective detectability in intact vs defective proviruses, and its clinical correlation, are unknown.

Methods: We analyzed 257 HIV-1 full-length proviral sequences (FLS) obtained by Illumina next-generation sequencing from PBMCs from 27 infants with HIV who started treatment in the first week of life in the Botswana EIT Study (ClinicalTrials.gov NCT02369406). Sanger sequencing of *pol* was performed for 22 mothers at delivery, and at clinical failure in children. DRMs were identified using the Stanford HIV Drug Resistance Database.

Results: Infant PBMCs were obtained at a median of 2 days (range 1, 32), with median HIV proviral load 492 copies/mL [IQR: 78, 1246 copies/mL]. Cell associated HIV DRMs were detected in 9/27 (33.3%) infants within 1 month of life. A total of 106 (41.3%) intact proviral sequences had at least 1 DRM; 29.2% had NNRTI, 7.5% NRTI, 0.9% PI and none with INSTI associated mutations. A total of 151 (58.7%) defective proviral sequences had at least 1 DRM; 31.8% NNRTI, 15.2% NRTI, 5.3% PI and 15.5% INSTI associated mutations. Higher frequency of DRM were detected in defective proviruses compared to intact infant proviruses, although not statistically significant (p= 0.14). The predominant NRTI, NNRTI, PI and INSTI associated mutations were M184I, M230I, D30N and G140R respectively, but direct exposure to these drug classes was not identified for PI or INSTI mutations. Archived proviral DRMs were detectable at later clinical rebound on only one occasion.

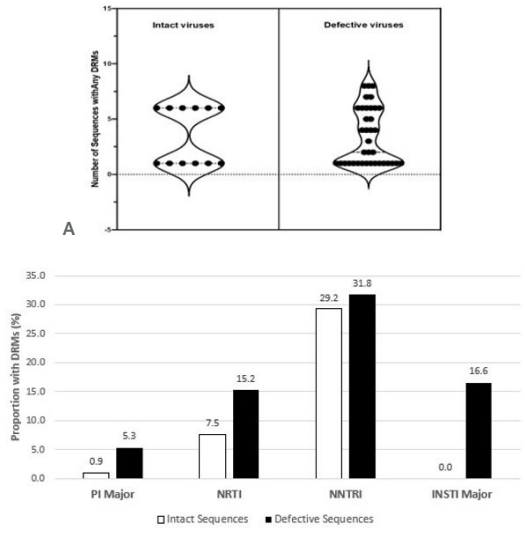

Figure 1. Frequency of any drug resistance mutations between intact and defective proviruses of infants within 1 month of life

Conclusions: The higher frequency of multiple HIV DRMs within defective proviruses warrants further study as this may overestimate presence of true DRMs in cases where defective and intact proviruses are not differentiated. The impact of proviral DRMs on long-term treatment outcomes warrants further investigation.

PEB080

Integrase genotyping is highly effective on diverse HIV-1 non-B clades circulating in Cameroon: toward a successful transition to dolutegravir-based regimens in Africa

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Background: Transition to dolutegravir-based regimens as preferred first-line antiretroviral therapy (ART) is underway in several African countries. A successful transition requires a thorough routine monitoring of integrase drug resistance for a long-term effectiveness of these drug regimens.
However, subtype diversity could impair integrase genotyping efficiency in Africa. We thus sought to evaluate the performance of our in-house integrase genotyping assay on a wide range of HIV-1 viral loads and clades.
Methods: We conducted a study among HIV-infected patients seen routinely from February 2019 through January 2021 at the CIRCB Virology laboratory in Cameroon. HIV-1 integrase sanger-sequencing was performed; sequence quality was validated following the WHO operational framework; and phylogeny was done using MEGAv.7. Desirable and fair sequencing rates were set at ≥80% and 60-79% respectively; then performance was stratified by viremia and subtype coverage was determined.
Results: Out of 188 (8 INSTI-exposed and 180 INSTI-naïve) patients enrolled, 127 had a viremia >1000copies/mL (i.e. WHO threshold for genotypic resistance testing in RLS). According to viremia, the sequencing performance was 81.10% (103/127) with >1000copies/mL versus 64.71% (11/17) with 500-1000copies/mL, p=0.11; and 45.45% (20/44) with<500copies/mL, p<0.0001. Of the 134 integrase sequences generated, 14 different subtypes were found: CRF02_AG (76), A1 (12), G (10), F2 (9), CRF11_cpx (9), CRF06_cpx (5), D (4), CRF01_AE (2), CRF18_cpx (2), A2 (1), CRF13_cpx(1), CRF26_AU (1), CRF36_cpx (1), and CRF37_cpx (1). Regarding INSTI-resistance, the only patient with therapeutic failure, after subsequent exposure to raltegravir and dolutegravir, was found with major integrase resistance associated mutations (L74I, E138KQ, G140A, Q148R, S147G and E157Q).
Conclusions: Our developed in-house HIV-1 integrase genotyping is highly effective on non-B clades, with a desirable performance for patients experiencing virological failure (>1000copies/mL) and an acceptable performance at low-level viremia of 500-1000copies/mL (early failure range).
Additionally, its wide subtype coverage underscores the usefulness of this assay for the surveillance of HIV-1 integrase resistance, to monitor the scale-up of dolutegravir-based regimens in African RLS.

Diagnosis of co-infections and co-morbidities

PEB081

Combination of Xpert® MTB/RIF and Determine™ TB LAM assay improves the diagnosis of extrapulmonary tuberculosis at Jimma University Medical Center, Southwest Ethiopia

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Background: Ethiopia is one of the high burden countries for extrapulmonary tuberculosis (EPTB); however, the prompt diagnosis of EPTB remains challenging. This study is aimed to evaluate the diagnostic performance of Xpert MTB/RIF and Determine TB LAM assay for the prompt diagnosis of EPTB in Ethiopia.
Methods: A total of 147 presumptive EPTB patients, including 23 HIV positive participants were enrolled. Extra-pulmonary samples were collected from all presumptive EPTB cases and examined for tuberculosis (TB) using fluorescent microscopy, Xpert MTB/RIF and culture. Additionally, urine samples were also collected from 126 participants and were tested by Determine TB LAM test (Alere Inc, Waltham, USA). Sensitivity and specificity of Xpert and TB LAM tests were calculated by comparing with a composite reference standard (CRS), which comprises smear microscopy, culture and response to empirical anti-TB treatment.
Results: Of 147 patients, 23(15.6%) were confirmed TB cases (culture-positive), 14 (9.5%) were probable TB (clinically, radiologically or cytologically positive and received anti-TB with good response), and 110 (74.8%) were classified as "non-TB" cases because of no evidence for TB. The overall sensitivity and specificity of Xpert MTB/RIF were 43.2% and 100%, respectively with the highest sensitivity for abscess (85.7%) and lower sensitivity for pleural fluid (14.2%) with 100% specificity for all specimen types. The sensitivity and specificity of TB LAM test were 30.6% and 93.3% respectively with the highest sensitivity for HIV co-infected participants (66.7%). The combination of Xpert MTB/RIF and TB LAM test detected 61.1% of all EPTB participants and 83.3% of HIV co-infected TB cases.
Conclusions: Determine TB LAM assay has low sensitivity for EPTB diagnosis; however, the combination of TB LAM and Xpert MTB/RIF improves the diagnosis of EPTB particularly for countries with high EPTB and HIV cases.

PEB082

Serum CA-125 in the diagnosis and therapeutic monitoring of tuberculosis in HIV infected patients

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Background: The diagnosis of active tuberculosis (TB) in patients with human immunodeficiency virus (HIV) co-infection is challenging, and few biomarkers are available to aid diagnosis. Serum CA-125 is a host biomarker elevated in pulmonary and extra-pulmonary TB in HIV-uninfected individuals. We investigated the use of serum CA-125 in the diagnosis of active TB with HIV co-infection.

Methods: We conducted a retrospective, case-control analysis of CA-125 in 109 stored serum samples of individuals with active TB disease compared to TB-uninfected controls, with or without HIV co-infection. Samples were collected from February to September 2009 by the Perinatal HIV Research Unit, South Africa. Kruskal-Wallis with Dunn's post-test was used for multiple groups and Wilcoxon matched-pairs signed-rank test for pre and post-treatment values.

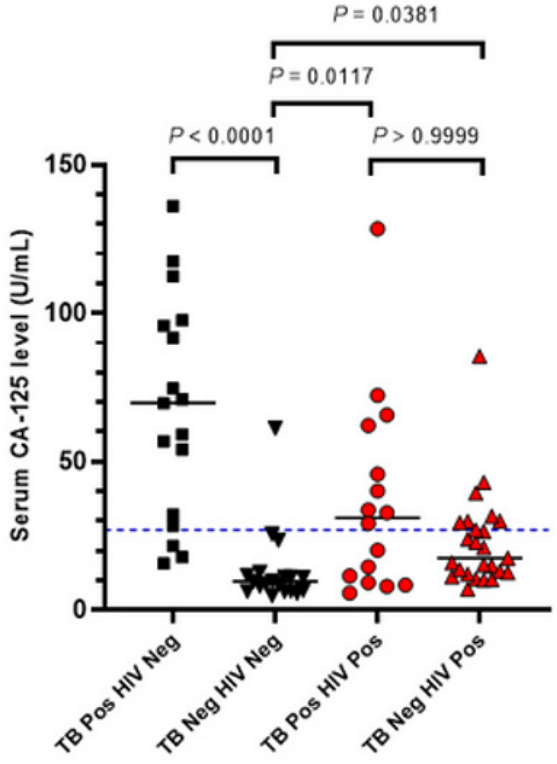

Figure: Serum CA-125 in the four groups
The dotted blue line represents the proposed cut-off (27 U/mL) for using CA-125 to diagnose active TB in HIV-uninfected patients.

Results: In HIV-uninfected individuals, pre-treatment measured serum CA-125 was significantly higher in the TB group compared to healthy controls (Figure). Using a receiver operating characteristic (ROC) curve, CA-125 had a sensitivity 82%, specificity 95%, positive predictive value (PPV) 93%, and negative predictive value (NPV) 86% at a threshold value of 27 U/mL (area under the curve, AUC = 0.96) (Figure, dotted blue line). Two months post-treatment, measured serum CA-125 declined significantly ($P < 0.0017$).

HIV-infected individuals showed no significant difference in measured serum CA-125 between those with and without active TB (Figure). At a threshold of 28 U/mL, CA-125 had sensitivity 56%, specificity 72%, PPV 56% and NPV 72% (AUC = 0.59). Following two months of TB treatment, measured serum CA-125 was not statistically different from pre-treatment levels.

Conclusions: Serum CA-125 level has potential for the diagnosis and therapeutic monitoring of TB in HIV-uninfected patients with the advantage of being a blood-based assay.

PEB083

Values & preferences on hepatitis C self-testing among populations at increased risk of HCV, healthcare workers, and the general population: a multi-country rapid qualitative assessment

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Background: Over 70 million people worldwide are infected with hepatitis C virus (HCV), but majority of them remain undiagnosed. To reach global HCV elimination goals, improving access to HCV testing is necessary to increase populations' knowledge of their HCV status facilitating linkage to treatment. HCV self-testing (HCVST) is an innovative approach that may enable testing those not reached by current testing approaches. We explored values and preferences of targeted end-users of HCVST to inform development of global normative guidance.

Methods: The assessment was conducted in Brazil, Costa Rica, India, Indonesia, Kyrgyzstan, Philippines, Rwanda, South Africa, Thailand, Ukraine, and was comprised of individual interviews, group interviews, and participatory action research activities. All assessments were guided by a Master Protocol.

Depending on local COVID-19- restrictions, activities were done face-to-face and/or over telephone/web-based platform. Informed consent was obtained for all participants. A thematic analysis was conducted to analyze findings.

Results: Of the 920 participants 66% were at-increased-risk individuals, 16% general population, and 18% healthcare workers. There were participants who appreciated that HCVST is an innovative tool that

could increase awareness of HCV status and motivate users to seek further HCV care, as well as a good option to easily test in private and keep results confidential. Disadvantages identified were the possibility of errors if the test instructions are not clear, as well as the potential for psychosocial harm. Participants acknowledged the need of confirmatory testing following a reactive HCVST. Participants preferred that HCVST service delivery models should be tailored to local contexts and accompanied by information and awareness related to HCV prevention, treatment, and care. Many participants preferred HCVST kits to be offered free of charge, to at least the most underserved groups, that HCVST kit instructions be accompanied by illustrations and links to video-tutorials. Participants strongly felt that care must be taken to avoid creating new stigma towards already stigmatized groups.

Conclusions: HCVST is perceived to be a valuable tool which could increase testing for HCV. Future research is warranted on acceptability and feasibility of different service delivery models to ensure that people using HCVST have paths to access confirmatory testing and HCV treatment.

Tuberculosis and other mycobacteria

PEB084

Gender differences among patients with drug resistant tuberculosis and HIV co-infection in Uganda: a countrywide retrospective cohort study

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Background: Gender differences among patients with drug resistant tuberculosis (DRTB) and HIV co-infection could affect treatment outcomes. We compared characteristics and treatment outcomes of DRTB/HIV co-infected men and women in Uganda.

Methods: We conducted a retrospective chart review of patients with DRTB from 16 treatment sites in Uganda between January - March 2020. Eligible patients had confirmed DRTB, HIV co-infection and a treatment outcome registered between 2013 and 2019. We compared characteristics and tuberculosis treatment outcomes between men and women using Pearson's chi-square test for categorical variables, two sample Kolmogorov–Smirnov test for continuous variables and predictors of mortality were determined by cox proportional hazard regression analysis. Statistical significance was set at $p<0.05$ at the 95% confidence interval (CI).

Results: Of 666 DRTB/HIV co-infected patients, 401 (60.2%) were men. The median (IQR) age of men and women was 37.0 (13.0) and 34.0 (13.0) years respectively ($p<0.001$). Men were significantly more likely to be on tenofovir-based antiretroviral therapy (ART) and to have history of cigarette or alcohol use. They were also more likely to have multi-drug resistant TB, Isoniazid and Streptomycin resistance and had higher creatinine, aspartate and gamma-glutamyl aminotransferase and total bilirubin levels. Conversely, women were more likely to be unemployed, unmarried, and to have anemia, a capreomycin-containing DRTB regimen and zidovudine-based ART. Treatment success was observed among 437 (65.6%) and did not differ between the sexes. However, mortality was higher among men (25.7% vs. 18.5%, $p = 0.030$) and men had a shorter mean (standard error) survival time (16.8 (0.42) vs. 19.0 (0.46) months), Log Rank test ($p = 0.046$). Predictors of mortality, independent of gender, were cigarette smoking (HR = 4.87, 95%CI 1.28 – 18.58, $p = 0.020$), an increase in alanine aminotransferase levels (HR = 1.05, 95%CI 1.02 – 1.07, $p<0.001$), and history of ART default (HR = 3.86, 95%CI 1.31 – 11.37, $p = 0.014$) while a higher baseline CD4 count was associated with lower mortality (HR = 0.94, 95%CI 0.89 – 0.99, $p = 0.013$ for every 10cells/mm^3 increment).

Conclusions: There are several socio-demographic and clinical differences between men and women with DRTB/HIV co-infection which could explain the higher mortality in men.

Viral hepatitis A, B, D and E

PEB086

Epidemiological trends of hepatitis B morbidity and mortality in Greece, Italy, Portugal and Spain, 2000-2019: a systematic analysis from the Global Burden of Disease Study 2019

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Background: Viral Hepatitis remains a health priority. We performed a comprehensive evaluation of epidemiological HBV estimates in Southern Europe and assessed the impact of the 2008 economic crisis on HBV burden.

Methods: We analyzed data of the Global Burden of Diseases to describe the patterns of six measures of HBV burden (prevalence, incidence, mortality, years lived with disability [YLDs], years of life lost [YLLs], disability adjusted life years [DALYs]) in Greece, Italy, Portugal, Spain. We assessed age-standardized rates (per 100,000 population) between 2000-2019, disaggregated by sex and age, and compared the annualized age-standardized rate of change (ARC%) in 2000-2010 (pre-austerity) and 2010-2019 (post-austerity).

Results: Overall, males were more affected than females. Regarding acute HBV, Greece presented the highest rates (fig.1A). Similar to Western Europe (WE) all countries showed decreasing trends of prevalence (pre-austerity ARC: -1.56%; post-austerity ARC: -2.24%), incidence (-1.56%;-2.24%), YLDs (-0.97%;-1.40%). Mortality decreased more in the pre-austerity than in the post-austerity period for Italy (-1.77%;-0.86%), Portugal (-17.26%;-2.01%) and Spain (-1.08%;-0.01%).

An opposite mortality pattern was observed in WE (-0.49%;-3.84%), while in Greece, pre-austerity estimates sharply increased (12.94%;-10.64%). Greek patients ≥70 years old had the highest mortality rate (1.22, 95%UL:0.88-1.53, in 2019). Regarding cirrhosis and other chronic

liver diseases (fig.1B) the six measures showed declining trends across all locations. Greece had the highest prevalence rate with 1374.6 (95%UI 1261.1–1505.6) in 2019. Mortality decreased more in the pre-austerity than in the post-austerity period: WE (-4.71;-2.96), Greece (-7.73;-0.81), Italy (-5.60;-1.85), Portugal (-8.07;-4.26), Spain (-8.36;-3.48), similarly to incidence, YLDs, YLLs, DALYs.Mortality rates of liver cancer have been relatively stable in all countries except for Greece (0.59%;1.36%,fig.1C).

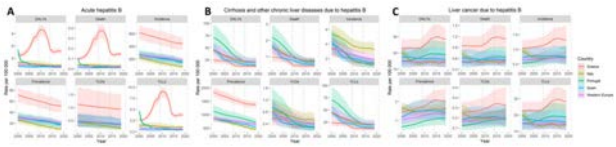

Figure 1 - Acute and chronic HBV age-standardized rates from 2000 to 2019

Conclusions: This information is critical for the global plan for eliminating hepatitis. Elimination of HBV by 2030 as endorsed the Global Health Sector Strategy remains a challenge.

PEB087

Molecular diversity of hepatitis B virus in HIV infected patients at Mbagathi District Hospital, Nairobi

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Background: With increasing access to antiretroviral therapy across Sub-Saharan Africa, HIV-infected individuals live longer and are frequently co-infected with HBV due to similar transmission routes. Patients who are co-infected with HIV and HBV progress more rapidly to end-stage liver disease. With 8-15% genomic divergence by DNA sequence, HBV is currently classified into ten genotypes (A-J), with various subtypes. HBV genotypes have been clarified as influencing the clinical outcome of the chronic disease in hosts.
Considering paucity of data on HBV genotypes in HIV-HBV co-infected patients in Kenya and the significance of HBV variants in antiretroviral therapy response, a study had to be conducted to determine the molecular diversity of Hepatitis B Virus and compare the HBV genotypes in HIV infected patients in Kenya with those identified elsewhere.
Methods: This was a cross-sectional study consisting of 180 HIV seropositive male and female individuals attending routine CD4+ T-lymphocyte and Viral load laboratory monitoring. An ELISA for qualitative detection of HBsAg in Human serum was used and HBV DNA was extracted from 9 HBsAg seropositive samples and HBV genotypes established in 5 nucleic acids by nested-PCR of pre-S gene, direct sequencing and phylogenetic tree clustering.
Results: The HBV prevalence was found to be 5.0% serologically and 2.8% by PCR. This study shows the HBV genotype A1(60%) and D (40%) are the most prevalent in Kenya and in this study, they showed very low genetic diversity. In addition, these strains showed very close phylogenetic relationship to those isolated from Sudan, S. Africa, Botswana and Tunisia. The five isolate genotypes were found to have susceptible mutations in S gene for Lamivudine, Adefovir, Entecavir and Tenofovir.
Conclusions: Inadequate HBV co-management in HIV-HBV co-infected patients is likely to lead to the emergence and circulation of HBV escape mutants of interest to public health management and there may be high HBV drug resistance strains to available ART options in Kenya among HIV patients.

Viral hepatitis C

PEB088

Clinically relevant depressive symptoms and initiation of hepatitis C virus (HCV) treatment in the HIV-HCV co-infected population in Canada

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Background: Psychiatric illness was a major barrier for Hepatitis C virus (HCV) treatment during the interferon (IFN) era due to medication-related neuropsychiatric side effects. While direct acting antivirals (DAA) are better tolerated, patient-level barriers to treatment initiation persist.
We assessed the effect of depressive symptoms on time to HCV treatment initiation among HIV-HCV co-infected persons during the IFN (2003-2010) and second-generation DAA eras (2013-2020).
Methods: We used data from a multicentre prospective cohort, the Canadian Co-infection Cohort and its associated food security substudy. We used marginal structural Cox proportional hazards models with inverse weighting for competing risks (death) to assess effect of predicted depressive symptoms on time to treatment initiation among HCV RNA+ participants. Depressive symptoms were predicted by a random forest classifier derived using the Center for Epidemiologic Studies Depression Scale-10. Exposure misclassification was addressed using predictive value-based record-level correction.
Results: We included 535 and 1,127 participants, from the IFN and DAA eras respectively, with 51% and 64% reporting baseline depressive symptoms. Treatment initiation rates increased from 9 (95%CI:8-11) to 21 (95%CI:19-22) per 100 person-years.
Results (table 1) indicate lower treatment initiation among those with depressive symptoms compared to those without in the IFN era and higher initiation among those with depressive symptoms in the DAA era. Effect attenuation was observed after misclassification correction.

Treatment era	Without exposure misclassification correction		With exposure misclassification correction	
	HR	95% CI	HR	95% CI
IFN era - 2003-2010	0.61	0.40-0.93	0.78	0.66-0.90
DAA era - 2013-2020	1.32	1.07-1.63	1.15	1.07-1.23

Table 1: Model results comparing association of depressive symptoms with HCV treatment initiation in the IFN and DAA eras
Abbreviations: IFN: Interferon, DAA: Direct acting antivirals, HR: Hazard ratio, CI: Confidence interval

Models were adjusted for - Baseline confounders: age, gender, race/ethnicity, education level, sexual orientation, previous IFN-based HCV treatment, immigration, marital status and province; Time varying confounders: living situation, employment, income, revenue source, injection drug use, alcohol use, smoking, incarceration, fibrosis stage, HIV viral load, CD4 count and antidepressant use.

Conclusions: Depression may no longer be a barrier to HCV treatment in the DAA era. The relatively higher rates of treatment initiation in patients with depressive symptoms suggest those previously unable to tolerate IFN are now accessing treatment.

PEB089

Hepatitis C reinfection risk following successful therapy among people living with HIV: a global systematic review, meta-analysis, and meta-regression

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Background: Varied rates of HCV reinfection after treatment have been reported among people living with HIV (PLHIV), which could jeopardize elimination efforts in some populations. The aim of this systematic review was to assess HCV reinfection incidence and identify factors associated with reinfection among PLHIV.

Methods: For studies evaluating post-treatment HCV reinfection among PLHIV, we searched bibliographic databases and conference abstracts. Meta-analysis was used to pool rates of reinfection and meta-regression was used to explore heterogeneity across studies.

Results: A total of 37 studies were included (13,009 person-years [PY] of follow-up). The overall incidence of HCV reinfection was 3.85/100PY (95%CI 2.82–5.27). Reinfection rates were 5.89/100PY (95%CI 4.41–7.87) among HIV-positive men who have sex with men (MSM) and 3.29/100PY (95%CI 2.01–5.39) among HIV-positive people who inject drugs (PWID). Among MSM, reinfection incidence was 4.75/100PY (95%CI 3.17–7.11) among those who had never injected drugs, 4.13/100PY (95%CI 2.21–7.69) among those who ever injected and 9.17/100PY (95%CI 5.93–14.17) among those for whom no injecting risk data were collected. Among PWID, reinfection rate among studies who restricted the study population to people with recent injecting drug use was 5.49/100PY (95%CI 2.08–14.48). Reinfection rates were comparable following interferon-based (4.45/100PY [95%CI 2.86–6.91]) and direct-acting antiviral treatment (3.95/100PY [95%CI 2.46–6.33]). Reinfection rate was higher among those treated for recent HCV (8.16/100PY [95%CI 5.77–11.54] compared to that among people treated for chronic HCV infection (2.87/100PY [95%CI 1.95–4.22]). In meta-regression analysis, incidence was significantly higher in studies with higher proportion of PWID in the study population (100% PWID vs <100% PWID; adjusted rate ratio [aRR] 4.94; 95%CI 1.96–12.44) and following treatment of recent HCV (recent HCV vs chronic HCV; aRR 2.61; 95%CI 1.03–6.59).

Conclusions: HCV reinfection risk following treatment among HIV-positive MSM is high irrespective of injecting status. This suggests that reinfection prevention services need to focus on a range of different modalities directed to possible sources of risk. Further, people with recent HCV are at higher risk of reinfection given likelihood of ongoing risk behaviour for transmission.

PEB090

Achieving an extremely high hepatitis C treatment success rate in people who inject drugs in Hai Phong, Vietnam: results of the ANRS 12380 DRIVE-C study

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Background: People who inject drugs (PWID) are a major population affected by hepatitis C virus (HCV) worldwide. DRIVE-C study aimed to assess the effectiveness and the impact of a community-based strategy for HCV mass screening associated with a simplified integrated hospital-based care, which may have the potential to eliminate HCV among PWID. Here, we evaluated the HCV treatment outcomes.

Methods: From October 2018 to August 2019, PWID living in Hai Phong were screened for HCV serology, and HCV RNA when positive, during both a respondent-driven sampling (RDS) survey and cohort follow-up visits of the Drug use & Infections in Vietnam (DRIVE) study, a community-based research programme. PWID with detectable HCV RNA were referred by members of community-based organisations (CBO) to one of the study clinics located in three public hospitals in Hai Phong.

The free of charge pan-genotypic treatment consisted of a 12 weeks sofosbuvir-daclatasvir regimen, with ribavirin if cirrhosis. CBO members intervened for RDS survey implementation, linkage and retention to care, drug delivery modalities in clinics, drug adherence counselling and harm reduction activities at community sites. The sustained virologic response (SVR) was assessed 12 weeks after the end of treatment.

Results: Among 1201 PWID screened with a detectable HCV RNA, 1021 (85%) were enrolled: 976/1021 (95.7%) were male, median age was 42 years, 461/1021 (45.2%) were HIV infected, 51/1021 (5.0%) were HBsAg-positive, 78/1021 (7.6%) had cirrhosis, 585/1021 (57.3%) were currently injecting and 730/1021 (71.5%) were on methadone maintenance therapy. The most frequent genotype was type 6 (37.9%), then 1a (33.4%), 1b (22.9%), 3 (4.4%) and 2 (1.4%).

Overall, 979/1021 (95.9%) participants initiated the treatment. SVR12 was achieved in 901/979 (92.0%) participants. Among failures, 55/979 (5,6%) participants did not attend the SVR12 visit, including 5 deaths, 2 withdrawals and 27 incarcerations. Of the 23/979 (2.3%) participants with detectable HCV RNA, 10 had a different genotype from the baseline one, strongly suggesting early reinfection.

Conclusions: High HCV treatment success rate can be achieved among the hard-to-reach population of PWID when optimized and tailored CBO support is implemented. Beside free access to treatment, CBO involvement is pivotal to reach elimination of HCV among PWID.

PEB091

The prevalence of hepatitis C virus (HCV) co-infection among people living with HIV (PLHIV) in Egypt: a cross-sectional study

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Background: Egypt is now one of the five fast track countries to meet the 2030 hepatitis C virus (HCV) elimination targets, especially after the successful mass screening and treatment campaign"100 million healths" that was recently implemented in 2019. To complement the national elimination efforts we conducted this study as an initiative to screen HIV-infected patients for HCV infection and link them to care.

Methods: A total of 1004 confirmed HIV-infected patients attending the two main HIV/AIDS reference centers in Cairo, Egypt (Imbaba & Al-abassia)over the period between January 2016 and March 2020 were screened for HCV antibody (Ab) by using fourth-generation HCV Ag-Ab enzyme-linked immunosorbent assay (ELISA). A structured questionnaire was used to capture socio-demographic data, risk factors associated with HCV/HIV co-infection, recent HIV viral load, and CD4+ T-cell counts. Univariate analyses were used to identify associated variables with anti-HCV positivity.

Results: Out of 1004 HIV-infected patients screened for HCV, 34.8% tested positive. HIV/HCV co-infected patients were younger with peak prevalence (47%) in the age group (between 30-39 years) and 89.4% were male. Injection drug use (86.8%) followed by dental procedure history (35.2%) and previous operations (19.8%) were the leading modes of acquiring HCV infection. Table 1and Table 2 show the characteristics of the studied population and risk factors for HCV-coinfection.

	HIV mono-infection	HCV co-infection	P value
Age, median (range)	36(17-70)	32(18-83)	**<0.001**
Males	482(73.6%)	312(89.4%)	**<0.001**
Females	173(26.4%)	37(10.6%)	
CD4 count (cells/mm3)			0.482
<200	118(18%)	66(18.9%)	
200 - 499	365(55.7%)	181(51.9%)	
≥500	172(26.3%)	102(29.2%)	
HIV RNA (copies/ml)			**<0.001**
>10,000	74(11.3%)	100(28.7%)	
≤10,000	17(2.6%)	13(3.7%)	
Undetectable	564(86.1%)	236(67.6%)	
ART Naïve	91(13.9%)	108(30.9%)	
On treatment	564(86.1%)	241(69.1%)	

Table 1. Characteristics of study population

	HIV mono-infection	HCV co-infection	P value
IV Drug use			**<0.001**
Yes	401 (61.2%)	303 (86.8%)	
No	254 (38.8%)	46 (13.2%)	
Risky sexual behavior			**<0.001**
Yes	192 (29.3%)	45 (12.9%)	
No	252 (38.5%)	174 (49.9%)	
Refused to specify	211 (32.2%)	130 (37.2%)	
Previous operation			**0.001**
Yes	77 (11.8%)	69 (19.8%)	
No	578 (88.2%)	280 (80.2%)	
Dental procedure			**<0.001**
Yes	68 (10.4%)	123 (35.2%)	
No	587 (89.6%)	226 (64.8%)	
History of Blood transfusion			0.125
Yes	41 (6.3%)	31 (8.9%)	
No	614 (93.7%)	318 (91.1%)	

Table 2. Risk factors for HIV/HCV co-infection

Conclusions: High HCV prevalence among HIV-patients in Egypt signifies the urgent need for targeted testing, linkage to care and treatment along with harm reduction interventions and strict infection control measures to cut the transmission cycle among this group and fulfil the elimination targets.

PEB092

Progress towards HCV elimination among HIV-positive men who have sex with men in Germany: a modeling analysis

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Background: Despite high hepatitis C virus (HCV) treatment rates, HCV incidence among HIV-positive men who have sex with men (HIV+ MSM) in Germany rose prior to HCV direct-acting antivirals (DAAs). Using data from a large national HIV/HCV coinfection cohort (NoCo), we model whether existing DAA treatment rates can achieve the World Health Organization (WHO) elimination target of 80% incidence reduction by 2030 among HIV+ MSM in Germany.

Methods: A previously published HCV transmission model among HIV-diagnosed MSM was adapted to evaluate progress towards HCV elimination in Germany. The model was calibrated to data from Germany, where HCV incidence among HIV+ MSM rose from 1996-2012 (from ~0.5/100py to 2.8/100py), 8.2% seroprevalence among HIV+ MSM in 2012, and stable HCV reinfection rates among HIV+ MSM in the pre-DAA and DAA era (6.82/100py from 2002-2014 and 7.33/100py from 2014-2018). Data from a national cohort of patients from six German HIV and hepatitis treatment sites (NoCo cohort) indicated that among MSM with a recently acquired HCV infection from 2014-2020, DAA treatment was initiated a median of 6 months after diagnosis in 81%

(n=148/182) of participants who did not spontaneously clear their infection, and 100% achieved sustained viral response (SVR). Using these data, we modelled HCV incidence among HIV+ MSM in Germany until 2030 (relative to 2015 WHO baseline) under scenarios of existing treatment and DAA scale-up.

Results: Continuing current treatment rates will reduce HCV incidence among HIV+ MSM in Germany by 30% across 2015-2030, from an estimated 2.7/100py to 1.8/100py. Scaling-up DAAs from 80% to 100% treated within 6 months of diagnosis from 2021 onwards will be insufficient to reach the incidence target (achieving a 60% reduction) unless combined with treatment of those previously diagnosed and untreated (at a rate of 30%/year).

Conclusions: HCV elimination among HIV+ MSM in Germany likely requires further DAA scale-up among those newly diagnosed combined with efforts to treat those previously diagnosed but untreated. Reducing the interval between diagnosis and treatment of recently acquired HCV may have a significant impact on elimination efforts.

Human papillomavirus

PEB093

A novel model for triaging HIV-positive patients for high-resolution anoscopy using high-risk human papillomavirus genotyping

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Background: High-risk HPV (hrHPV) genotyping could be an effective way to triage abnormal anal cytology (AC) results for patients with HIV (PWH) at risk for anal high-grade anal dysplasia (AIN2/3) for high-resolution anoscopy (HRA).

Methods: This retrospective chart review encompasses 186 HRA encounters for 174 adult men and trans-women PWH referred for HRA at a major urban HIV clinic in the Southeastern United States between from 1/1/18 to 11/16/20. During their HRA visits, anal sampling was performed for repeat AC and hrHPV testing. Samples positive for hrHPV were subsequently genotyped for HPV16/18/45. HRA was performed, and all lesions concerning for dysplasia were biopsied. For each subject the following information at time of screening was retrieved: age, gender, race, referral or most recent AC, dysplasia history, cytology and histology findings, sexual orientation, sexually transmitted infection (STI) history, HIV viral load, and CD4 count. All analyses were performed using SAS 9.3 (SAS Institute, Cary, NC) software with an alpha of 0 to determine the best predictor model for AIN2/3. This model is being tested for patients seen since November 2020.

Results: The study group had a mean age of 44±12 years, and 74% were African American. Ninety-seven percent were MSM, and 75% had a prior STI, including 34% with prior rectal gonorrhea/chlamydia. Their mean CD4 count was 515±278 cpml. They were all on ART, and 93% had an undetectable viral load. Among the 186 AC, there were 94 (50%) with hrHPV, of which 58 (62%) had AIN2/3. hrHPV testing improved the sensitivities of ASCUS, LSIL, and ASC-H to 60%(+32%), 87%(+45%), and 94%(+70%), respectively. Significant independent predictors of AIN2/3 were abnormal AC, dysplasia history, positive hrHPV, low CD4 count, and tobacco smoking history. A multivariate model derived by backward regression identified the following significant predictors of AIN2/3: positive hrHPV, CD4 count less than 300, and smoking history. This model was found to have a sensitivity of 96% for predicting AIN2/3 in our cohort.

Conclusions: The proposed model may effectively triage PWH for HRA without AC. We are currently testing this model, which will require validation in larger studies and an analogue for non-PWH.

Syphilis and other sexually transmitted infections

PEB094

Prevlence of trichomonas vaginalis and mycoplasma genitalium among women randomized to DMPA-IM, copper IUD and levonorgestrel implant in the echo trial

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Background: *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG) are associated with numerous adverse reproductive health sequelae among women, but data on their prevalence among women using contraceptive methods are limited.

Methods: This three-site (Cape Town, Johannesburg, Kisumu) study nested within the ECHO trial evaluated final visit TV and MG prevalence among 458 women randomized to injectable depot medroxyprogesterone acetate (DMPA-IM), copper intrauterine device (Cu-IUD), or levonorgestrel (LNG) implant. Symptomatic sexually transmitted infections (STIs) were treated syndromically during follow-up. Logistic regression was used to compare TV and MG final visit prevalence by randomized contraceptive group.

Results: Final visit TV and MG prevalence were 9.2% and 8.4% respectively (Figure 1). TV was significantly more prevalent among Cu-IUD (15.3%) than DMPA-IM (5.6%) or LNG implant (6.5%) users; no significant associations were observed between MG and contraceptive method (Table 1). Results were similar in a model controlling for detection of prostate specific antigen (PSA), a proxy measure for recent condomless vaginal sex.

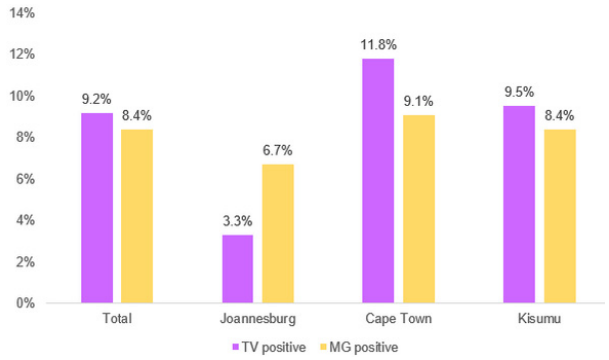

Figure 1. TV and MG prevalence in total and by site location.

STI	IUD vs. DMPA-IM OR (95% CI)	DMPA-IM vs. Implant OR (95% CI)	IUD vs. Implant OR (95% CI)
TV^	3.29 (1.42, 7.64)	0.83 (0.31, 2.17)	2.72 (1.25, 5.93)
TV#	3.57 (1.47, 8.69)	0.80 (0.29, 2.19)	2.86 (1.30, 6.28)
MG^	0.97 (0.41, 2.29)	0.82 (0.36, 1.86)	0.79 (0.36, 1.77)
MG#	0.88 (0.37, 2.09)	0.92 (0.40, 2.13)	0.81 (0.36, 1.81)

^ Odds ratios and 95% confidence intervals from a logistic regression model controlling age and site.
# Odds ratios and 95% confidence intervals from a logistic regression model controlling age, site and PSA detection.

Table 1. Comparison of TV and MG prevalence by randomized contraceptive arm.

Conclusions: TV and MG are highly prevalent among reproductive aged women in these settings. The significantly higher TV risk among Cu-IUD users when controlling for PSA detection suggests a biologic, rather than behavioral, mechanism and corroborates earlier findings reported from the MTN 020/ASPIRE study.

TV is associated with numerous adverse reproductive health sequelae and is a risk factor for other STIs including HIV; consideration should be given to STI counseling and testing among Cu-IUD users. Additional research is needed to understand the biological mechanism(s) of potential increased TV risk among Cu-IUD users.

PEB095

Prevalence of curable sexually transmitted infections among women with HIV in sub-Saharan Africa: a systematic review and meta-analysis

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Background: Sexually transmitted infections (STIs) can increase HIV transmission and cause significant morbidity among women with HIV (WWH). However, pathogen-specific testing for STIs is not widely implemented in sub-Saharan Africa (SSA) and the burden of STIs among WWH is unknown. We aimed to estimate the prevalence of four STIs among WWH in SSA and to compare STI prevalence among women with and without HIV.

Methods: We performed a comprehensive database search for studies published January 1, 1999 – December 19, 2019 that reported the prevalence of gonorrhea, chlamydia, trichomoniasis, or *Mycoplasma genitalium* among adolescent and adult WWH in SSA, following PRISMA guidelines (PROSPERO#: CRD42020167328). Facility- and population-based studies were included.

We excluded studies conducted in high-risk groups such as female sex workers. We extracted data on laboratory-confirmed STIs among WWH and, when comparable cohorts were included in the same study, among women without HIV.

We estimated pooled prevalence for each STI among WWH and compared STI prevalence to women without HIV using inverse variance heterogeneity meta-analysis. The influences of regional differences, pregnancy, and testing site type were examined in subgroup analyses.

Results: We identified 4,459 unique records, of which 67 studies were included in the meta-analysis. Pooled prevalence of STIs ranged from 3.5% for gonorrhea to 15.6% for trichomoniasis (Table).

Chlamydia prevalence was higher in Southern (12.5%) than Eastern (2.8%) Africa; prevalence of other STIs was similar across regions. Chlamydia and trichomoniasis were more prevalent among WWH tested in STI clinics (14.5% and 29.8%) than in general care (3.0% and 13.5%). STI prevalence was similar among pregnant and non-pregnant WWH. The prevalence of all four STIs was higher among WWH than women without HIV (Table).

	Pooled prevalence meta-analysis			Comparative meta-analysis			
Sexually transmitted infection	Studies (n)	Total tested	Pooled prevalence among women with HIV (95% CI)	Studies (n)	Total tested with HIV (n)	Total tested without HIV (n)	Relative risk, with HIV vs without HIV (95% CI)
Gonorrhea	44	18,255	3.5% (1.3 – 6.1)	24	8,777	19,334	1.89 (1.48 – 2.41)
Chlamydia	45	17,486	4.0% (0.9 – 7.8)	25	8,106	16,889	1.83 (1.13 – 2.95)
Trichomoniasis	51	21,364	15.6% (11.4 – 20.0)	31	12,205	17,604	1.54 (1.35 – 1.75)
Mycoplasma genitalium	13	3,685	10.2% (6.5 – 14.2)	9	1,625	2,660	1.71 (1.05 – 2.78)

Table.

Conclusions: Gonorrhea, chlamydia, trichomoniasis, and *Mycoplasma genitalium* are common among WWH in SSA, and more common than in women without HIV. STI testing and treatment integrated with HIV care could have a substantial impact on STI burden among WWH in SSA, with potential downstream impacts on HIV transmission.

PEB096

Low rates of testing for sexually transmitted infections in an insured cohort of men and women living with HIV

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Background: Guidelines recommend annual testing for bacterial sexually transmitted infections (STI), including gonorrhea/chlamydia (GC/CT) and syphilis, among persons with HIV (PWH). We used the prevention index (PI) as a quality-of-care indicator to quantify the extent to which STI testing was completed at guideline-recommended frequency among PWH in Kaiser Permanente Northern California.

Methods: The PI is the proportion of person-time covered by a recommended service divided by the total person-time that an individual is eligible for that service. PI scores for GC/CT and syphilis from 2015-2019

were calculated overall and by calendar year using data from the electronic health record (EHR). We defined scores ≥90% as indicating compliance with testing recommendations. Data on demographics, smoking status, history of alcohol and drug use disorders, and HIV viral load were also extracted from the EHR. Neighborhood-level socioeconomic status was assessed using the neighborhood deprivation index. We estimated adjusted prevalence ratios (aPR) and 95% confidence interval (95% CI) using Poisson regression with robust variance to identify factors associated with overall GC/CT and syphilis PI scores ≥90%.

Results: Among 9655 PWH, mean age was 48 (range 18-90); 52.9% were white, 70.0% men who have sex with men, and 9.6% female. Overall mean PI scores were 58.1% (SD 38.6%) and 72.5% (SD 33.2%) for GC/CT and syphilis, respectively, indicating testing rates below guideline-recommended frequency. Testing rates for GC/CT increased from 49% in 2015 to 62% in 2019, while rates for syphilis remained stable between 71%-74% during the same time period.

In adjusted analyses, older PWH (aPR 0.75 [95% CI 0.72-0.77]), women (aPR 0.24 [0.18-0.31], current smokers (aPR 0.81 [0.72-0.91]), and persons with a detectable viral load (aPR 0.88 [0.77-1.00]) were less likely to receive annual GC/CT testing.

Similarly, older age (aPR 0.87 [0.85-0.89]), female sex (aPR 0.30 [0.24-0.36]), smoking (aPR 0.90 [0.83-0.98]), and detectable viral load (aPR 0.88 [0.80-0.97]) were associated with lower syphilis testing rates. We also found that lower neighborhood-level socioeconomic status was associated with lower syphilis testing rates (aPR 0.86 [0.80-0.92]).

Conclusions: Our findings underscore a critical lapse in HIV care. Efforts are needed to improve STI testing, particularly among key PWH subgroups.

PEB097

High burden of bacterial sexually transmitted infections among young men who have sex with men and transgender women in Thailand

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Background: The burden of sexually transmitted infections (STIs) such as *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and syphilis among key populations (KPs) in Thailand is not well assessed, especially among young men who have sex with men (MSM) and transgender women (TGW). To increase access to STI services for KPs, we integrated CT/NG testing by GeneXpert into key population-led health services (KPLHS) in four community-based organizations (CBOs) in Thailand. We report STI prevalence and incidence among MSM and TGW by age.

Methods: Thai MSM and TGW ≥18 years, with at least one HIV risk in the past 6 months (unprotected anal intercourse, >5 sexual partners, history of STIs, and/or use of stimulant drugs), were enrolled. Single participant pooled urine, pharyngeal, and rectal samples, collected by trained KP-lay providers or self-collection, were used for CT/NG testing. Plasma was used for syphilis serology (SD BIOLINE Syphilis 3.0 and rapid plasma reagin). Data from August 2019 to July 2020 were used to calculate STI prevalence and incidence (reported per 100 person-years – PY).

Results: 875 (86.8%) MSM and 133 (13.2%) TGW enrolled. Among 240 MSM <24 years, prevalence of any STI/CT/NG/syphilis was 107 (44.6%)/71 (29.7%)/51 (21.3%)/26 (10.8%), incidence was 38.8/24.8/14.4/13.6 per 100PY. Among 295 MSM 24-29 years, prevalence of any STI/CT/NG/syphilis was 114 (38.6%)/70 (23.8%)/58 (19.7%)/30 (10.2%), incidence was 44.6/23.9/25.4/4.7 per 100PY. Among 340 MSM ≥30 years, prevalence of any STI/CT/NG/syphilis was 111 (32.7%)/65 (19.1%)/45 (13.2%)/36 (10.6%), incidence was 43.8/23.9/26.6/7.1 per 100PY. Among 27 TGW <24 years, prevalence of any STI/CT/NG/syphilis was 14 (51.9%)/11 (40.7%)/4 (14.8%)/3 (11.1%), incidence was 59.4/60.7/0/0 per 100PY. Among 45 TGW 24-29 years, prevalence of any STI/CT/NG/syphilis was 13 (28.9%)/9 (20.0%)/5 (11.1%)/7 (15.6%), incidence was 30.3/21.9/10.7/13.8 per 100PY. Among 61 TGW ≥30 years, prevalence of any STI/CT/NG/syphilis was 15 (24.6%)/9 (14.8%)/9 (14.8%)/5 (8.2%), incidence was 24.7/16.4/16.4/0 per 100PY.

Conclusions: After integrating CT/NG testing into KPLHS at CBOs in Thailand, we observed high burden of STIs among MSM and TGW, especially among young KPs. Routine STI prevention, screening, and management should be offered to all KPs, with particular emphasis on reaching and facilitating service uptake among young MSM and TGW.

PEB098

Implementation of diagnostic testing for sexual transmitted diseases in people living with HIV as compared to the current standard of care within Eswatini: a cost-effectiveness modeling analysis

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Background: Current approaches to sexually transmitted infection (STI) treatment in resource-limited settings rely on symptom presentation, which leads to both overtreatment and underdiagnosis, particularly in women. This is of particular significance for people living with HIV who may be more likely to experience STI complications. We used data from Eswatini to model the costs of STI diagnostic testing vs. syndromic management in a representative clinical cohort of 19-24-year-old young adults living with HIV.

Methods: The excel based cost-effectiveness model was deterministic and run on a closed cohort, with quarterly timesteps run over 5 years. Both scenarios incorporated STI screening four times a year. In the syndromic management scenario, treatment began after screening for symptoms (Sensitivity/Se: Male 80%, Female 20%; Specificity/Sp: Male 95%, Female 80%).

In the diagnostic scenario, those screened for STI symptoms underwent molecular testing for Chlamydia Trachomatis (CT) (Se: 97%; Sp: 98%) and Neisseria gonorhoeae (NG) (Se:99%; Sp:99%) before treatment; female clients received at least one molecular test for sub-clinical STI infection in a year.

Costs per STI treatment were calculated based on prices in Eswatini and converted to USD (Azithromycin $4.13, Ceftriaxone $0.33, Metronidazole $0.07). Testing costs were estimated at $16.00 per CT/NG test. Estimated DALYs saved per correctly treated case of CT or NG was 5.08, incorrect treatment for CT or NG was 0.96, and HIV cases averted per treated case of CT or NG was 0.13 (based on WHO publications).

Results: More clients were accurately treated for STIs in the diagnostic scenario (17,906 vs. 14,085). The syndromic management scenario administered 155,159 courses of inappropriate therapy as compared to 3,085 in the diagnostic scenario. The cost per case accurately found in the diagnostic scenario was $919.41; however, more DALYs were lost due to inappropriate treatment in the syndromic management scenario (285,289 vs. 27,283). This difference results in an incremental cost-effectiveness ration of $12.71 per DALY saved by implementing the diagnostic testing and screening.

Conclusions: Diagnostic testing greatly reduces unnecessary treatment, but this is balanced by the upfront cost of testing. Eliminating unnecessary treatment is an critical outcome of adopting diagnostic STI testing to reduce antibiotic resistance and stigma.

SARS-CoV-2

PEB099

SARS-CoV-2 prevalence by self-reported HIV status: six Districts in Zambia, July 2020

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Background: Information about severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection among persons living with HIV (PLHIV) is limited. Data from sub-Saharan Africa indicate PLHIV with SARS-CoV-2 infection have increased mortality compared to persons without HIV. However, whether PLHIV are at increased risk of SARS-CoV-2 infection remains unknown. Zambia is experiencing a generalized HIV epidemic with a prevalence of 11.1% in persons aged 15-49 years. A population-based SARS-CoV-2 prevalence study conducted in Zambia provided an opportunity to investigate SARS-CoV-2 prevalence among PLHIV.

Methods: During July 2020, a multi-stage cluster-sampled household survey was conducted in six districts that are home to one-quarter of Zambians. All household members were eligible to participate. A questionnaire, including self-reported HIV infection, was administered to consenting participants. Nasopharyngeal swabs and blood were collected and tested for SARS-CoV-2 infection using reverse transcription polymerase chain reaction (RT-PCR) and for SARS-Cov-2 antibodies using enzyme-linked immunosorbent assay (ELISA), respectively. Prevalence estimates and 95% confidence intervals (CIs), adjusted for the survey design, were calculated for each test.

Results: Of the 4,258 study participants, 3,790 (89.9%) reported their HIV status, of whom 2,410 (63.6%) provided nasopharyngeal swabs and 2,228 (58.8%) provided blood. Self-reported HIV prevalence was 5.1% (95% CI: 3.0-7.2%). Mean ages were 40.8 and 21.3 years among PLHIV and persons not reporting HIV, respectively (p<0.01), while the proportion female was similar (54.8% vs. 51.4%, respectively; p=0.22). RT-PCR-positive SARS-CoV-2 prevalence was 15.3% (95% CI: 0.6-30.0%) among PLHIV and 6.9% (95% CI: 4.3-9.4%) among persons without HIV. Likewise, prevalence of SARS-CoV-2 antibodies was 6.5% (95% CI: 0.0-16.8%) among PLHIV and 2.3% (95% CI: 1.9-3.3%) among persons not reporting HIV.

Conclusions: While both SARS-CoV-2 prevalence estimates were higher among PLHIV than persons who do not report HIV, wide confidence intervals make comparisons difficult. The low self-reported HIV prevalence and older age among PLHIV participants could indicate underreporting of HIV status or enrollment of a non-representative sample of PLHIV. All persons, including PLHIV, should adhere to non-pharmaceutical preventive measures, including physical distancing, face mask use, hand hygiene, and avoiding crowds. As more data on SARS-CoV-2 are published from Africa, further analyses should explore SARS-CoV-2 infection risk among PHLIV.

PEB100

Meta-analysis of randomized trials of ivermectin to treat SARS-CoV-2 infection

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Background: Ivermectin is a well-established anti-parasitic drug with potential anti-inflammatory and anti-viral properties against SARS-CoV2 in-vitro. It is currently under clinical investigation in over 70 trials worldwide.

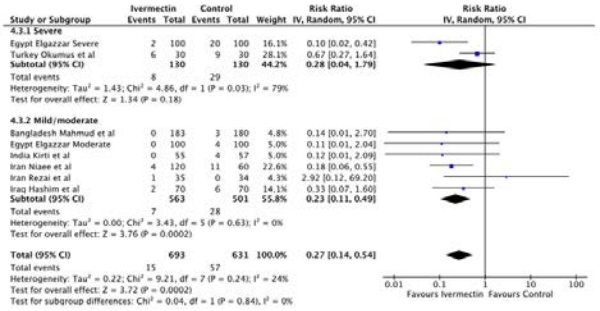
Methods: A PRISMA-concordant systematic review and meta-analysis was conducted. Trial registries, PUBMED, EMBASE, alongside preprint server Medrxiv were searched to identify RCTs evaluating ivermectin treatment for SARS-CoV-2 infection. The primary outcome was all-cause mortality and secondary outcomes were viral clearance and clinical recovery times. Statistical analyses were conducted using Revman 5.3 from data summaries on the intention-to-treat population, including all randomized patients. Data were pooled using the random-effects inverse-variance model; a continuity correction of 0.5 was applied to treatment arms without deaths. For mortality, clinical trials with at least one death reported were included in this analysis.

Results: 17 RCTs (n=2182) were included: four published papers, nine pre-prints, two sets of unpublished results shared for this analysis, and two reported results within a trial registry. Sample sizes ranged between 24-400 participants. In seven RCTs of moderate/severe infection, we find a 73% reduction in mortality (RR=0.27 [95%CI 0.13-0.60];p=0.001; 15/693 (2%) deaths on ivermectin; 57/361 (9%) deaths in controls). Overall viral clearance time in six studies was significantly reduced, with a MD of -3.33 [95%CI -5.63, -1.02];p=0.005. Clinical recovery time within the ivermectin group was significantly reduced, overall MD in six studies was -1.54 [95%CI -2.85, -0.23];p=0.02.

Regarding risk of bias: six trials were classified as low-risk, six of some concerns and five high-risk for the primary outcome. In an analysis excluding high-risk studies, the mortality results were consistent.

Conclusions: This meta-analysis showed a 73% improvement in survival, faster time to clinical recovery and signs of a dose-dependent effect of viral clearance for patients given ivermectin versus control.

Although preliminary findings are encouraging, further evidence from larger and higher-quality studies are warranted before ivermectin can be justified for approval.



Other bacterial, viral and parasitic infections

PEB101

Analysis of gut viroma in patients newly diagnosed with human immunodeficiency virus (HIV)

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Background: Viral metagenomic has enables to identify viruses associated with gastroenteritis, mainly affecting the immunosuppressed. It is known that people living with HIV/AIDS show impaired immune system and that one of the main persistent viral replication sites is the gut, cause an imbalance in the intestinal microbiota. In addition, the identification of other viruses presents in the human microbiota, has become important due to their pathogenic potential. Therefore, this study was to identify viruses in fecal samples from newly diagnosed HIV patients using the viral metagenomic.

Methods: 19 samples of newly diagnosed HIV patients were sent to Retrovirology Laboratory/UNIFESP from State of São Paulo in 2019. Both patients were under cART and showed no signs of diarrhea or gastroenteritis symtoms. The feces were disrupted using beads and the DNA/RNA was extracted. The cDNA and the complementary strand was generated. The libraries were prepared using the Nextera XT protocol for sequencing on the Miseq Desktop. To analyze a possible similarity with viral sequences, contigs generated were submitted to BLASTx.

Results: Among the patients these study 88% of these were male; with an average age was 33.5 years (range 23 to 55), CD4
T cell count of 502.7 (range 34 to 1040) and an average viral load in log 5.01 (> Lmin-5.63). It was identified 24 giant viruses of which three belong to Pandoraviridae family (28,107 hits) and one to Pithoviridae (2,531 hits). We find two viruses of the family of Phycodnaviridae (14,141 hits) and four viruses belonging to the Marseilleviridae (59,662 hits) and 15 belonging to Mimiviridae (89,109 hits). In addition we detected in two individuals the presence of Pecovirus sp. (272 hits).

Conclusions: We observed through viral metagenomics the identification of viruses fragments in fecal samples from newly diagnosed patients with HIV. Although giant viruses are commonly associated with marine organisms; the presence of these viruses in the gut microbiota of newly diagnosed patients with HIV may to be related to the impairment of their immune system. We also emphasize that Pecovirus sp. identified in this study, was observed in children with gastroenteritis, however, the individuals involved in this study did not have gastroenteritis.

PEB102

High prevalence of circulating dual-class resistant *Mycoplasma genitalium* in asymptomatic men who have sex with men in Tokyo, Japan

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Background: *Mycoplasma genitalium*, is the causative agent of a sexually transmitted infection. Patients living with HIV (PLWH) are considered to be more frequently infected with *M. genitalium* compared to non-HIV patients. We aimed to assess the prevalence and antibiotic resistance profile of *Mycoplasma genitalium* detected in the urogenital/rectal swab samples obtained from men who have sex with men (MSM) in Tokyo, Japan.

Methods: We performed PCR-based screenings for *M. genitalium* urogenital/rectal infection in 981 asymptomatic MSM between 1 January 2019 and 5 November 2020. Mutations in antibiotic resistance-associated genes *gyrA* and *parC*, and the 23S rRNA of *M. genitalium* were analysed.

Results: The prevalence of *M. genitalium* infection was 6.1%, in which, the prevalence of rectal infection was 4.7% and that of urogenital infection was 1.4%. The prevalence of *M. genitalium* infections among PLWH was 7.5%, while that in the non-HIV cohort was 4.8% (the difference was not statistically significant [p=0.083]). Of the total cases, 48 cases were successfully analysed for 23S rRNA, 41 cases for *parC* mutations, and 37 cases for *gyrA* mutations. Among the isolates, 89.6% were macrolide-resistant (23S rRNA mutation) and 75.6% were quinolone-resistant (*parC* or *gyrA* mutation). Further, 75.0% isolates were resistant for both macrolide and quinolone, and both *parC* and *gyrA* mutations were detected in 25.0% of isolates. No significant association was observed between the presence of antibiotic resistance and antibiotic exposure for either macrolide or fluoroquinolone (p=0.785 and 0.402).

Conclusions: Alarmingly high prevalence of *M. genitalium* infections harboring macrolide associated mutations and quinolone associated mutations were found in MSM without antibiotic exposure in Tokyo, Japan. Sitafloxacin-based therapy has potentially better efficacy for quinolone resistant *M.genitalium* than moxifloxacin-based therapy, but given high prevalence of combination of *parC* and *gyrA* mutated *M. genitalium*, even efficacy of sitafloxacin was very limited. Alternatives to fluoroquinolone-based therapy are required.

Neurologic disorders

PEB103

Incidence and risk factors of ischemic stroke and transient ischemic attack among Thai HIV-infected individuals: a longitudinal cohort study

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Background: As HIV-infected patients have longer life-expectancy, non-infectious comorbidities including ischemic cerebrovascular disease, have emerged as the common cause of morbidities and mortalities. To add to the limited data in Asian population, we aimed to determine the incidence and risk factors of ischemic stroke (IS) and transient ischemic attack (TIA) among Thai HIV-infected individuals.
Methods: Data from the HIV-NAT 006 cohort which prospectively enrolled and followed HIV-infected adults (aged >18 years) since 1996 was included in the analysis. IS was defined as an episode of focal neurological dysfunction with brain imaging confirming infarction and TIA was defined as a focal cerebral ischemic event with symptoms lasting <24 hours and no evidence of acute infarction. Competing-risks regression was used to determine the factors associated with incident stroke.
Results: Among 2020 HIV-infected participants included in the analysis, 16 (0.8%) developed new IS/TIA (15 had IS and 1 had TIA) over 23579 person-years of follow-up (PFYU), accounting for an overall incidence of 0.7 per 1000 PFYU (95%CI 0.4-1.1). The median age of IS/TIA incidence was 53.3 (43.7-63.6) years. Hypertension (75%), hypertriglyceride (68.8%), chronic kidney disease (50%), and diabetes mellitus (43.7%) were the common comorbidities among those who developed IS/TIA. The median CD4 before developing IS/TIA was 480 (287.5-685.5) cells/mL and 87.5% had plasma HIV-RNA <50 copies/mL. Incidence of IS/TIA was significantly higher among those who initiated ART at age ≥35 years (incidence rate [per 1000 PFYU] 1.2 vs 0.4, p=0.01), had hypertension (1.8 vs 0.2, p<0.001), had diabetes mellitus (2.2 vs 0.4, p=0.002), and had chronic kidney disease (2.1 vs 0.4, p=0.004). In multivariate models, hypertension was the only factor associated with IS/TIA incidence (adjusted subhazard ratio 4.4; 95%CI 1.2-15.6, p=0.02). HIV-related factors including CD4 cell counts, virological status, and ART regimen were not significantly associated with IS/TIA incidence. Mortality rate was significantly higher among those who developed IS/TIA compared to those who did not (31.3% vs 4.9%, p=0.001).
Conclusions: The incidence of IS/TIA was relatively low among well-controlled HIV-infected Thai individuals. Traditional vascular risk factors, particularly hypertension, still play an important role in developing IS/TIA.

PEB104

Poor sleep quality in people with HIV linked to lower amyloid beta 42 levels in cerebrospinal fluid

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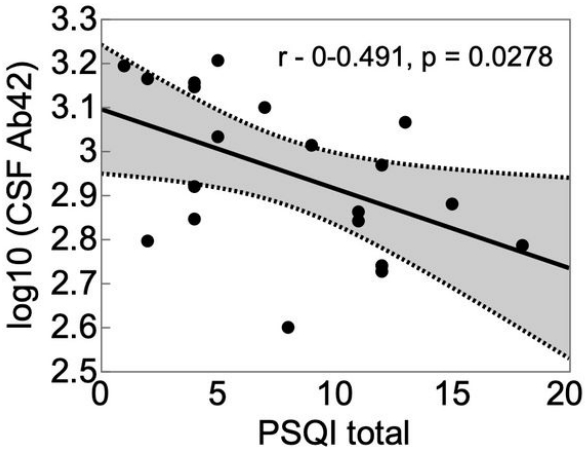
Background: Previous studies have shown that poorer sleep quality increases the risk of Alzheimer's Disease (AD) and that individuals with AD have both poorer sleep quality and lower levels of cerebrospinal fluid (CSF) amyloid beta 42 (Ab42) (in association with greater brain tissue amyloid deposition) than healthy elderly. These relationships have yet to be explored in people with HIV (PWH).
Methods: Participants were ambulatory, community-dwelling PWH who had lumbar punctures to collect CSF (CSF). Sleep quality during the past month was assessed using the Pittsburgh Sleep Quality Index (PSQI) and Ab42 was measured in CSF and plasma using the Simoa platform. Pearson's correlation coefficient was calculated to assess the relationship between sleep quality and CSF Ab42.
Results: Participants were 19 virally suppressed PWH, 15% female, 65% non-Hispanic white, 10% black, mean (SD) age 63.7 (8.1) years, median nadir and current CD4 136 and 541, mean SD PSQI 8.0 (4.8), PSQI > 5 = 12/19 (63%). As sleep quality became poorer, CSF Ab42 levels became lower (r = -0.491, p = 0.0278). In contrast, sleep quality was not related to Ab42 in plasma (r =-0.00973, p = 0.968). Age was not related to PSQI or CSF Ab42.



Conclusions: In this cohort of older PWH who on average had poor sleep quality, poorer sleep quality was linked to lower CSF Ab42, a pattern similar to that seen in AD. This may reflect greater amyloid aggregation and deposition in brain tissue, possibly indicating a greater risk of subsequent AD in PWH.

Depression and other psychiatric manifestations

PEB105

Psychological stress is associated with carotid inflammation in persons with treated HIV infection

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Background: While excess stroke risk in persons with HIV (PWH) may be attributed to traditional cardiovascular disease (CVD) risk factors and HIV-related variables, other novel factors prevalent in PWH, such as stress, may also play a role. We examined the relationship between stress, metabolic activity in stress-related brain regions, and arterial inflammation on ^{18}F-fluorodeoxyglucose (FDG)-PET, the latter being predictive of ischemic stroke and other CVD events.

Methods: Thirty-two ART-treated PWH (mean age 60 years, 97% men) with undetectable viral load underwent FDG-PET and detailed clinical and neuropsychiatric testing. Thirty age- and sex-matched controls (mean age 62 years, 93% men) were selected for FDG-PET comparisons. FDG-PET standard uptake value ratios maps were calculated in template space based on a pons reference region. Voxelwise group comparisons were performed with a primary threshold of p<0.001 uncorrected for multiple comparisons and a cluster-size threshold of 100. FDG uptake in the ascending aorta and carotids—a validated measure of arterial inflammation—were estimated with an established protocol. Linear regression analyses evaluated the relationships between stress, metabolic activity in eight *a priori* defined stress-responsive regions of interest (ROI) (e.g., medial temporal, medial and dorsolateral prefrontal cortex) and regions in which metabolism differed significantly by HIV status, and arterial inflammation.

Results: Metabolic activity was significantly lower in the bilateral entorhinal cortex (EC) in PWH compared with controls. Within this cluster, age-adjusted linear regression analyses showed a significant negative association of perceived/traumatic stress and depression with metabolic activity. Of the *a priori* defined ROIs, perceived/chronic/traumatic stress and depression were significantly and differentially associated with lower amygdalar and hippocampal metabolic activity. Carotid inflammation was significantly associated with greater perceived/chronic stress (Table) but not with regional glucose metabolism. Aorta inflammation was significantly associated with metabolic activity in dorsolateral and medial prefrontal regions (p<0.05).

	Regional metabolic activity, 95% CI (p value)			
	Entorhinal cortex	Amygdala	Hippocampi	Carotid
Perceived stress	-0.030, -0.057 to -0.003 (p=0.031)	-0.028, -0.007 to -0.049 (p=0.011)	-0.026, -0.004 to -0.048 (p=0.022)	0.122, 0.014 to 0.230 (p=0.029)
Chronic stress	NS	-0.025, -0.003 to -0.047 (p=0.027)	NS	0.115, 0.011 to 0.219 (p=0.032)
Post-traumatic stress	-0.031, -0.058 to -0.004 (p = 0.025)	-0.027, -0.005 to -0.048 (p=0.016)	NS	NS
Depression	-0.032, -0.058 to -0.005 (p = 0.020)	NS	-0.031, -0.011 to -0.052 (p=0.004)	NS

Table: Associations of stress and depression with neural metabolic activity and arterial inflammation

Conclusions: These findings warrant further investigation into the mechanisms by which stress and brain metabolic activity in stress-responsive regions are associated with greater arterial inflammation in an ART-treated HIV population.

PEB106

Changes in depression, anxiety and substance use during the COVID-19 pandemic in an HIV primary care population in the United States

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Background: Substance use and mental health problems among people with HIV (PWH) may be exacerbated by the COVID-19 pandemic. We examined depression (including suicidal ideation), anxiety, and substance use among PWH screened in primary care within an integrated healthcare system in California before and during the pandemic.

Methods: From October 2018 to July 2020, electronic screening (via tablets or email) for depression (Patient Health Questionnaire [PHQ-9] score ≥10), suicidal ideation (any endorsement on PHQ-9), anxiety (Generalized Anxiety Disorder [GAD-2] score ≥3) and substance use (Tobacco, Alcohol, Prescription medication, and other Substance use [TAPS] score ≥1) was implemented at HIV care visits (including virtual) for adult (≥18 years) PWH at three medical centers. We compared screening completion and results before and after the start of COVID-19 shelter-in-place on March 17, 2020, using logistic regression with GEE adjusted for demographics, HIV risk factor and medical center.

Results: There were 3,904 screens (3,484 pre-COVID, 420 during COVID) completed by 2,865 PWH (92% men, 56% White). Screening completion decreased during COVID vs. pre-COVID (38% vs. 44% of eligible visits; adjusted odds ratio [aOR]=0.74, 95% CI=0.65-0.85). There was no significant change during vs. pre-COVID in depression (13% vs. 13%; aOR=1.13, 95% CI=0.84-1.51) or anxiety (12% vs. 13%; aOR=1.05, 95% CI=0.77-1.47) (Figure). During COVID (pre-COVID reference), participants were less likely to report tobacco use (aOR=0.65, 95% CI=0.47-0.91), any substance use (aOR=0.82, 95% CI=0.67-1.00), and suicidal ideation (aOR=0.52, 95% CI=0.31-0.85). There were no significant changes in alcohol (aOR=0.91), cannabis (aOR=1.02), stimulant (aOR=0.85), or other drug use (aOR=0.90) (all *P*>0.05).

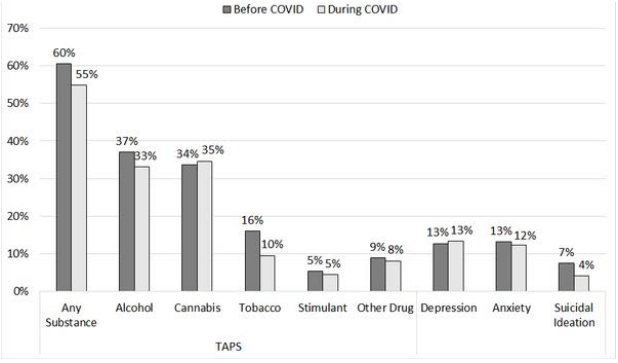

Figure. Unadjusted screening results before COVID compared to during COVID

Conclusions: In this sample of insured PWH during the COVID-19 pandemic, mental health and substance use screening decreased, and among those screened, we noted decreases in suicidal ideation, tobacco use, and any substance use. These results may reflect reduced engagement with telemedicine or lower screening rates among those at higher risk.

PEB107

Resilience and frailty in people living with HIV during the COVID era: two complementary constructs?

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Background: Resilience is defined as an individual's positive adaptation to significant stressors. COVID pandemic represents a generalized stressor which may impact differently people living with HIV (PLWH). The objective was to explore relationship between frailty and resilience, identifying frailty-resilience phenotypes, which may impact quality of life (QoL).

Methods: This was an observational study of PLWH attending Modena HIV Metabolic Clinic. Frailty was assessed in 2019, prior to the onset of COVID pandemic by using 37-Item frailty index (FI) ranging from 0 to 1. FI score was categorized as fit (<0.25) or frail (>0.25). In January 2021, PLWH were offered to complete a set of electronic questionnaires including the CD-RISC-25 for resilience and EQ-5D5L for QoL. Resilience was defined as CD-RISC-25 score >75.7 (ranging from 0 to 100).

Results: Out of 800 PLWH reached via mail, 575 (72%) completed the questionnaires. Median age and HIV duration were 54.5 and 24.3 years, respectively. Table 1 shows four frailty-resilience phenotypes. In a logistic regression, impaired resilience was associated with loneliness (OR=2.39; 1.20;4.76, p<0.001), while age, sex, HIV risk, HIV duration and nadir CD4 were not. Predictors for EQ-5D5L >93% (4th quartile) were phenotypes "frail/non-resilient" (OR=3.64, 1.98;6.7, p<0.001) and "fit/non-resilient" (OR=3.88, 2.17;6.95, p<0.001) after correction for age, sex, HIV duration and nadir CD4.

	Fit & resilient N=69 (12%)	Fit & non resilient N=242 (42.1%)	Frail & resilient N=50 (8.7%)	Frail & non resilient N=214 (37.2%)	p
Age, years, mean (± SD)	52.9 (8.6)	52.7 (7.5)	56.9 (7.6)	56.5 (6.3)	<0.001
HIV duration, months, median (IQR)	246 (139 - 307)	263 (152 - 334)	290.5 (207.3 - 347.5)	326 (267 - 386)	<0.001
Nadir CD4, c/microL, median (IQR)	250 (162 - 361)	261 (127 - 350)	202.5 (84.8 - 363.5)	190.5 (66.3 - 284.8)	<0.001
Multimorbidity (%)	52 (75.4%)	163 (67.4%)	46 (92%)	199 (92.9%)	<0.001
Loneliness (%)	7 (10.1%)	53 (21.9%)	4 (8%)	59 (27.6%)	<0.001

Table 1.

Conclusions: Resilience characterizes well-being of PLWH during COVID crisis, highlighting that this construct is complementary to frailty in the identification of clinical phenotypes with different impacts on relevant clinical outcomes including QoL. Loneliness in PLWH requires further attention and dedicated interventions.

Malignancies (BIDS and non-AIDS related)

PEB108

Cervical cancer screening yield and associated factors among women living with HIV in Uganda

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Background: Women living with HIV (WLHIV) are at risk of developing cervical cancer. Early detection of premalignant lesions can help to reduce the incidence of cervical cancer and related mortality. In Uganda, annual screening for cervical cancer among WLHIV is recommended from the age of 25 years. Mildmay Uganda Hospital (MUgH), a large peri-urban HIV care facility, through the Sexual reproductive health program has been conducting cervical cancer screening among HIV positive and HIV negative women.
In this study, we report the positivity yield of cervical cancer screening and factors associated with a positive screening test among HIV positive women.

Methods: This was a retrospective study among WLHIV who accessed care from MUgH between the years 2012 and 2019. We extracted data from the Mildmay cervical cancer screening database. Cervical cancer screening was performed using visual inspection with acetic acid (VIA) or a Papanicolaou (PAP) smear. WLHIV were eligible for cervical cancer screening annually according to the national guidelines. A descriptive statistical approach was undertaken to determine the proportion of eligible WLHIV screened, and the positivity yield. We used logistic regression analysis to determine factors associated with a positive screening test.

Results: Among 7,441 WLHIV who were eligible for cervical cancer screening, only 3,782 (50.8%) were screened. Of these, only 696 (18.4%) were screened at least three times during the 8-year period. Among those screened, 184 (4.9%) had a positive VIA or abnormal PAP smear. Factors associated with a positive VIA or abnormal PAP smear were: Being divorced/separated (adjusted odds ratio (AOR) = 0.52, 95% confidence interval (CI) 0.27 – 0.99, p =0.048), HIV stage III disease (AOR=5.58, 95%CI 1.77 – 17.58, p = 0.003), HIV stage IV disease (AOR=26.91, 95%CI 1.16 – 621.88, p = 0.040 and being screened 2-3 times (AOR=1.94, 95%CI 1.10 – 3.43, p=0.023.

Conclusions: Few eligible WLHIV were screened for Cervical cancer. The positivity yield was low. Marital status, HIV stage and frequency of screening were associated with a positive result. To increase the positivity yield, there's need to screen severally and focus more on WLHIV in active sexual relations such as marrieds and WLHIV with stage III and IV disease.

PEB109

The effect of HIV infection on the 5-year survival of cervical cancer patients at Cancer Diseases Hospital, Lusaka, Zambia. A retrospective cohort study

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Background: Cervical cancer is the leading cause of cancer morbidity and mortality in Zambia, likely in part because of the high HIV prevalence (13.6 %) among women in Zambia. However, cervical cancer is preventable through routine screening. This study examined the effect of HIV infection on cervical cancer 5-year survival rates in Zambia.
Methods: A retrospective cohort study was conducted using hospital records of patients diagnosed with cervical cancer in 2014 at the Cancer Diseases Hospital in Lusaka, the only specialty cancer hospital in Zambia. Data was collected on age, HIV status, cancer stage, mode of treatment, time to treatment and haemoglobin level. All the patients with known outcomes at 5 years were included (290 [49%] patients were excluded because of unknown outcomes). The Kaplan-Meier method and the stratified Cox-proportional regression were used to calculate the survival probability and hazard rates (HR), respectively.
Results: The study included 293 cervical cancer patients. Median age was 49 (range: 26-89). The incident death rate was 77/1000 patients per year. The median survival time was > 60 months. The lower-quartile survival time was 41 months. Majority of the patients 268 (91.4%) had an HIV status recorded in their medical records. Of these, 114 (42.6%) were HIV positive. HIV status was not associated with the overall survival HR of 1.04 (95 CI: 0.53-2.04; p-value=0.904). Cancer stage at diagnosis was a significant predictor of survival with a HR of 2.39 (95% CI: 0.49-3.87; p ≤ 0.05).
Conclusions: In this single cohort study, HIV status was not associated with lower 5-year survival rate for cervical cancer; however, stage at diagnosis was. All women regardless of the HIV status should be encouraged to screen for cervical cancer because early detection identifies low-grade lesions which can be acted upon to improve overall survival for all women.

PEB110

Cumulative viral load on antiretroviral therapy and breast cancer risk among women with HIV in North America

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Background: Lower risk of breast cancer seen in women with versus without HIV may be partly attributed to HIV viremia. This has not been explored in the context of long-term infection or suppressive antiretroviral therapy (ART). We quantified the association between cumulative viral load (cVL) and breast cancer in women with HIV initiating ART.
Methods: We included women with HIV in the North American AIDS Cohort Collaboration on Research and Design, ≥25 years old, with: no history of cancer, 2+ viral load measurements, and ≥6 months of follow-up from 1997-2016. Women were followed from ART initiation to the earliest of: breast cancer, death, loss to follow-up, 12/31/2016, or cohort-specific cancer validation end date. We measured cVL from ART initiation to the end of follow-up. We used joint longitudinal survival models to estimate longitudinal log10 cVL as a predictor of breast cancer. Hazard ratios (aHR) were adjusted for AIDS diagnosis before ART, and age/calendar year at ART initiation. cVL on ART was lagged 1-5 years to account for cancer latency.
Results: There were 29 breast cancers among 5279 women contributing 32988 person-years. Median follow-up was 5 (IQR 2, 9) years, median baseline age was 41 (IQR 34, 49) years, and median baseline calendar year was 2007 (IQR: 2002, 2011). Median cVL at the end of follow-up was 17306 (IQR: 1419, 101338) copies x years/mL. Per $\log_{10}$ increase in current cVL, there was a 9% reduced risk of breast cancer (aHR: 0.91, 95% CI 0.63, 1.32). Lagged 5 years this strengthened to 22% reduced risk (aHR: 0.78, 95% CI 0.55, 1.10).

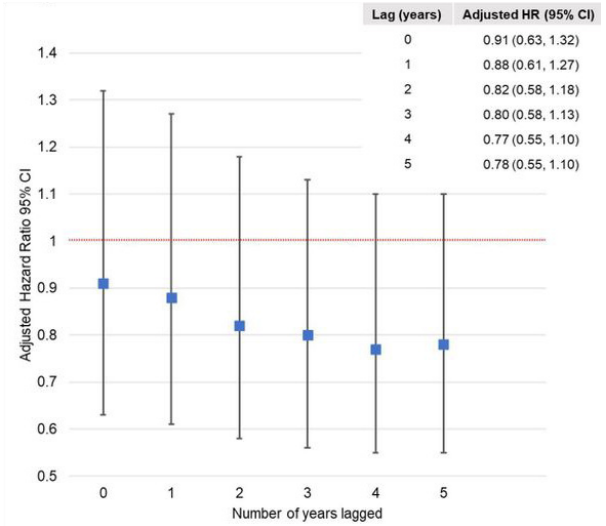

Figure 1. Association between cumulative viral load on ART and breast concer risk with 0-5 year lag

Conclusions: We observed an inverse association between cVL on ART and breast cancer which strengthened with increasing lag. Findings should be interpreted cautiously given limited sample size. Future work should consider cumulative viremia and cancer latency when assessing breast cancer risk in women with HIV.

PEB111

Evaluation of four chemotherapy regimens for treatment of AIDS-associated Kaposi's sarcoma in Kenya: a cost-effectiveness analysis

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Background: For treatment of AIDS-associated Kaposi's sarcoma (KS) in Sub-Saharan Africa, the most effective agents, paclitaxel (*PTX)* and pegylated liposomal doxorubicin (*PLD),* are not routinely used due to high costs. We examine the cost-effectiveness of *PTX* and *PLD* compared with currently used regimens, oral etoposide (*ETOP)* and bleomycin-vincristine (*BV),* across Kenya.

Methods: We used the CEPAC-International model to project clinical and economic outcomes among adults with HIV and KS on ART and initiating chemotherapy with:

1) *ETOP;*
2) *BV;*
3) *PTX;* and
4) *PLD.*

We derived cohort characteristics and costs from the Kenyan AMPATH network; adverse events and short/long-term survival were from a clinical trial (Table-Inputs/Footnotes). We projected discounted (3%/year) life expectancy and per-person lifetime costs and calculated incremental cost-effectiveness ratios (ICERs) (Table-Footnotes).

	Model Inputs		Model Outputs (Discounted)		
Strategy	Cost, per cycle[1]	48-week PFS[2]	Per-person life expectancy (years)	Per-person lifetime cost	ICER[3] ($/YLS)
Oral etoposide (*ETOP*)	$40	22%	4.25	$2,030	--
Bleomycin-vincristine (*BV*)	$50	45%	5.99	$2,620	330
Paclitaxel (*PTX*)	$60	62%	7.66	$3,250	380
Peglylated liposomal doxorubicin (*PLD*)	$180	62%[4]	7.93	$3,870	2,390

Table. Footnotes

[1]We derived per-cycle cost from Kenya-specific pharmacy data, costs reported in 2019 USD ($); [2]We derived progression-free-survival (PFS) at 48 weeks from clinical trial data (Krown, *Lancet* 2020), and defined PFS as complete, partial, or stable response among those who completed chemotherapy treatment. The model was separately calibrated to overall survival at 18 months (*ETOP*) and 30 months (*BV/PTX*), derived from Krown, *Lancet* 2020, to account for survival among those who had progressive KS after treatment; [3]ICER: Incremental cost-effectiveness ratios are defined as the difference in cost divided by the difference in life expectancy between a given strategy and the next least costly strategy. In competing-choice analysis, the most effective strategy with an ICER below the defined threshold is the preferred, cost-effective strategy. The threshold was assumed to be 0.5x the annual Kenyan *per capita* GDP (threshold=$860 per year-of-life-saved [YLS]); [4]We assume *PLD* has the same 48-week PFS as *PTX* (Cianfrocca, *Cancer* 2010), but with lower loss to follow-up due to fewer adverse events (loss to follow-up=13%/month with *PLD* and 15%/month for all other strategies, derived from AMPATH data and Stewart, *J Clin Oncol* 1998).

Table. Model inputs and outputs

We considered ICERs<0.5x Kenya's annual *per capita* GDP as cost-effective ($860/year-of-life-saved [YLS]). We performed model input sensitivity analyses. We conducted budget impact analysis from the health-sector perspective to compare total undiscounted 5-year life-years and costs with *BV* or *PTX,* assuming 3,830 Kenyan patients with KS require and initiate chemotherapy annually.

Results: Compared with other strategies, *PTX* was the most cost-effective strategy (ICER=$380/YLS) (Table-Outputs). *PTX* was cost-effective across a broad range of inputs, including median CD4 at chemotherapy initiation, relapse rates, KS-associated mortality and loss to follow-up. When simultaneously varying *PTX* progression-free-survival (PFS) and cost, *PTX* remained cost-effective unless PFS was ≤48% (base-case=62%) and per-cycle cost was ≥$90 (base-case=$60/cycle). *PLD* was cost-effective only if its cost was reduced to $80/cycle (base-case=$180/cycle). Implementing *PTX* instead of *BV* in Kenya would save ~6,000 life-years and increase overall 5-year costs by $3.1 million; 72% of increased costs are HIV-related given improved survival.

Conclusions: For adults with KS requiring chemotherapy in Kenya, *PTX* should be widely implemented because it is cost-effective and will increase life expectancy compared with *BV. PLD* would only be cost-effective if its price were substantially reduced.

PEB112

Cancer among people living with HIV in Ontario, Canada: a population-based matched cohort study among individuals with and without HIV

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Background: Cancer is an important comorbidity among people living with HIV (PLWH). We aimed to compare cancer burden among PLWH with that of the general HIV-negative population.

Methods: We conducted a population-based matched cohort study of PLWH (≥18 years) using provincial health administrative data housed at ICES in Ontario, Canada. Incident cancers from 01/01/1996 to 31/12/2018 were categorized as AIDS-defining cancers (ADC), infection-related non-ADC (NADC) and infection-unrelated NADC. Individuals with and without HIV were matched 1:1 based on year of cohort entry, birth year, sex, census district, neighbourhood income quintile, and birth region. We estimated incidence rate ratios (IRR) with 95% confidence intervals (CI) using generalized estimating equations with a log link and Poisson distribution, and an unstructured working correlation structure; adjusted models included comorbidity burden and immigration status.

Results: 17,052 people with HIV were matched with people without HIV for a total sample of 34,104 participants. There were 1,291 cancers diagnosed among people with HIV and 673 cancers among people without HIV over the 23-year study period. The median follow-up was 9.5 years (IQR 5, 15) for people with HIV and 11 years (IQR 6, 16) for people without HIV. The rate of cancer was 2.01 times higher among PLWH than their corresponding matched participants (aIRR 2.01; 95% CI 1.82, 2.22). The increased relative rate of cancer among PLWH was also seen

for ADC (aIRR 15.08; 95% CI 10.52, 21.61), all NADC (aIRR 1.27; 95% CI 1.14, 1.42), infection-related NADC (aIRR 5.11; 95% CI 3.76, 6.94), and all infection-related cancers (aIRR 9.20; 95% CI 7.27, 11.65). The rate of infection-unrelated NADC was similar between the matched participants (aIRR 0.90; 95% CI 0.80, 1.02).

Conclusions: Our findings demonstrate substantially higher rates of infection-related cancer among people with HIV than without HIV, but not infection-unrelated cancers. The elevated rate of cancer among PLWH highlights the continuing contribution of immune function to cancer risk and the importance of ongoing efforts to promote early, sustained antiretroviral therapy and cancer screening and prevention measures.

PEB113

Efficacy and safety of topical trichloroacetic acid vs. electrocautery for the treatment of anal intraepithelial neoplasia in HIV-positive patients (TECAIN): a randomized controlled trial

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Background: Screening for and treatment of anal intraepithelial neoplasia (AIN) as anal cancer precursor lesions are recommended in guidelines for people living with HIV (PLHIV). Current treatment options are suboptimal and data from prospective trials is limited.

Methods: The TECAIN Study is a randomized, unblinded, multicenter trial investigating the efficacy and safety of electrocautery (ECA) as standard of care vs. topical application of trichloroacetic acid (TCA) for the treatment of AIN diagnosed with high-resolution anoscopy (HRA) and targeted biopsies. PLHIV with histologically confirmed AIN were recruited from HIV-outpatient clinics with specialised proctologic care in Germany. The primary efficacy endpoint was therapeutic success defined as clinically and histologically confirmed resolution (or regression) of AIN marker lesions 4 weeks (FU4) after the last treatment of a maximum of 4 interventions every 4 weeks within 16 weeks since randomization. Secondary endpoints were the number of interventions, adverse events (AE) and recurrence of AIN 24 weeks after the end of TECAIN treatment (FU24).

Results: 155 PLHIV (98.1% males, 81% MSM, mean age 48.6 ± 10.6 (SD) years, mean CD4 count 637 ± 291.1 (SD) cells/µl) with AIN grade I (42.6%) or high-grade AIN (57.4%) were evaluated so far. 76 PLHIV were treated with ECA and 79 with TCA. Treatment success as defined by the protocol was demonstrated in 67% of the ECA-group (after a mean of 2.3 interventions) and in 61% of the TCA-group (after a mean of 2.6 interventions) (p=0.34). Clinical resolution of AIN was diagnosed in 85% and 77% of the ECA-group and in 78% and 79% of the TCA-group at FU4 and FU24, respectively. Histological resolution or regression were documented in 75% and 70% of the ECA-group compared to 74% and 65% of the TCA-group at FU4 and FU24, respectively. AEs were reported in 87.3% of the ECA- and in 93.4% of the TCA-group until FU24, without any persistent conditions. Serious AEs were reported in seven patients from each group, with only one event classified as probably treatment-associated, respectively.

Conclusions: This is the first prospective, randomized study demonstrating comparable outcomes of TCA and ECA for the treatment of AIN in PLHIV.

Cardiovascular disease

PEB114

Smoking and binge alcohol use are associated with incident venous thromboembolism in an HIV cohort

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Background: People living with HIV (PLWH) are at increased risk of cardiovascular comorbidities. Substance use is a concern and a potential predisposing factor in this population. We evaluated associations between smoking and alcohol use with incident venous thromboembolism (VTE) in PLWH in a US cohort.

Methods: We assessed incident VTE among PLWH in care at 6 sites within the Centers for AIDS Research Network of Integrated Clinical Systems (CNICS) cohort between 1/2009-12/2018. VTEs were centrally adjudicated in CNICS by expert reviewers. We used separate Cox proportional hazards models to evaluate associations of self-reported time-updated alcohol and cigarette use with incident VTE. Alcohol use was parameterized using categorical and continuous AUDIT-C scales, frequency of use, and binge frequency. Cigarette use was evaluated as never, former, or current use and adjusted for current cigarettes per day (centered at 10/day). We adjusted models for age, sex, race/ethnicity, hepatitis B/C virus coinfection, diabetes, treated hypertension, dyslipidemia, kidney function, smoking status (in alcohol models), and time-updated CD4 cell count and HIV viral load. We also adjusted for self-reported illicit substance use in sensitivity analyses.

Results: Among 12,957 PLWH (18% female, 43% White, 38% Black), with median age of 44 years and follow-up of 3.6 years (40% current smokers, 33% binge drinkers), 213 developed a VTE. Current (HR:1.44, 95%CI:1.02-2.03) and former (HR:1.44, 95%CI:0.99-2.07) smokers were at increased VTE risk compared to PLWH who never smoked in adjusted analyses. Among current smokers, increased number of cigarettes per day were associated with incident VTE in a dose-dependent manner (HR:1.15 per 10 cigarettes per day; 95%CI:0.92-1.43). Frequency of binge drinking in adjusted analyses was associated with incident VTE (HR:1.30 per 7 days/month, 95%CI:1.11-1.52), while alcohol use frequency was not (HR:1.04 per 7 days/month, 95%CI: 0.87-1.23). Severity of alcohol use by AUDIT-C score was not associated with VTE in either continuous or categorical parameterizations. In sensitivity analyses adjusting for illicit drug use, the overall patterns of associations remained consistent.

Conclusions: Current smoking and binge drinking behaviors are associated with the development of VTEs among PLWH. Interventions for smoking and binge drinking may have additional benefits including decreasing VTE risk among PLWH.

PEB115

The association of coronary calcification with visceral adiposity in people living with HIV. Results from the Liverpool multiparametric imaging collaboration

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Background: Visceral adiposity has been demonstrated to have a significant association with subclinical cardiovascular disease in HIV-negative cohorts. We sought to investigate the association between coronary calcification seen on computed tomography with the presence of epicardial adipose tissue (EAT) volume, hepatosteatosis (HS) and their discriminatory abilities to predict cardiovascular disease (CVD) compared to Framingham risk score (FRS).

Methods: Data was collected from the prospective Liverpool Multiparametric Imaging Collaboration (LMIC). Chest and abdominal cross-sectional imaging studies from the last 10 years were analysed for the presence of coronary calcification and HS. EAT volume was quantified using QFAT semi automated machine learning software.

We compared clinical and imaging covariates in those with elevated EAT volume and those without elevated EAT volume. We constructed a multivariate model using important clinical covariates to assess measures of ectopic fat deposition with coronary calcification. Receiver operator characteristic curves were constructed and the area under the curve was calculated to assess the predictive values of sequential models.

Results: The LMIC database contains 1295 patients. There were 197 cases where assessment for coronary calcifications, EAT volumes and quantification of HS was possible. Coronary calcifications were also increased in the raised EAT volume ($p<0.005$). The sensitivity of FRS >10%, high EAT volume and presence of HS to detect coronary calcifications was 50%, 45.8% and 52.6% respectively. The specificity of FRS>10%, high EAT volume and presence of HS was 80.3%, 85.4% and 82.6% respectively. The discriminatory ability of FRS to detect coronary calcification was modest (area under the receiver operator curve [AUC] 0.798). The addition of HS and EAT volume improved the discriminatory ability of the model significantly (AUC:0.856).

Conclusions: The presence of raised EAT volume was significantly associated with coronary artery calcification. These findings highlight the unique role of ectopic fat in the development of CVD in HIV-positive patients. The additive discriminatory ability of the metrics of visceral adiposity to traditional risk factors highlights the potential clinical utility of measuring these. These results are hypothesis generating and further prospective study is required to evaluate the preventative/clinical utility of measuring HS and EAT volume in HIV cohorts.

PEB116

Virological suppression in people living with HIV infection is not protective of subclinical atherosclerosis

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Background: The rising rates of cerebrovascular and cardiovascular diseases (CBD/CVD) are intersecting with an ageing population in Africa. People living with HIV (PLWH) and starting antiretroviral therapy (ART) may confer additive risk and may not completely suppress CBD/CVD risk. We sought to evaluate the effect of surrogate markers of infection and traditional vascular risk factors on sub-clinical atherosclerosis in PLWH and starting ART.

Methods: The RHICCA study is a cohort of 783 PLWH initiating ART and 190 HIV-negative participants followed up for a minimum of 24-months (ISRCTN42862937) and recruited from government ART clinics and the community between April-2017 and November-2020. Carotid artery intima-media thickness (CIMT) and pulse wave velocity (PWV) are markers of sub-clinical atherosclerosis and arterial stiffness respectively and used to estimate CBD/CVD risk. These were measured at baseline and follow-up visits; PWV 6-monthly and CIMT at 24 months. Our primary exposures of interest included PLWH and traditional vascular risk factors. Multivariable linear regression modelling was fitted to assess the associations between PLWH and HIV negative-participants, and factors related to change in CIMT and PWV over time.

Results: Participants were followed up for a minimum of 24 months. A significant difference in PWV between PLWH and HIV-negative participants was found (PLWH: b=-0.2644 SE[0.1191],p=0.0267), as was a significant decrease over time in PWV (b= -0.0248, SE[0.0023], p<0.001). After adjusting for age, sex, systolic and diastolic blood pressure, body mass index (BMI), HIV viral load (b=0.1193 SE[0.0331], p=0.0003) and CD4 count, the decreasing trend for PWV remained (b=-0.0182, 95% SE[0.0041]p<0.0001). For CIMT, unadjusted analysis found a significant difference between PLWH and HIV-negative participants (PLWH: b=-0.0193, SE[0.0088], p=0.0292), a significant increase over time (b = 0.0007, SE[0.0003], p=0.002) and a significant difference in trend for PLWH (b=0.0008, SE[0.0008], p=0.003). After adjusting for vascular risk factors, HIV viral load and CD4 count, the significant increase in trend remained (b = 0.0008, SE[0.0003],p=0.0025).

Conclusions: The overall significant reduction in PWV and increase in CIMT persist over time. In PLWH, virological suppression was not protective. The RHICCA longitudinal study will enable us to explore other immunopathological mechanisms including the role of viral coinfections.

PEB117

Prediction of coronary artery disease in high-risk people living with HIV in Asia

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Background: There is paucity of data to support the use of risk prediction tools in predicting coronary artery disease (CAD) in people living with HIV (PLWH) in Asia.

Methods: We performed a prospective study to determine the prevalence of CAD in a cohort of PLWH with ≥1 risk factor for cardiovascular disease in Hong Kong. Coronary atherosclerosis was defined as presence of plaque in ≥1 coronary artery segments, and obstructive CAD as presence of lesion(s) causing ≥70% stenosis on coronary CT angiogram. We calculated 10-year cardiovascular disease risk using four risk prediction scores. We determined the performance of different models (using traditional and HIV-related variables derived from our cohort, and the risk prediction scores) by comparing the area under curves (AUCs).

Results: We analysed 118 PLWH without underlying CAD, but with ≥1 risk factor for cardiovascular disease. Mean ±SD age was 54±10years, 89% male, 23% smokers, 39% diabetes, 47% hypertension, 35% taking statin, and 63% taking integrase inhibitor. Duration of HIV diagnosis was 11(IQR 6-16) years, CD4 625(IQR 457-839) cells/mm^3, and 95% HIV RNA <50 copies/mL.

Seventy-four (63%) had coronary atherosclerosis, which was independently associated with age ≥55years (adjusted odds rate/aOR 2.5, 95% CI 0.99-6.5), hypertension (aOR 2.7, 95% CI 1.1-6.8), use of statin (aOR 4.7, 95% CI 1.6-13.5), and CD4:CD8 ≤0.8 (aOR 2.6, 95% CI 1.0-6.7). A combination of these variables had the best performance (AUC 0.721) in predicting coronary atherosclerosis, while the other risk prediction scores performed poorly (Figure 1a).

Twenty-four (20%) had obstructive CAD, which was independently associated with age ≥55years, hypertension, dyspnoea, and use of statin. A combination of these variables had the best performance in predicting obstructive CAD (Figure 1b).

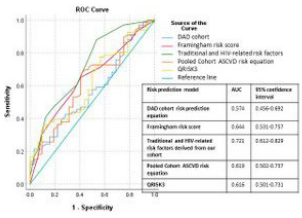

Figure 1a. ROC curves showing the prediction of coronary atherosclerosis using various risk prediction scores

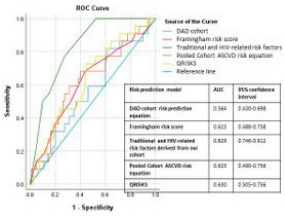

Figure 1b. ROC curves showing the prediction of obstructive-coronary artery disease using various risk prediction scores

Conclusions: Existing risk prediction scores had poor performance in predicting CAD in at-risk PLWH in Asia. Better tools are urgently needed for risk stratification.

Renal disease

PEB118

Ageing and renal insufficiency in persons living with and without HIV in AFRICOS

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Background: People living with HIV (PLWH) are at risk for renal insufficiency. This is not well characterized in ageing African cohorts. We examine the prevalence of renal insufficiency in PLWH and factors associated in its development.

Methods: The African Cohort Study is a prospective cohort enrolling adults with and without HIV at 12 sites in Kenya, Tanzania, Uganda and Nigeria. Data were collected from January 2013 to December 2020 evaluating for the prevalence at enrollment and subsequent development of renal insufficiency and elevated blood pressure (BP). Renal insufficiency was defined as having one value of estimated glomerular filtration rate <60 mL/minute/1.73m^2. Elevated BP was defined as having any systolic blood pressure of >139 mmHg or diastolic BP of >89 mmHg. Multivariable logistic regression with generalized estimating equations was used to estimate odds ratios and 95% confidence intervals (CI) for factors associated with renal insufficiency.

Results: Of 3557 participants enrolled, 2953 (83.0%) were PLWH. Of PLWH, 2472 (83.7%) were age <50 and 481 (16.3%) were >50. At enrollment, renal insufficiency prevalence was similar among PLWH age <50 (n=30, 1.2%) and >50 (n=8, 1.7%). Elevated BP prevalence at enrollment was greater among PLWH age >50 (n=128, 26.8%) than <50 (n=246, 10.0%). After adjustment for gender, study site, and elevated BP, the odds of renal insufficiency at all visits compared to people without HIV age <50 were: 3.50 (95% CI: 1.44-8.50) in PLWH age <50, 3.28 (95% CI: 0.94-11.52) in people without HIV age >50, and 5.87 (95% CI: 2.39-14.40) in PLWH age >50. Abuja & Lagos, Nigeria had the greatest adjusted odds of renal insufficiency at all visits compared to Kayunga, Uganda, 5.23 (95% CI: 2.53-9.52).

Conclusions: Age and HIV are associated with development of kidney disease with the greatest odds in PLWH age >50. There is geographic heterogenicity in development of renal insufficiency requiring further investigation. These factors should be considered when determining screening practices for renal insufficiency, particularly if tenofovir disoproxil fumarate is prescribed.

Metabolic, lipid and endocrine complications (including obesity, hyperlipidaemia and lipodystrophy)

PEB119

Impact of COVID-19-related lockdown on the metabolic profile of people living with HIV in Argentina

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Background: The spread of SARS-CoV-2 required widespread lockdown to mitigate the pandemic. Argentine authorities imposed preventive social isolation for 234 days (March 20th to November 9th 2020). This measure led to major changes in the population's lifestyle, including restrictions to physical activity and modifications of eating habits, which may induce deleterious changes in metabolic profile of people living with HIV (PLWH).This study examined the influence of COVID-19 lockdown measures on the metabolic profile of PLWH in Argentina.

Methods: Retrospective cohort study of 10300 PLWH under follow up in a private clinic for HIV care. Adult patients with ongoing ART and a baseline determination of blood glucose, LDL-cholesterol, triglycerides done before lockdown (BL: second semester of 2019) and a second determination during lockdown (DL: May 2020) were included. Patients with recent changes in ART that may have metabolic impact, those starting lipid/glucose lowering agents and pregnant women were excluded. Age, sex, BMI, basal cardiovascular risk, baseline lipid-lowering medication, and ART data were collected. Parametric or non- parametric tests were used to compare the variables. Statistical significance was set with p<0.05.

Results: 534 individuals met inclusion criteria. Their baseline characteristics are described in table 1.

Characteristic	Mean ± SD or n (%)
Age (years)	45.15 ± 10.9
Males	393 (73.6%)
BMI (KG/M²)	26.7 ± 4.6
Cardiovascular risk (WHO, Latin American)	
Low	504 (95.1%)
Moderate	12 (2.3%)
High	2 (0.4%)
Very high	12 (2.3%)
Lipid-lowering medication	83 (15.6%)
Antiretroviral therapy	
INSTI	72 (13.6%)
NRTI	513 (96.8%)
NNRTI	274 (51.75)
IP	206 (38.9%)
Entry inhibitor	4 (0.8%)

Table.

There was a significant increase in the percentage of patients that met criteria for hyperglycemia (BL 17.7% and DL 21.1%, p<0.001). We also observed significant (p<0.001) increase in mean (±SD)/median (IQR) BL vs DL values in LDL-cholesterol [111.8±31.3 vs 120.7±34.8 mg/dl]; and triglycerides [118.0 (87-170) vs. 130.5 mg/dl (95.3-181.8)]. The proportion of patients within the recommended LDL goal were 88.3% vs. 83.2% (p<0.001).

Conclusions: The impact of COVID-19 lockdown was associated with worsening of the lipid and glucose profile after at least 40 days of onset. PLWH have increased cardiovascular risk, therefore, our results highlight the need for intensified cardiovascular prevention among this population during lockdown periods.

PEB120

Dolutegravir-based regimen is associated with metabolic syndrome components among persons with HIV in sub-Saharan Africa

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Background: Metabolic syndrome (MS) is the synchronization of obesity-related cardiovascular disease (CVD) risk factors which include includes hypertension, abdominal obesity, dyslipidemia and insulin resistance. Integrase strand transfer inhibitors (INSTI) have been associated with weight gain and insulin resistance in people with HIV (PWH). However, in sub-Saharan Africa, with a higher prevalence of HIV and CVD, little is known on the effect of INSTI on metabolic derangement. Therefore, this study aimed to determine the association between metabolic syndrome components and dolutegravir (DTG)-based regimen among adult patients in Zambia.

Methods: We conducted a cross-sectional study of 635 PWH at Livingstone Central Hospital between April 2019 and March 2020. Data collected comprised demographic, physical measurements, clinical, lipid profiles and fasting blood sugar (FBS). We compared antiretroviral therapy (ART)-based regimens (Non-nucleoside reverse transcriptase inhibitors (NNRTI): efavirenz & Nevirapine, Protease inhibitors (PI): Lopinavir/ritonavir & atazanavir/ritonavir and INSTI: DTG and metabolic components (high density lipoprotein cholesterol (HDL-c), fasting blood glucose (FBG), waist circumference (WC), Triglycerides (TG) and blood pressure (BP)) using Kruskal Wallis test.

Results: Among 635 participants, median (interquartile range (IQR)) age was 44 years (37, 52), median time on current NNRTI, PI and INSTI were 66 months (42, 71), 13 (10, 31) and 6 (4, 8), respectively. Individuals on DTG-based regimen had significantly higher values of median (IQR) systolic BP [132 (118, 150) vs. NNRTI 120 (110, 133) and PI 117 (106, 128); p=0.0001], diastolic BP [82 (73, 91) vs. 77 (70, 85) and 74 (67, 80); p=0.0001] and WC [83 (76, 92) vs. 80 (72, 88) and 77 (70, 86); p=0.0009] and lower values of HDL-c [1.05 (0.90, 1.30) vs. 1.3 (1.1, 1.6) and 1.2 (1, 1.5); p=0.0001]. The values of FBG were significantly higher among patients on NNRTI [median (IQR); 5 (4.6, 5.4) Vs. PI 4.7 (4.2, 5) and INSTI 4.8 (4.2, 5.4); p=0.0026]. Triglyceride values were comparable.

Conclusions: Our study showed that PWH on DTG-based regimen tends to have higher BP, WC and deranged lipids associated with metabolic syndrome. However, there is a need for more robust study designs to determine the real effect of INSTI on metabolic syndrome and its components in SSA.

PEB121

Weight gain following the single substitution of TDF by TAF in people living with HIV (PLWH) in the French Dat'AIDS cohort

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Background: Overweight is an increasingly recognized issue among PLWH which has been associated with prescription of some antiretrovirals, including tenofovir alafenamide (TAF). As many confounders contribute to weight gain, making it hard to decipher a specific drug effect, we describe weight changes observed during the single substitution of tenofovir disoproxil-fumarate (TDF) by TAF.

Methods: Retrospective multi-center study including virologically suppressed (<200 copies/mL) adult PLWH switching from TDF/emtricitabine/rilpivirine (TDF/FTC/RPV) to TAF/FTC/RPV or from TDF/FTC/elvitegravir/cobistat (TDF/FTC/EVG/c) to TAF/FTC/EVG/c between 01/2004 and 12/2019 in the French Datu2019AIDS cohort. Participants with (at least) one weight measure in the year before and after the switch and a full demographic dataset were included. Main objective was to compare mean weight during the 12-months period before and after this switch, and to search for factors associated with weight variation using multivariate mixed-linear models.

Results: Overall, 1184 PLWH on TDF/FTC/RPV (n=587) or TDF/FTC/EVG/c (n=597) were included. Main characteristics were: 73% male, native from France (65.7%) or sub-Saharan Africa (20.5%), mean age 48.6 years (standard deviation u00b111.1), duration of HIV-infection 12.7 (u00b18.5) years, nadir CD4 T-cell count of 291 (u00b1182) cells/u00b5L, history of AIDS in 14.8%, MSM in 47.8%. Mean duration on TDF- and TAF-based regimens were 34.5 (u00b117) and 13.6 (u00b15.7) months, respectively. After the switch mean weight increased from 74.76 (u00b114.56) to 76.04 (u00b114.68) (+1.28 kg; 95%CI: 0.99-1.56, p<0.001) after adjusting for the initial weight, sex, age, mode of HIV-infection, geographic origin, viral load at the time of switch, duration of HIV-infection and duration of TDF-based regimen (Table). A higher weight before the switch was also positively associated with weight gain after (p<0.001) whereas a longer duration with HIV was negatively associated (p=0.007). In subanalyses, weight gain after switch remained significant in Caucasian male and female, female of African origin, but not in male of African origin.

Conclusions: In our study, a mild but significant weight gain was observed in virologically suppressed PLWH switching from TDF to TAF

PEB122

Weight changes, metabolic syndrome and all-cause mortality in persons living with HIV

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Background: We investigated weight changes after antiretroviral therapy (ART) initiation, and the development of metabolic syndrome (MetS) and its association with all-cause mortality in an Asian cohort.

Methods: Participants enrolled in a regional HIV cohort (TAHOD) with weight and height measurements at ART initiation were eligible for analysis. MetS was defined using the International Diabetes Foundation criteria as clinical obesity (BMI>27.5kg/m^2) plus any two of the following: triglycerides ≥150mg/dL, HDL ≤40mg/dL for males and ≤50mg/dL for females, high blood pressure (SBP ≥130mmHg and DBP ≥85mmHg) and fasting blood glucose ≥100mg/dL. Factors associated with weight changes and incident MetS were analyzed using linear mixed models and Cox regression, respectively. Competing-risk models were used to investigate the association of MetS with all-cause mortality.

Results: Of 4931 participants, 66% were male. At ART initiation, the median age was 34 (IQR, 29-41) years, median weight was 55 (IQR, 48-63) kg and median BMI was 20.5 (IQR, 18.4-22.9) kg/m^2. A total of 92%, 6.6% and 1.2% initiated ART with non-nucleoside reverse transcriptase inhibitors (NNRTI), protease inhibitors (PI), and integrase strand inhibitors (INSTI). At 1, 2 and 3 years of ART, overall mean (±SD) weight gain was 2.2 (±5.3), 3.0 (±6.2) and 3.7 (±6.5) kg, respectively. Participants with baseline CD4 ≤ 200 cells/mm^3 (difference [diff]=2.2 kg, 95% CI, 1.9-2.5), and baseline HIV RNA ≥100,000 copies/mL (diff=0.6kg, 95% CI, 0.2-1.0) and those starting with INSTI-based ART (diff=2.1 kg, 95% CI, 0.7-3.5 vs. NNRTI) had higher weight gain. After excluding those with abnormal baseline levels of MetS components, 295/3503 developed incident MetS (1.18 [95% CI, 1.05-1.32]/100 person-years [PYS]). Factors associated with MetS development were baseline BMI, and time-updated AIDS events, CD4 count, HIV RNA level, and stavudine exposure. The mortality rate was 0.7 (95% CI, 0.6-0.8)/100 PYS. Association of MetS

with all-cause mortality was not statistically significant in adjusted competing-risk models (adjusted sub-distribution HR=0.63, 95% CI, 0.25-1.59, p=0.328).

Conclusions: Weight gain after ART initiation was significantly higher among those initiating ART with low CD4, higher HIV RNA and INSTI-based ART after controlling for baseline BMI. Greater efforts to identify and manage MetS among PLHIV, especially in LMIC, are needed.

PEB123

Patterns of weight gain in Bictegravir/Emtricitabine/Tenofovir alafenamide (B)

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Background: B has been linked to weight gain, but very few studies addressed the change in weight over time. We were interested in observing the trend of weight gain in those who experienced excessive weight gain while on B.

Methods: A retrospective cohort analysis in patients who received B and gained ≥10% of their baseline weight while on therapy. Weight was stratified into 24-week periods throughout the entire course of therapy, up to 10/30/20.

Results: From 07/02/18 to 10/30/20, 81 out of 523 person living with HIV (PLWH) that received a prescription for B, gained ≥ 10% of their baseline weight. Twelve were excluded from the study due to intermittent high viral loads indicating poor adherence to therapy.

Of the remaining 69 PLWH who gained ≥10% weight, the average time on therapy was 88.9 weeks and time to initially exceed 10% weight was 44.3 weeks. Their average age was 51.7 years old; 44 (64%) males. Majority were Blacks (64%), followed by Latinx (22%) and Whites (14%).

Twenty-six (34.7%) patients gained ≥10% of baseline weight by the first 24 weeks on therapy, the pattern of their weight gain overtime is shown in the chart below. Thirty-five (47%) reached that endpoint between week 24 and 48.

Conclusions: Weight gain is now being recognized as an adverse effect of antiretroviral therapy, our study shows that 15 % of our patients who started on B gained ≥ 10 % of their baseline weight, mostly within the first 48 weeks, moreover 15% of the patients who gained excessive weight were poorly adherent to therapy. Clearly more prospective studies on weight gain with its consequences are needed in PLWH.

PEB124

Does weight gain on Bictegravir/Emtricitabine/Tenofovir Alafenamide (B) lead to metabolic syndrome?

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Background: Second generation integrase inhibitors (INI) and Tenofovir Alafenamide (TAF) have been linked to increased weight gain, but no clear link to an increase in metabolic syndrome has been found yet.

Methods: A retrospective cohort analysis was conducted on all patients living with HIV (PLWH) at our inner-city clinic who received a prescription for B. We excluded patients with virus load >1000c/ml 12 weeks after starting B, and those that have been on therapy for <6 months. We stratified the cohort into 2 groups: those that gained ≥10% weight, and <10% weight from their baseline since the initiation of B. The risk of metabolic syndrome was assessed by medications that were newly started during B therapy. The chi-square (χ) test was used to identify the associations between categorical variables. GraphPad statistical software was used for data analysis.

Results: From February 2018 to October 2020, there were 523 PLWH with new prescription for B, 280 met our exclusion criteria. Of the remaining 243 patients, 69 (28.4%) gained ≥10% weight, while 174 (71.6%) gained <10% weight.

The demographic and clinical characteristic of the 2 groups are presented in Table 1. Of note, the only statistically different clinical characteristic between the 2 groups was a lower CD4 count in those with higher weight gain on therapy. There was no statistical difference on the new initiation of blood pressure medication [Odds Ratio (OR) 1.692, 95% confidence interval (CI) 0.9125 – 3.168), diabetes medications (OR 1.049, 95% CI 0.4553 – 2.410) and hyperlipidemia medications (OR 1.038, 95% CI 0.4822 – 2.212) between the 2 groups.

		≥10% weight gain (n=69)	<10% weight gain (n=174)	p-value
Average time on therapy (weeks)		88.9	87.9	0.8112
Gender	Male	44 (64%)	123 (71%)	0.2959
	Female	25 (36%)	51 (29%)	
Ethnicities	Black	44 (64%)	116 (67%)	0.0551
	Latinx	15 (22%)	46 (26%)	
	White	10 (14%)	10 (7%)	
Age (years)		51.7	52	0.8696
CD4 count (cells/uL)	<350	29 (42%)	31 (18%)	<0.0001
	>350	40 (58%)	143 (82%)	
Average weight gain for the first 6 months on Biktarvy therapy (lbs)		14	0.64	<0.001
Initiation of new blood pressure medications		23 (33%)	39 (22%)	0.0918
Initiation of new diabetes medications		8 (12%)	19 (11%)	0.9146
Initiation of new lipid medications		10 (14%)	24 (14%)	0.9267

Table 1. Demographic and clinical characteristics of PL WH who has ≥10% and <10% weight change since the initiation of Bictegravir/Emtricitabine/Tenofovir Alafenamide

Conclusions: Despite ≥10% weight gain from baseline over a median of 88.9 weeks, we did not see an increase in metabolic syndrome in this group compared to those with less weight gain. We may need more patients with longer follow up to answer this very important question.

PEB125

Weight gain or "return to health"? Changes in body weight in aging people living with HIV compared with the general population from the German Ruhr-area over 5 years

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Background: The prevalence of obesity has increased worldwide within the last decades. This analysis compared weight changes in people living with HIV (PLHIV) and the general population.

Methods: Descriptive statistics for baseline and 5-year-follow-up in the prospective HIV-HEART Aging study (HIVH) and the population-based Heinz Nixdorf Recall Study (HNR) (inclusion criteria: age ≥45 years), both recruiting in the same German Ruhr-area since 2004, were compared. The cohorts were matched 1:2 by age and sex. The shift between BMI-groups during the observation period in HIVH and HNR was visualized. Linear regression models were calculated to assess the effect of HIV on weight, BMI, and waist-hip-ratio at baseline and percentage change after 5 years of follow-up.

Results: The matched HIVH and HNR participants (N=389 and N=778, respectively; 13% females) had a mean age of 53.6±6.3 years at baseline. 83% of PLHIV took antiretroviral therapy at baseline and 99% after 5 years. The regression models showed 8kg (95%-CI: 6.17-9.63) lower mean baseline weight in PLHIV compared to HNR controls. Accordingly, we observed 2.92 units (95%-CI: 2.44-3.41) lower baseline BMI in PLHIV. After 5 years, BMI and weight gain were 0.4% higher in PLHIV. The shift from normal to overweight BMI was especially prominent in PLHIV (Figure 1). At baseline, the waist-hip-ratio was 0.04 (95%-CI: 0.02-0.05) units higher for PLHIV compared to HNR-controls. After 5 years, PLHIV gained 1.6% (95%-CI: 0.46-2.78) more in waist-hip-ratio.

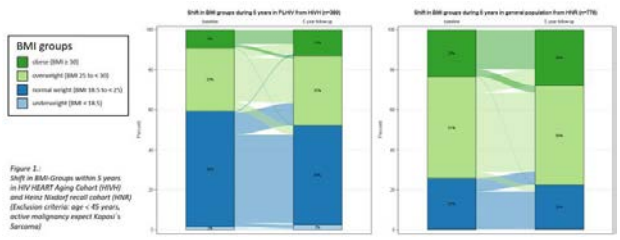

Figure 1.

Conclusions: While PLHIV showed a lower weight and BMI than the general population at baseline, relative weight and BMI gain after 5 years was slightly higher in PLHIV. A stronger effect was observed for waist-hip-ratio. However, the proportion of overweight and obesity in PLHIV was still much lower compared to the general population, suggesting that the BMI shift among PLHIV reflected coming-back-to-normal effects of the ART.

PEB126

Low proportion of individuals develop Metabolic Syndrome (MetS) or hepatic fibrosis after switch to Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (D/C/F/TAF) in virologically suppressed patients: a post-hoc metabolic analysis

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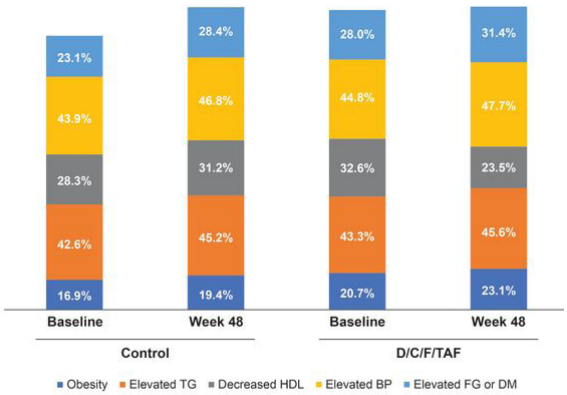
Background: Greater weight gain has been observed following initiation of integrase inhibitor (INI)-based regimens compared to non-nucleoside reverse transcriptase inhibitor- or boosted protease inhibitor (bPI)-based regimens and after switching from tenofovir disoproxil fumarate (TDF) to TAF, particularly with an INI. Little is known about the implications of weight gain on metabolic parameters and advanced hepatic fibrosis in people with HIV-1. Among EMERALD patients who switched from bPI+F/TDF to D/C/F/TAF at baseline, median weight change was +1.3kg at Wk48. This post-hoc analysis evaluated the proportion of EMERALD patients with baseline and developing MetS and advanced hepatic fibrosis.

Methods: The phase 3 EMERALD study (ClinicalTrials.gov:NCT02269917) randomized (2:1) virologically suppressed adults receiving bPI+F/TDF to switch to once-daily D/C/F/TAF 800/150/200/10mg or continue their current regimen. This post-hoc analysis evaluated proportion of patients who met criteria for MetS (per International Diabetes Federation definition) and advanced hepatic fibrosis (according to nonalcoholic fatty liver disease [NAFLD] fibrosis score) at Wk48 in each treatment arm.

Results: At baseline, 108/760 (14.2%) and 35/377 (9.3%) patients receiving D/C/F/TAF and control regimen, respectively, had MetS. At Wk48, 108/725 (14.9%) and 49/356 (13.8%) patients receiving D/C/F/TAF and control regimen had MetS, representing changes from baseline of +0.8% and +4.2%, respectively. Among these patients, the most frequently observed MetS components at baseline were hypertension and hypertriglyceridemia; findings were similar at Wk48 (Figure).



MetS, metabolic syndrome; D/C/F/TAF, darunavir/cobicistat/emtricitabine/tenofovir alafenamide; TG, triglycerides; HDL, high-density lipoprotein; BP, blood pressure; FG, fasting glucose; DM, diabetes mellitus; BMI, body mass index.
*Percentages were calculated based on the number of patients with observed values for each component of MetS.
†Patients may have multiple components of MetS; therefore, percentages may not total 100%.
‡International Diabetes Federation criteria for MetS include: obesity (BMI ≥30 kg/m²) and 2 of the following criteria (or treatment for them): elevated TG (≥150 mg/dL); decreased HDL (<40 mg/dL [males] or <50 mg/dL [females]); elevated BP (systolic ≥130 mmHg or diastolic ≥85 mmHg); elevated FG (>5.5 mmol/L) or type 2 diabetes diagnosis.

Figure. Proportion of patients with components of MetS at baseline and Wk48. *,†,‡

According to NAFLD score, the proportion of patients with advanced hepatic fibrosis at baseline was low (D/C/F/TAF, 17/739 [2.3%]; control, 4/362 [1.1%]) and remained low at Wk48 (D/C/F/TAF, 20/691 [2.9%]; control, 5/343 [1.5%]).

Conclusions: At Wk48, switching to D/C/F/TAF did not appear to be associated with increased prevalence of MetS or hepatic fibrosis compared to continuing bPI+F/TDF. The minimal change in weight observed for these patients in EMERALD did not appear to impact the metabolic parameters described here, even when switching from TDF to TAF.

PEB127

Obesity, raised blood pressure and diabetes in women with and without HIV: a pooled analysis of 17,450 women in four countries in sub-Saharan Africa

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Background: New generation antiretroviral therapy (ART) regimens drive weight gain and associated cardiovascular risk factors, particularly in women living with HIV (WLHIV). We aim to describe the epidemiology of obesity, raised blood pressure (BP) and diabetes (DM) in women with and without HIV in sub-Saharan Africa (SSA), prior to the initiation of these ART regimens.

Methods: We performed a pooled cross-sectional analysis of the Demographic and Health Surveys (DHS) conducted in four SSA countries (South Africa, Lesotho, Namibia and Ghana) from 2013-2016. The outcomes of interest were overweight/obesity (body mass index (BMI) ≥25 kg/m2), raised BP (systolic BP ≥130 or diastolic BP ≥85 mmHg) and DM (fasting glucose ≥7.0 mmol/L or HbA1c ≥6.5%, available in only Namibia and South Africa). We compared the proportion of women with and without HIV with these conditions using chi-squared tests. We then performed a multivariable logistic regression analysis with country-fixed effects using a complex survey design to evaluate the association between HIV serostatus and each of these outcomes. We adjusted for age, residence, education, wealth, marital and smoking status.

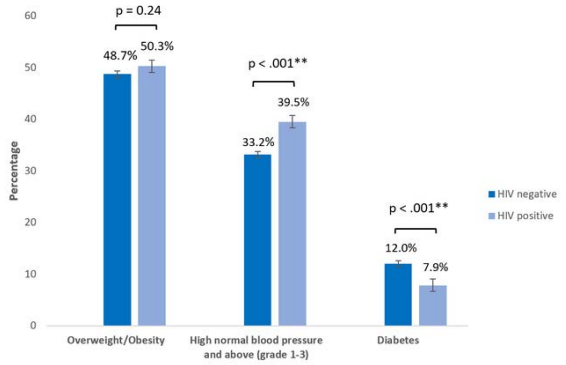

Figure. Prevalence of overweight / obesity, elevated blood pressure and diabetes[a] by HIV status in women in sub-Saharan Africa
[a] Results of diabetes prevalence were limited to the DHS surveys of South Africa and Namibia.
** p<0.05 ** p<0.001, Pearson's chi squared test was used to compare proportions.*

Results: The study sample consisted of 17,450 women. We found a high prevalence of overweight/obesity, with no difference between HIV serostatus (p=0.24). By contrast, we found a higher prevalence of raised BP and lower prevalence of DM in WLHIV (p<.001, figure).
In multivariable models, WLHIV had a lower odds of overweight/obesity [AOR=0.62 (0.55-0.71)], but without significant difference in the odds of raised BP [AOR:0.90 (0.78-1.04)] or DM [AOR:0.75 (0.44-1.02)].

Conclusions: WLHIV in SSA had high rates of overweight/obesity and hypertension prior to the switch to new generation ART. Additionally, HIV is still associated with a lower BMI, however, this gap seems to be narrowing with high rates of overweight/obesity in WLHIV. Future research should focus on approaches to prevent weight gain and its associated cardiovascular risk factors.

PEB128

Metabolic syndrome and estimated 10-year cardiovascular disease risk among HIV-positive and HIV-negative adults in Zambia and Zimbabwe

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Background: People living with HIV (PLWH) on antiretroviral therapy are experiencing improved life expectancy but are confronted with cardiovascular diseases (CVD) and metabolic complications. We explored the determinants of metabolic syndrome (MetS) and assessed the 10-year CVD risk of adults in Southern Africa.

Methods: Treatment naïve PLWH ≥30 years were consecutively enrolled from primary care clinics in Zambia and Zimbabwe. HIV-negative participants were seronegative partners or persons presenting for HIV testing. We defined MetS as the presence of central obesity plus any two of the following: raised blood pressure, impaired fasting glucose, reduced HDL cholesterol, raised triglycerides. We used logistic regression to determine factors associated with MetS and calculated 10-year CVD risk using the Framingham risk equation. Enrolment is ongoing. We report findings among patients with complete data.

Results: Between August 2019 and January 2021, we enrolled 173 (41%) HIV-positive and 252 (59%) HIV-negative adults. Median age was 40 years (interquartile range [IQR] 34-47), and 270 (64%) were female. Among HIV-positives, median CD4+ was 249 cells/mm^3 (IQR 120-441) and viral load 10,716 copies/ml (IQR 60-141,972). MetS was diagnosed in 78/425 (18%, 95% CI 15-22%), and prevalence was higher among women than men (Figure).

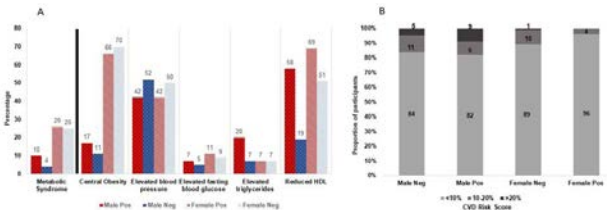

Figure. Panel A-Metabolic Syndrome, Panel B-CVD risk among 425 adults

In multivariable analysis, factors associated with MetS were female sex (adjusted odds ratio [aOR] 5.05, 95% CI 2.31-11.05), age ≥50 years (aOR 3.13, 95% CI 1.51-6.50) and highest socioeconomic status (aOR 3.51, 95% CI 1.39-8.86), whereas HIV status was not associated with MetS (aOR 1.22, 95% CI 0.71-2.09). Estimated 10-year CVD risk was >10% in 17% of men, and 4-11% of women (Figure).

Conclusions: We showed a high prevalence of central obesity and metabolic syndrome among women in urban Zambia and Zimbabwe. There was no evident difference in MetS prevalence between HIV-positives and HIV-negatives. Although less than 10% of men had metabolic syndrome, 10-year CVD-risk was higher among men than women.

PEB129

Endocrine pathways of non-alcoholic fatty liver disease (NAFLD) in people living with HIV

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Background: NAFLD is related to insulin resistance (IR), vitamin D deficiency/insufficiency and diabetes. The objective was to explore, using Bayesian networks, the dynamic interplay among multiple endocrine disorders and NAFLD or NAFLD with fibrosis in people living with HIV (PLWH).

Methods: This was a cross-sectional study of PLWH attending Modena HIV Metabolic Clinic in Italy. NAFLD was assessed by transient elastography as controlled attenuation parameter ≥248 dB/m, while significant liver fibrosis/cirrhosis as liver stiffness measurement ≥7.1 kPa. NAFLD with fibrosis was defined as the contemporary presence of NAFLD and significant liver fibrosis. Independent predictors of NAFLD and NAFLD with fibrosis were identified in logistic regressions. Bayesian Networks were applied to identify the structure of the relationship network among the different predictors and the outcomes through a Directed Acyclic Graph (DAG).

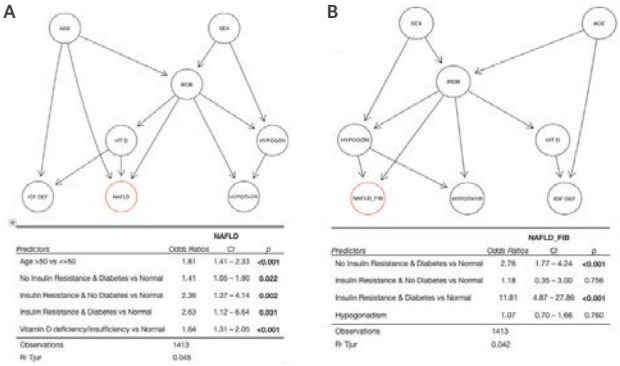

Figure 1

Results: We enrolled 1434 PLWH (75.5% males). Mean age was 54.2 (±9.1) years, mean BMI 24.2 (22.2-26.4), median CD4=702/µL (541.5-900.5). NAFLD was diagnosed in 563 patients (39.3%), while NAFLD with fibrosis in 116 (8.2%). DAG model for NAFLD identified direct associations with age, IR and diabetes combined in one variable (IRDB in Figure 1) and vitamin D insufficiency. In the logistic regression model, using as a reference "no IR-no diabetes", IR alone is more strongly associated with NAFLD than diabetes alone. DAG model for NAFLD with fibrosis (NAFLD_FIB in Figure 1) identified direct association with IR-diabetes only. The association between age and NAFLD with fibrosis was mediated by IR-diabetes (Figure 1).

Conclusions: The dynamic interplay among multiple endocrine disorders and NAFLD in PLWH were driven by IR, diabetes, vitamin D insufficiency and age. DAG models revealed that IR is more strongly associated with NAFLD than diabetes, while NAFLD with fibrosis is mainly driven by diabetes rather than IR. This suggests a significant role of diabetes on fibrosis progression in PLWH.

PEB130

Switch to INSTI more than offset negative effects of weight gain on incidence of insulin resistance in people living with HIV

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Background: The objective was to evaluate incidence and predictors of IR in PLWH switching to INSTI in relation to weight gain (WG).

Methods: This was a longitudinal matched-cohort study including PLWH attending Modena HIV Metabolic Clinic, Italy. Participants were divided into two groups: INSTI-naive and INSTI-switchers (INSTI-s) and matched for the duration of observational period and body mass index (BMI) at baseline. Three definitions of WG were used: delta increase of weight from the baseline visit to follow-up; an increase of 5% of weight; an increase of 7% of BMI. Outcome was IR. A mediation analysis was performed to test the mediation effect of BMI and weight change in the causal path between the switch to INSTI and the incidence of IR.

Results: We analyzed 290 PLWH (67% males), 158 INSTI-s and 132 INSTI-n with the median age 47 (43-52) years. Median BMI was 22.6 kg/m^2. Figure 1A shows that switching to INSTI reduced the risk of IR by 28.9% as the net result of the favorable direct effect of INSTI-s vs INSTI-n (32.1%) and the mediation effect of a potential harm of weight gain (4.7%). Similarly, Figure 1B shows that switching to INSTI reduced the risk of IR by 29.5% as the net result of the favorable direct effect of INSTI-s vs INSTI-n (32.2%), with the mediation effect of a potential harm of BMI gain (4.0%).

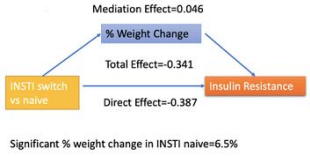

Fig. 1A

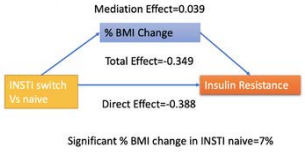

Fig. 1B

Conclusions: The protective effect of switching to INSTI more than offset the risk IR, induced by weight gain with a net result of 29%. Despite WG, INSTI still represent a metabolic friendly option in PLWH. These

data contribute to a data driven definition of WG both in terms of weight or BMI quantification in relation to a clinically meaningful end-point.

Hepatic complications (including NASH)

PEB131

Combination of high liver and visceral fat predicts diabetes in people living with HIV

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Background: The objective was to investigate the relationship between diabetes mellitus (DM) and concordant or discordant visceral adipose tissue (VAT)-liver fat (LF) phenotypes in people living with HIV (PLWH).
Methods: 186 individuals from Modena HIV Metabolic Clinic, Italy were contemporary assessed for VAT using lumbar computed tomography imaging and for LF using transient elastography. High VAT was defined as above the median (VAT>174.5 cm^2 for men and 144 cm^2 for women). High LF was defined as controlled attenuation parameter ≥248 dB/m. Four phenotypes, mutually exclusive, were defined: low VAT-low LF (VAT-LF-), low VAT-high LF (VAT-LF+), high VAT-low LF (VAT+LF-) and high VAT-high LF (VAT+LF+). Bayesian networks were applied to identify the interplay among the different predictors of DM through a Directed Acyclic Graph (DAG).
Results: The study cohort consisted of 14% females with a median age of 57 (51.3-61) years and body mass index (BMI) of 24.9 (22.8-27.3) kg/m^2. The prevalence of fat phenotypes were: VAT-LF- 35.5%, VAT-LF+ 13.4%, VAT+LF- 18.8% and VAT+LF+ 32.3%. DM prevalence was 20.4% (38 cases).

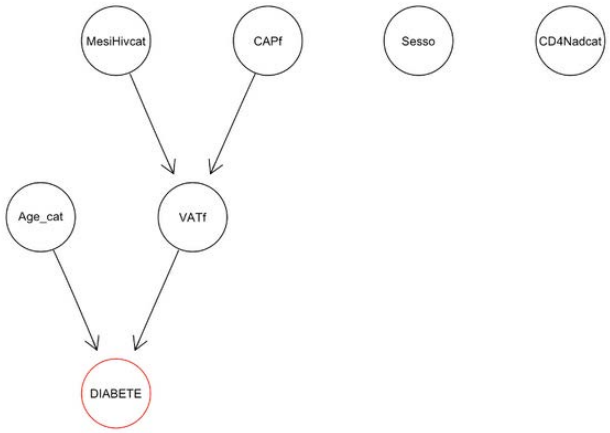

Figure 1

The Bayesian network depicted in Figure 1 shows the direct effect of age and VAT on DM, while the association between LF and DM is mediated by VAT. Both VAT and LF were associated with DM in separate logistic regressions. Another logistic regression highlighted a higher risk of DM in presence of both VAT and LF (OR=4.2, CI=1.5-12.6, p=0.006).
Conclusions: The combination of high LF and high VAT identifies a clinical phenotype with enhanced risk of DM. The DAG model confirms the interaction of HIV duration on VAT, but not on LF, suggesting specific HIV pathways in the continuum of metabolic changes in PLWH.

Ageing with HIV (including polypharmacy and frailty)

PEB132

Circulating GDF15 levels are associated with aging, risk of non-AIDS comorbidities and integrated HIV DNA in ART-treated people living with HIV

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Background: Growth differentiation factor-15 (GDF15) is a transforming growth factor-β family member known to regulate several biological processes. Circulating levels of GDF15 are a marker of aging and mitochondrial cellular stress, elevated in people with cardiovascular diseases, cancer and severe COVID-19. As people living with HIV (PLWH) have been shown to age faster than controls, we assessed whether plasma GDF15 levels were associated with inflammation markers, risk of non-AIDS comorbidities and HIV reservoir size in PLWH taking antiretroviral therapy (ART).
Methods: Plasma and peripheral blood mononuclear cells (PBMCs) were obtained from ART-treated PLWH and age-matched uninfected controls. GDF15, validated markers of inflammation (IL1β, IL6, IL8, TNFα, IP10, CXCL13, sCD14), gut permeability (LPS, REG3α and IFABP) and non-AIDS comorbidities (soluble urokinase plasminogen activator receptor [suPAR]) were quantified in plasma samples by ELISA. Coronary plaque volume was assessed by CT-scan in ART-treated PLWH and controls. HIV reservoir size was quantified by measuring integrated HIV DNA by nested-qPCR in sorted CD4 T-cells.
Results: PLWH were on ART for a median of 14.5 years and had undetectable viremia. Median age of PLWH and controls was 54 and 53 years, respectively. In PLWH compared to controls, plasma GDF15 levels were higher (p<0.0001) and correlated with age (r=0.4, p<0.01) and duration of infection. Type or class of ART did no influence GDF15 levels. In ART-treated PLWH, GDF15 levels were not associated with CD4 count, weight, gut permeability, disease progression nor inflammatory markers. GDF15 levels were also associated with levels of suPAR (r=0.68, p<0.0001, n=55) in ART-treated PLWH. In addition, GDF15 levels were associated with subclinical coronary atherosclerosis plaque volume in both ART-treated PLWH (r=0.27, p=0.009, n=90) and uninfected controls (r=0.62, p<0.001, n=40). GDF15 levels were also strongly associated with integrated HIV DNA levels (r=0.49, p<0.001, n=55) independently of age, sex, and CD4 count.
Conclusions: GDF15 levels were higher in ART-treated PLWH compared to controls and were associated with risk of non-AIDS comorbidities and HIV reservoir size, independently of classical inflammatory markers.

As cellular stress participates in faster aging, HIV reservoir size and non-AIDS comorbidities, further studies on GDF15 contribution are warranted in ART-treated PLWH.

PEB133

Sexual minority stress and accelerated cellular aging in treated HIV infection

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Background: Gay, bisexual, and other men who have sex with men experience stigma related to their sexual minority status that is theorized to drive negative health outcomes. Among people living with HIV, even those who achieve an undetectable viral load display immune dysregulation, which could be amplified by sexual minority stress to accelerate cellular aging.

Methods: This cross-sectional study enrolled 51 methamphetamine-using sexual minority men with an undetectable viral load. Participants completed measures assessing sexual minority stress, negative attitudes towards being a sexual minority (i.e., internalized heterosexism), and degree of openness about one's sexual minority status (i.e., outness). The epigenetic clock, a validated measure indexing methylation of specific CpG sites, and leukocyte telomere length were estimated using genome wide DNA methylation. Soluble markers of immune activation (e.g., sCD14) and inflammation (e.g., TNF-αRII) were measured in plasma.

Results: Participants were on average 43 years old (SD = 9), non-Hispanic White (51%), exclusively gay (76%), and had been diagnosed with HIV for an average of 14 years (SD = 9). As shown in the Figure, sexual minority stress was associated with a faster epigenetic clock.

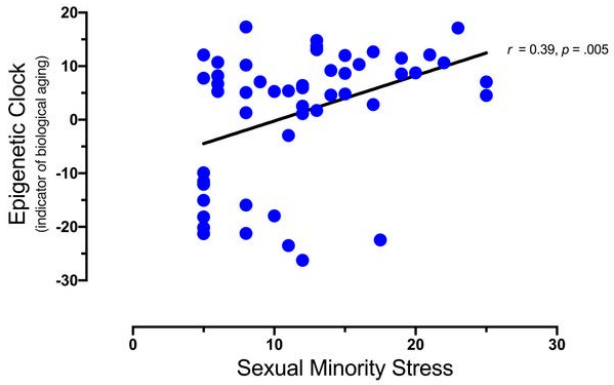

Figure. Greater sexual minority stress associated with a faster epigenetic clock among a sample of sexual minority men living with suppressed HIV (N = 51)

Even after adjusting for negative affect and recent stimulant use, greater sexual minority stress was independently associated with a faster epigenetic clock (β = 0.33, p <= 0.018) and shorter estimated leukocyte telomere length (β = -0.48, p = 0.001). Although greater internalized heterosexism (r = -0.31, p < = 0.029) and decreased outness (r = 0.28, p = 0.046) were associated with shorter leukocyte telomere length, these associations were not statistically significant in adjusted models. Soluble markers of immune activation and inflammation were not significantly associated with methylation-derived measures of cellular aging.

Conclusions: Longitudinal research is needed to elucidate the bio-behavioral mechanisms linking sexual minority stress processes with accelerated cellular aging in sexual minority men with and without HIV.

PEB134

Prevalence and predictors of hypertension in aging people living with HIV attending care in Zambia

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Background: Cardiovascular disease (CVD) is an important cause of global morbidity and mortality among aging PLWH usually associated with high prevalence of risk factors such as hypertension. Despite this, there is limited data on the prevalence predictors of hypertension among PLWH in low-income settings. This study aimed to examine the prevalence and predictors of hypertension including time and type of ART among PLWH in Zambia.

Methods: A multi-site retrospective cohort analysis using the national electronic health record (EHR) across all ten provinces and 640 clinics in Zambia (SmartCare) was conducted. All individuals with a clinic visit recorded between 1 January 2007 and 31 December 2019 were included Those individuals aged ≥45 years of age with at least one blood pressure measure record were eligible for analysis. Hypertension was defined as at least one measure of systolic or diastolic blood pressure (BP) greater than or equal to 140mmHg or 90mmHg, respectively. Mixed effects regression was used to assess the association between ART regimen and hypertension adjusting for age, sex, and ART start date allowing for random effects at the individual level.

Results: A total of 387,814 observations among 36,430 individuals were included in a mixed effects Poisson regression allowing random effects at the individual level. We found that ART regimen, body mass index (BMI), age, and time in care, were significantly associated with hypertension (Table 1).

Covariate	*PR*	*95% CI*	*p-value*
EFV	ref	ref	ref
PI	0.94	(0.88, 1.01)	0.087
DTG	1.15	(1.13, 1.18)	<0.001
other	1.02	(1.00, 1.04)	0.017
NVP	1.05	(1.02, 1.09)	0.005
45-49 years	ref	ref	ref
50-54 years	1.22	(1.18, 1.27)	<0.001
55-59 years	1.52	(1.45, 1.58)	<0.001
60-64 years	1.78	(1.68, 1.88)	<0.001
65-69 years	1.91	(1.76, 2.07)	<0.001
70+ years	1.91	(1.73, 2.11)	<0.001
Female	ref	ref	ref
Male	0.93	(0.91, 0.96)	<0.001
Underweight (BMI <18)	ref	ref	ref
Normal Weight (BMI 18-24.9)	1.34	(1.29, 1.39)	<0.001
Overweight (BMI 25-30)	1.79	(1.72, 1.86)	<0.001
Obese (BMI >30)	2.11	(2.02, 2.21)	<0.001
<1 year	ref	ref	ref
1-5 years	1.26	(1.23, 1.28)	<0.001
6-10 years	1.64	(1.59, 1.68)	<0.001
>10 years	2.35	(2.24, 2.45)	<0.001
Notes: PR-prevalence ratio, CI-confidence interval, EFV-efavirenz,PI-protease inhibitor, DTG-dolutegrevir,NVP-neviripine, BMI-body mass index			

Table 1. Adjusted prevalence ratios for hypertension

Conclusions: We found that hypertension is more prevalent among those on a regimen including dolutegravir or nevirapine compared to those on an efavirenz-based first-line regimen or regimens that include a protease inhibitor. Additionally, time in care is independently associated with a higher prevalence of hypertension. This suggests that hypertension screening and referral services should be strengthened to reduce risk of CVD as those in care continue to age and use/availability of dolutegravir increases in Zambia.

Other non-communicable diseases

PEB135

Thirty-day hospital readmission rates among North Americans living with HIV, 2005–2015

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Background: Persons with HIV (PWH) demonstrated high 30-day hospital readmission rates in the early 2000s. We examined readmission rate trends 2005-2015 in five US and one Canadian clinical cohorts.

Methods: Among PWH engaged in care, we defined index hospitalizations as having a live discharge and not being a 30-day readmission, and we used Clinical Classifications Software to categorize primary discharge diagnosis ICD codes. We estimated the 30-day probability of readmission for any reason. Linear-risk models with GEE estimated risk differences (RD) for calendar time trends, adjusted for cohort, demographics, HIV risk, CD4 count, and viral suppression <400 copies/mL.

Results: We included 16,107 index hospitalizations among 7,328 patients (73% men, 39% Black, 39% White). From 2005 to 2015, the median age at index hospitalization increased from 44 to 52 years, median CD4 count from 250 to 435 cells/μL, and viral suppression from 49% to 78%.

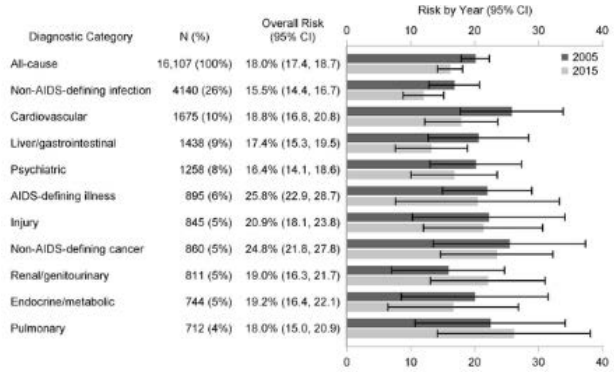

Figure 1. Unadjusted 30-day readmission risk overall (2005-2015), in 2005 and in 2015 for the most frequent categories of index discharge diagnosis

The all-cause unadjusted 30-day readmission risk decreased from 20.1% in 2005 to 16.2% in 2015 (Fig. 1), an absolute change of -0.34% annually (95% CI -0.55% to -0.13%). Readmission risk was highest for index hospitalizations due to an AIDS-defining illness (25.8%), and lowest for those due to a non-AIDS-defining infection (15.5%) (Fig. 1). The adjusted absolute change in all-cause readmission risk was -0.23% annually (-0.45% to -0.02%). Adjusted readmission risk was higher for patients who were 50-59 (RD 2.6%) or ≥60 (RD 3.7%) vs. <40 years, not virally suppressed (RD 1.6%), and with CD4 count <200 vs. ≥200 cells/μL (RD 7.4%) (all $P<0.05$).

Conclusions: Partly because of improving viral suppression and immune status, all-cause 30-day readmissions among PWH decreased 3.9 percentage points to 16.2% in 2015, an estimate comparable to that of the general population of Medicare beneficiaries ≥65 years. Readmission rate is an important hospital care quality metric, and efforts are needed to ensure this trend continues among PWH.

PEB136

Loss of retinal nerve fiber layer and contrast sensitivity in people living with HIV with well controlled disease

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Background: Antiretroviral therapy (ART) has decreased the prevalence of retinal opportunistic infections in PLWH. However, abnormalities in visual function have persisted in other forms and may be associated with accelerated/accentuated aging in PLWH. We examined the Retinal Nerve Fiber Layer (RNFL) thickness and visual function in PLWH receiving ART and HIV seronegative controls.

Methods: In this cross-sectional study, 202 PLWH without retinal opportunistic infection and 182 age-matched, HIV seronegative individuals were enrolled. PLWH were recruited from the Infectious Disease clinic at the University Malaya Medical Centre. Controls were recruited among the hospital staff and community volunteers. RNFL thickness was measured with spectral domain optical coherence tomography (SDOCT). Visual function include visual acuity using logMAR chart and contrast sensitivity using Pelli-Robson Chart. T-test was used to examine the difference in visual acuity, contract sensitivity and RNFL thickness among PLWH and controls. Generalized Linear Models (GLM) were used to assess the association between key factors and RNFL thickness in PLWH and controls.

Results: PLWH had undetectable HIV RNA (<50 copies/ml) and 61.2 % had a CD4 count more than 500 cell/μl. Participants were predominantly male, 162 (80.2%) PLWH and 119 (65.4%) controls. Mean age was 46.1 years ± 0.7 in PLWH and 44.5 years ± 0.8 in controls. The mean visual acuity was similar between the two groups (LogMAR 0.05 vs. 0.07, p = 0.115). Contrast sensitivity was lower in PLWH compared to controls (1.90 vs 1.93, p = 0.032) . RNFL thickness was significantly lower in the temporal quadrant for PLWH compared to controls (68.89 μm vs 74.08 μm, p = 0.001). Both in PLWH and controls, diabetes was significantly associated with reduced RNFL thickness in multiple quadrants while hypertension and age were not significant.

Conclusions: Changes in RNFL thickness and contrast sensitivity were seen in PLWH, independent of HIV-related parameters, despite their relatively young age and well controlled HIV disease. These changes may be associated with accelerated/accentuated ageing seen in this population. Diabetes was a significant driver in RNFL thinning in both PLWH and controls. The changes reflect structural and functional deficits, and could have long-term implications on their health trajectory.

Other ART complications and adverse reactions

PEB137

Attained stature of HIV exposed Ugandan children by 6-18 years of life according to *In-utero* or peripartum antiretroviral therapy exposure type

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Background: Children perinatally HIV infected (CPHIV) or HIV exposed but uninfected (CHEU), are exposed to antiretroviral drugs in early life with unknown impact on attained stature in the long-term.
Methods: 759 children (254 CPHIV, 254 CHEU and 251 HIV-unexposed uninfected (CHUU) born between the years 2000 and 2011 were enrolled at 6 to 18 years old and followed for 12 months with height-for-age (HAZ) determined at intake, 6 and 12 months relative to WHO reference. HIV exposed children's *in-utero/peripartum* antiretroviral (IPA) exposure was established by objective medical records and categorized as: no IPA, single-dose nevirapine with/without zidovudine (sdNVP±AZT), sdNVP+AZT+Lamivudine (3TC), or combination ART (cART). Standardized mean differences (SMD) with 95% confidence intervals (CI) in HAZ over 12 months according to IPA exposure for CPHIV and CHEU relative to CHUU were estimated using multivariable linear regression models in Statistical Analysis Software (v.9.4) with adjustment for time and caregiver factors (sex, age, education, functioning in caregiving role and lifetime adversity).
Results: Most HIV-exposed children (n=250, 49.2%) had no IPA, while 108 (21.5%), 75 (14.8%) and 75 (14.8%) were respectively exposed to sdNVP±AZT, sdNVP+AZT+3TC and cART. Regardless of IPA type, CPHIV were at growth disadvantage relative to CHUU by school-age/adolescence (SMD=-0.36, 95%CI: -0.54, -0.18). For CHEU compared to CHUU, attained stature by school-age/adolescence varied by IPA exposure type. Specifically, CHEU exposed to sdNVP±AZT (SMD= -0.21, 95%CI: -0.54, 0.09) and CHEU exposed to sdNVP+AZT+3TC (SMD=0.06, 95%CI: -0.21, 0.32) had comparable stature whereas no IPA exposure (SMD= -0.27, 95% CI: -0.52, -0.01) predicted a growth disadvantage relative to CHUU. However, CHEU with cART-based IPA exposure (SMD=0.40, 95%CI: 0.08, 0.71) achieved greater stature than CHUU by 6-18 years.
Conclusions: The finding that CHEU with IPA regimen exposure grew as well as or better (if cART-based IPA) than CHUU by 6 – 18 years old is encouraging evidence that CHEU thrive with respect to attained stature in the long-term despite IPA exposure. However, growth deficits persisted for CPHIV regardless of IPA exposure type and for CHEU without any IPA exposure highlighting the need for continued vigilance and interventions in these subgroups to support achievement of their growth potential.

Substance abuse (including opioid use disorder)

PEB138

Opioid agonist treatment improves progression through each stage of the HIV cascade of care among people living with HIV who use opioids

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Background: Opioid agonist treatment (OAT) has been shown to improve certain HIV outcomes among people living with HIV (PLHIV) with opioid use disorder. However, there is very limited data on the impacts of OAT along the full continuum of HIV care.
Methods: Using data from an ongoing cohort of PLHIV who use drugs in Vancouver, Canada, we used cumulative link mixed-models to estimate the independent effect of OAT on achieving each step in the HIV cascade of care among illicit opioid users between 2005 and 2017, after adjustment for a range of confounders.
Results: We included 639 PLHIV using illicit opioids (median age 48, 59% male, 56% white), of whom 80% were on OAT at their most recent follow-up. In adjusted analyses, the cumulative odds of successfully achieving each step of the HIV cascade was significantly higher among those on OAT compared to those off OAT: for linkage (versus non-linkage, Adjusted Odds Ratio [AOR] = 1.60, 95% Confidence Interval [CI]: 1.08–2.37); for ART engagement (AOR = 5.02, 95%CI: 3.94–6.11); for ART adherence (AOR = 4.83, 95%CI: 3.83–6.11); and HIV viral suppression (AOR = 3.99, 95%CI: 3.14–5.07).
Conclusions: This study found a high level of engagement in OAT among PLHIV using opioids and that engagement in OAT resulted in significantly increased progression through each step of the HIV care cascade. While these findings are encouraging, they also highlight the need for novel interventions to reach populations off OAT to maximize the clinical and community benefits of ART.

PEB139

Depression, anxiety, and polysubstance use among persons with HIV: baseline findings from the Promoting Access to Care Engagement (PACE) trial

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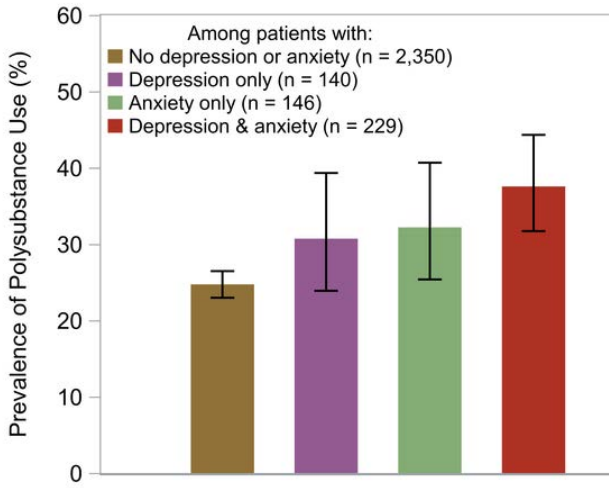
Background: In persons with HIV (PWH), mental health disorders and polysubstance use are associated with worse health outcomes, but few studies have examined patterns of their co-occurrence. We examined associations of depression and anxiety with polysubstance use among PWH in a primary care setting in the United States.
Methods: The PACE trial in Kaiser Permanente Northern California implemented computerized mental health and substance use screening and treatment in three HIV clinics. Among patients screened in

2018-2020, we estimated the prevalence of polysubstance use, defined as a Tobacco, Alcohol, Prescription medication and other Substance use (TAPS) score ≥1 (problem use or higher risk of use disorder) for two or more substances. Poisson regression with robust variance estimated unadjusted prevalence ratios (PRs) comparing patients with only depression (PHQ-9 score ≥10), only anxiety (GAD-2 score ≥3), both, or neither.

Results: We included 2,865 patients who were 92% men, 56% White, 19% Black, 15% Hispanic, and had a median age of 55 years (IQR 46-62). Five percent had a positive screen for depression only, 5% anxiety only, and 8% both. Overall, 757 (26%) patients reported polysubstance use. Among these, 73% used two substances, 21% used three, 6% used more than three, and the most frequent combination of used substances was alcohol and cannabis (42%). Polysubstance use prevalence ranged from 25% in patients with no depression or anxiety to 38% in patients with both conditions (Fig.). Compared with patients with no depression or anxiety, the PR was 1.24 (95% CI 0.96-1.61) for those with depression only, 1.30 (1.02-1.66) for those with anxiety only, and 1.52 (1.27-1.82) for those with both.



Conclusions: One-quarter of PWH in this setting reported polysubstance use, and this was higher among PWH with comorbid depression and anxiety. PWH may benefit from integrated treatment for mental health and multiple substance use disorders.

PEB140

Results from a randomized controlled trial of smoking cessation medications for alcohol reduction among HIV-positive heavy drinkers and daily smokers in St. Petersburg, Russia

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Background: People with HIV (PWH) who smoke and drink are undertreated. Nicotinic partial agonists have potential to treat both.

Methods: We conducted a randomized controlled trial among 400 heavy drinking (≥5 heavy-drinking days [HDD] in past month) and daily-smoking PWH from 2017–2020 in St. Petersburg, Russia. All participants received brief alcohol/tobacco counseling, one medication, and one placebo (P), yielding 4 arms:

Arm 1: varenicline+P-NRT (nicotine replacement therapy);

Arm 2: P-varenicline+NRT;

Arm 3: cytisine+P-NRT; and

Arm 4: P-cytisine+NRT.

The 3 main pairwise comparisons were: Arms 1vs2; 3vs4 ; 1vs3. Three, 6, and 12 months outcomes were past-month HDD (primary outcome-3 months), cigarettes per day (CPD), biochemically-verified 7-day point prevalence abstinence from smoking. Alcohol abstinence at 3 months was defined as no self-reported alcohol consumption in past 30 days with biochemical confirmation (phosphatidyl ethanol level <8 ng/mL).

Outcome	4 trial arms (total n = 400)			
	Varenicline + P-NRT (Arm 1) N=100	P-varenicline + NRT (Arm 2) N=99	Cytisine + P-NRT (Arm 3) N=100	P-cytisine + NRT (Arm 4) N=101
Baseline				
HDD Mean (SD) Median (IQR)	9.5 (6.1) 7 (5, 11)	9.3 (5.7) 8 (6, 10)	8.9 (5) 8 (6,10)	9.6 (6.3) 7 (6, 10)
CPD Mean (SD) Median (IQR)	21.7 (8.2) 20 (17.9, 27.1)	20.4 (8.2) 20 (15, 22.9)	20.8 (7.3) 20 (17.5, 22.1)	20.9 (8.6) 20 (15, 25)
3 months				
	N= 89	N=88	N=83	N=88
HDD Mean (SD) Median (IQR)	1.9 (3.6) 0 (0, 3)	2 (4.2) 0 (0, 2)	1.4 (3.3) 0 (0, 1)	2.3 (5.3) 0 (0, 2)
CPD Mean (SD) Median (IQR)	4.8 (6.8) 1.9 (0, 6.0)	6 (7.2) 3.2 (0.8, 9.1)	6.3 (7.5) 2.6 (0, 10)	6 (7.2) 4.4 (0, 9.7)
Smoking abstinence	22 (24.7%)	12 (13.6%)	23 (27.7%)	20 (23%)
Alcohol abstinence	22 (24.7%)	18 (20.5%)	18 (22.5%)	17 (20.5%)
6 months				
	N=86	N=88	N=83	N=86
HDD Mean (SD) Median (IQR)	1.7 (3.8) 0 (0, 2)	1.0 (2.2) 0 (0, 1)	1.4 (3.4) 0 (0, 1)	2.1 (4.9) 0 (0, 1)
CPD Mean (SD) Median (IQR)	7.5 (6.5) 7.1 (0.4, 10)	7.3 (7.9) 5 (0.4, 10.4)	6.7 (7) 5 (0, 10)	7.9 (8) 5 (0.1, 14.6)
Smoking Abstinence	12 (14.1%)	14 (16.3%)	17 (20.7%)	17 (20.2%)
12-months				
	N=79	N=82	N=80	N=85
HDD Mean (SD) Median (IQR)	2.4 (5.7) 0 (0, 2)	1.6 (3.9) 0 (0, 1)	2 (5.3) 0 (0, 1)	3 (6.7) 0 (0, 1)
CPD Mean (SD) Median (IQR)	8.4 (6.7) 8.6 (2.1, 11.4)	7.8 (8.1) 5.4 (0.6, 15)	7.2 (7.5) 5 (0, 11.1)	8.2 (8) 7 (0.4, 13.7)
Smoking abstinence	14 (17.7%)	15 (18.3%)	20 (25.3%)	17 (20.2%)

HDD=number of heavy drinking days; **CPD**=cigarettes smoked per day
Smoking abstinence is biochemically validated at all time points
Alcohol abstinence is biochemically validated at 3 months

We modeled HDD with negative binomial regression to estimate incidence rate ratios (IRR) and controlled for randomization stratification factors: past week alcohol consumption, daily cigarettes, and current ART use.

Results: There were no major imbalances across randomized groups. Baseline characteristics were 66% male, mean age 39 years, mean CD4 count 391 cells/mm^3, and 57% undetectable HIV viral load. All groups improved from baseline on primary and secondary outcomes at all time points (Table). There were no significant differences in our three main comparisons for number of HDD at 3 months: arms 1vs2 (IRR 0.91; 95%CI 0.51- 1.65, p=0.76), arms 3vs4 (IRR 0.68; 95%CI 0.37 -1.23, p= 0.60; arms 1vs3 IRR 1.12 (0.62, 2.03) p= 0.76. There were no serious medication-related adverse events.

Conclusions: Among PWH with heavy drinking, daily smoking, there were no differences in the number of HDDs between varenicline, cytisine and NRT. All groups reduced alcohol consumption and smoking through 12 months. These medications were well-tolerated. Future research should further investigate integrated alcohol/smoking care in PWH.

PEB141

Anxiety and alcohol consumption in the Miami Adult Studies on HIV (MASH) cohort during the COVID-19 pandemic

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Background: Mental health problems have increased during the COVID-19 crisis and could be especially challenging for people living with HIV and/or substance use disorders. Anxiety and other mental health disorders may contribute to increased alcohol consumption; however, few studies have investigated this relationship during the pandemic. In this study, we examined whether the presence of anxiety symptoms was associated with changes in alcohol use in response to the COVID-19 outbreak among participants from the Miami Adult Studies on HIV (MASH) cohort.

Methods: A telephone survey was administered to 314 MASH participants between July-August of 2020. In this study we examined (1) changes of alcohol use prior to and during the pandemic and (2) whether alcohol use was influenced by anxiety. The Alcohol Use Disorder Identification Test-Consumption (AUDIT-C) was used to determine alcohol misuse and binge drinking. The presence of anxiety symptoms was determined with the Generalized Anxiety Disorder-7. McNemar's tests (to compare frequencies between two time-points) and binary logistic regressions were performed (SPSS V.20).

Results: Thirty-nine percent of participants reported anxiety symptoms. A total of 34.4% and 11.9% reported alcohol misuse and binge drinking during the pandemic, respectively (Table 1). Overall, no changes in alcohol consumption were noted (P>0.5). However, among participants with anxiety symptoms during the pandemic, but not those without, there were significant increases in alcohol misuse (34.5% to 50.0%; P=0.005) and binge drinking (10.7% to 25.5%; P< 0.001). Additionally, participants with anxiety symptoms during the pandemic were at increased risk for alcohol misuse and binge drinking during, but not prior to the pandemic (Table 1).

		Anxiety symptoms (during the pandemic)				
	Total	No (N=191)	Yes (N=123)	OR	95% CI	P
Before pandemic						
Alcohol misuse	27.5%	26.1%	34.5%	1.49	0.63-3.50	0.356
Binge drinking	7.2%	6.5%	10.7%	1.73	0.43-6.85	0.433
During pandemic						
Alcohol misuse	34.4%	31.0%	50.0%	2.22	1.23-4.00	0.008
Binge drinking	11.9%	8.9%	25.5%	3.47	1.65-7.30	0.001

Table 1. Anxiety symptoms as a potential modifier of alcohol use during the COVID-19 pandemic (N=314)

Conclusions: Anxiety may be a significant risk factor for alcohol misuse and binge drinking during the COVID-19 crisis. Strategies to mitigate mental health problems and hazardous drinking are needed, particularly in vulnerable populations such as the MASH cohort.

ART in acute infection

PEB142

OPTIPRIM 2-ANRS trial comparing dolutegravir vs darunavir in acute HIV-1 infection

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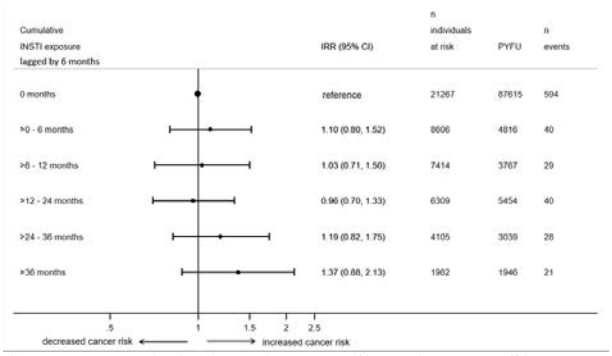
Background: Hypothesis: A dolutegravir +TDF/FTC once daily regimen (Arm1) compared to a darunavir/cobicistat +TDF/FTC once daily regimen (Arm2) initiated during acute-HIV-1 infection, could rapidly inhibit viral replication and also reduce the viral reservoir size, evaluated by the total HIV-DNA level in PBMC at 48 wks.

Methods: Adult patients with a recent/acute HIV1-infection were enrolled in OPTIPRIM-2-ANRS169 randomised open-label multicenter trial, if they had a western-blot <5 antibodies or immunoblot <3 antibodies dated less than 10 days ago and a detectable plasma-HIV-RNA. The endpoint was the total HIV-DNA level in PBMC at 48 weeks. HIV-DNA and HIV-RNA measurements were done centrally by ultrasensitive PCRs (Biocentric-France).

Results: Between April 2017 and August 2018, 101 patients were enrolled in 31 french hospitals. Most patients were men (94%), MSM (81%), median age 37 years, 80% from Europe. At inclusion, 17% were in Fiebig3 or less stage. Median [IQR] plasma-HIV-RNA was 5.8 $\log_{10}$ copies/mL [5.0; 6.6], median CD4 436/mL [333; 602], median total HIV-DNA 3.87 $\log_{10}$ copies/million PBMC [3.52; 4.15].

Overall, 49 patients in Arm1; 48 in Arm2 stayed until the end of the trial. Median HIV-DNA at wk 4, 8, 12 were: 3.24 [2.93; 3.58], 3.06 [2.81; 3.45], 2.94 [2.45; 3.26] in Arm1 and 3.34 [3.04; 3.71], 3.18 [2.92; 3.58], 3.00 [2.74; 3.38] in Arm2. At wk 48, HIV-DNA levels were lower in Arm1 (median 2.34 log vs 2.56, p=0.031). However, the median decrease in HIV-DNA levels at wk 48 was -1.48 log copies/million PBMC in Arm1 [-1.74;-1.06], in Arm2: -1.39 [-1.55;-0.98], p=0.52. The decrease to HIV-RNA level <50 copies/mL was 24% in Arm1 vs. 0% in Arm2 at wk 4, 55% vs. 2% at wk 8, 67% vs. 17% at wk 12 and 94% vs. 90% at wk 48, respectively. Cumulative viremia until wk 48 adjusted for baseline HIV-RNA level was significantly lower in Arm1 than in Arm2 (p<0.001).

Conclusions: The dolutegravir-based regimen had a much faster and powerful effect on viral replication within the first weeks following acute HIV infection, when viral replication level is particularly high with a major risk of HIV transmission; but this was not enough to further reduce the viral reservoir size.



Abbreviations: INSTI-integrase strand transfer inhibitor; IRR-incidence rate ratio; CI-confidence interval; PYFU-person years of follow-up IRR adjusted for age, sex, ethnicity, HIV risk group, antiretroviral experience, CD4 cell count, CD4 nadir, prior hypertension, prior diabetes, prior AIDS, prior cancer (all fixed at baseline), calendar year, smoking status, nucleoside reverse transcriptase inhibitor backbone, cumulative exposure to atazanavir and indinavir (all time updated)

Figure. Association between cancer risk and cumulative exposure to INSTIs lagged by 6 months, adjusted for potential cofounders

Conclusions: In this large cohort, there was no association between lagged INSTI exposure and cancer risk, although this differed by prior ART exposure. Confounding by indication cannot be excluded.

ART in first- and second-line therapies

PEB143

Integrase strand transfer inhibitor (INSTI) use and cancer incidence

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Background: Limited data exist examining the association between cancer and INSTI use. We aimed to assess whether cumulative INSTI (dolutegravir, raltegravir, elvitegravir) exposure was associated with increased cancer risk.

Methods: RESPOND participants INSTI-naïve at baseline (latest of local cohort enrolment or 1 January 2012) were followed until earliest of first cancer, final follow-up, or 1 October 2018. Negative binomial regression assessed associations between cancer incidence and time-updated cumulative INSTI exposure, adjusted for potential confounders (Figure). INSTI exposure was lagged by 6 months, accounting for possible confounding by indication and reverse causality.

Results: Of 21,267 individuals included, 73% were male, 21% antiretroviral treatment (ART)-naïve, with median age 45 years (interquartile range [IQR] 37-52).

Overall, 9698 (46%) started INSTIs during follow-up. Median cumulative exposure on INSTIs was 26 months (IQR 13-40). During 106,637 person-years of follow-up (PYFU), there were 752 events (incidence rate [IR] 7.1/1000 PYFU [95% CI: 6.6-7.6]): 139 AIDS, 613 non-AIDS cancers. The commonest cancers were lung (11%), anal (9%) and non-Hodgkin's lymphoma (8%).

After adjustment, there was no association between cancer risk and lagged INSTI exposure (global p=0.69, Figure). Results were similar when stratified by age, excluding those with cancer prior to baseline, or analysing AIDS/non-AIDS cancers separately.

There was a significant interaction between INSTI exposure and ART-experience at baseline (interaction p=0.004). After adjustment, those ART-naïve (n=4502, 132 events) had a lower cancer incidence at >6 months vs no INSTI exposure (>0-6 months: IR ratio 0.78 [95% CI: 0.41-1.48]; >6 months: 0.51 [0.30-0.88]). Conversely, those ART-experienced with viral load <200 copies/mL (n=15147, 568 events) had a higher cancer incidence at >6 months vs no INSTI exposure (>0-6: 1.05 [0.69-1.60]; >6: 1.29 [1.01-1.65]).

PEB144

Antiretroviral therapy for HIV controllers: indications and outcomes in the French ANRS-CO21 CODEX cohort

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Background: Less than 1% of HIV-infected individuals are able to achieve spontaneous viral control without requiring antiretroviral therapy (ART). Whether these HIV controllers (HIC) are at risk of HIV-associated comorbidities and could benefit from ART is debated, but recent studies reported decreased T-cell activation upon ART initiation. We report the frequency of ART initiation, reasons to treat, treatment outcome on immunovirological parameters, and rate of side-effects and treatment discontinuation in the French cohort of HIC.

Methods: Participants included in the ANRS CODEX cohort of HIC were prospectively followed. ART initiation, indication, discontinuation, non-AIDS-defining events, side-effects, and immunovirological parameters were recorded. Undetectable HIC (u-HIC) were defined as participants with strictly undetectable viral loads based on routinely used assays throughout the follow-up and blipper HIC (b-HIC) as participants with possible detectable viral loads above the detection threshold during follow-up.

Results: Among 302 HIC followed for a median of 14.8 years [10.3-20.2], 90 (30%) received ART (7 u-HIC and 83 b-HIC). The main reasons for ART initiation were decreased CD4 T-cell counts (n=36, 40%), loss of virological control (n=13, 14%), and non-AIDS-defining events (n=12, 13%). Sixteen (18%) participants experienced 17 grade 1-2 adverse events. In b-HIC, ART slightly increased the CD4/CD8 ratio (median +0.19, p<0.0001) and decreased the frequency of circulating $CD38^+$ $HLA\text{-}DR^+$ CD4 and CD8 lymphocytes (median -0.75%, p=0.003, and

-2%, p<0.0001, respectively), but these changes were not observed for treated u-HIC. Thirteen (14%) participants discontinued ART (5 (38%) because of side-effects, and 10 remained HIC after treatment cessation (median follow-up: 305 days [235-728]).

Conclusions: Only 30% of participants in this large cohort of HIC required ART during a median follow-up of 14.8 years. These results show that HIC status is very stable and can be maintained for decades and vouch for a patient-centered treatment decision based on the individual benefit/risk balance.

PEB145

Are patients starting first-line ART with a 2-drug regimen (2DR) with dolutegravir/lamivudine different from those initiating 3-drug regimens (3DR) based on an integrase strand transfer inhibitor (InSTI), plus tenofovir alafenamide/emtricitabine?

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Background: Aim: To identify patients' profiles associated with the initiation of a 2DR vs. a 3DR regimen with an InSTI plus tenofovir alafenamide/emtricitabine in an ART-naive population.

Methods: Retrospective cohort study. All adults enrolled in the ICONA Cohort Study who started their first-line ART since January 1, 2019 with a 2DR of dolutegravir/lamivudine or a 3DR based on an InSTI plus tenofovir alafenamide/emtricitabine were included.

Primary outcome: initiation of a 2DR rather than a 3DR as first-line ART. Patients' characteristics were summarized by treatment group and compared by hypothesis testing. A logistic regression model was used to derive a propensity score (PS) for both groups.

We also established the sample size of a population obtained by PS 1:1 matching and a caliper of ±0.25 and compared the PS in this subset.

Finally, unadjusted and adjusted odds ratios (ORs) from fitting a logistic regression were shown for the variables included in the PS (Figure).

Results: 761 patients; 157(20.6%) started ART with a 2DR, 604(79.4%) with a 3DR. Main baseline characteristics reported in figure.

Factors showing the greatest imbalance by treatment groups: age, HIV risk factor, calendar year of initiation, geographical region, days from HIV diagnosis to initiation, immune-virological parameters and AIDS status, as reflected in the estimated ORs(Figure) as well as in the distribution of PS in the full dataset. PS matching led to a small loss in sample size(n=132 matched-pair). Residual imbalance was within the threshold of 25%, without drastic changes in the characteristics of the target population.

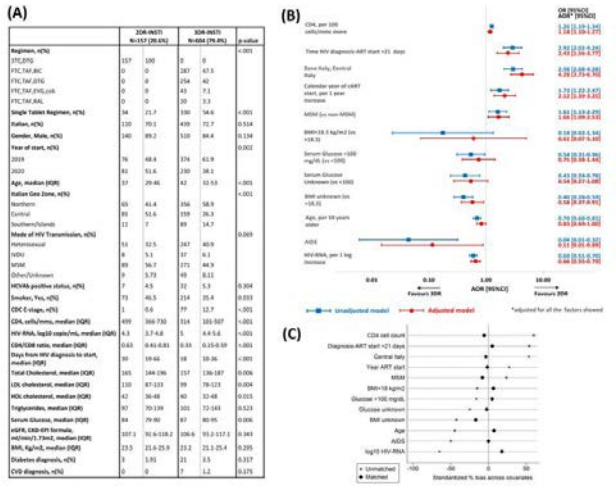

Figure.

Conclusions: ART-naïve patients in our cohort starting their first-line ART with 2DR or 3DR differed for a number of key characteristics associated with response to treatment. However, imbalance could be entirely corrected by selecting a PS matched subset. Emulation of a trial comparing the two arms is likely to be possible with cumulating follow-up.

PEB146

High rates of viral suppression sixteen weeks after transition from EFV- to DTG-based ART regardless of viral load at transition: the DO-REAL cohort study in Lesotho

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Background: Since 2018, the WHO has recommended dolutegravir (DTG)-containing antiretroviral therapy (ART) for most people living with HIV (PLHIV). Countries across Africa have since rolled out DTG. However, there are concerns that functional monotherapy among ART-experienced PLHIV transitioning to DTG-based ART may impact treatment outcomes, and uncertainty thus remains concerning the optimal modality of roll-out.

Methods: The *Dolutegravir in Real-Life* cohort (NCT04238767) enrols PLHIV initiating DTG-based ART in Lesotho. Here, we present data of adult (≥18 years) participants at Butha-Buthe Government Hospital transitioning from EFV- to DTG-based first-line ART. Patients with a last viral load (VL) above 1000 copies/mL were not transitioned within first-line ART. Blood samples were collected at transition and at 16 weeks (window 10-24) follow-up for VL and genotypic resistance testing. Participants were enrolled from February 2020 until December 2020. Data was closed for analysis on February 1, 2021.

Results: Among 1308 PLHIV enrolled, 936 (71.6%) completed follow-up before data closure and had an available VL result before, at, and 16 weeks after transition. 572/936 (61.1%) were female; at enrolment, median age was 47 years (IQR=[38-56]) and median time taking ART was 6.0 years (IQR=[3.5-8.9]). The last pre-transition VL preceded

transition by a median of 16.0 weeks (IQR=[12.0-24.1]), median time from transition to follow-up was 16.0 weeks (IQR=[13.1-16.1]).
The figure shows VL dynamics. At follow-up, 923/936 (98.6%) had a VL <100 copies/mL and 852/936 (91.0%) had a VL <20 copies/mL. Among all assessed strata of viremia at transition (see figure), at follow-up, ≥95% achieved viral suppression to <100 copies/mL and ≥77% achieved viral suppression to <20 copies/mL.

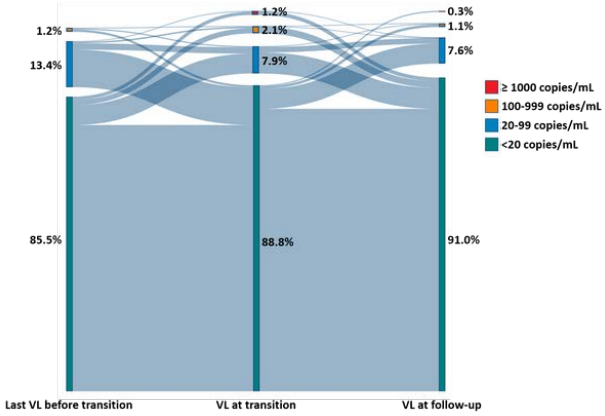

Figure. Viral load (VL) of last measurement pre-transition from EFV to DTG, measured at transistion, and measured at 16 weeks follow-up among those with a VL result at all three time points (N=936).

Conclusions: Regardless of the VL at transition, the vast majority of participants had reached a VL <20 copies/mL at follow-up. These data are encouraging regarding the safety of programmatic transition form EFV- to DTG-basd ART – even if the VL was unsuppressed at transition.

PEB147

The safety and efficacy of maintenance with doravirine/lamivudine/tenofovir through 192 weeks in adults with HIV-1: results from the DRIVE-AHEAD clinical trial

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Background: DRIVE-AHEAD is a phase 3 trial with a completed double-blind phase comparing doravirine/lamivudine/tenofovir disoproxil fumarate (DOR/3TC/TDF) to efavirenz/emtricitabine/TDF (EFV/FTC/TDF) and an ongoing open-label extension. At 48 and 96 weeks, once-daily DOR/3TC/TDF demonstrated non-inferior efficacy to EFV/FTC/TDF, superior CNS safety, and a favorable lipid profile. Here we present efficacy and safety results through Week 192 (W192).
Methods: Participants who completed the 96-week double-blind phase and met inclusion criteria were eligible to receive open-label DOR/TDF/3TC in a 96-week extension. Efficacy and safety were assessed in 2 groups: participants initially randomized to DOR/3TC/TDF and maintained on DOR/3TC/TDF (N=291) and those who switched from EFV/FTC/TDF to DOR/3TC/TDF (N=269).
Results: HIV-1 RNA <50 copies/mL was maintained through W192 in 84.9% of participants who continued DOR/3TC/TDF and 80.3% of those who switched to DOR/3TC/TDF. Protocol-defined virologic failure occurred in 2.4% and 4.8%, respectively, and the development of genotypic resistance was low in both groups (table). Discontinuation due to adverse events was also low (table). Neuropsychiatric adverse event rates during the extension (6.2% and 9.3%, respectively) were substantially lower than during the base study (DOR/3TC/TDF group 26.4%; EFV/FTC/TDF group 58.5%). Fasting LDL-cholesterol, non-HDL-cholesterol, and triglycerides showed minimal change in participants maintained on DOR/3TC/TDF and were reduced in those who switched to DOR/3TC/TDF (table). Participants maintained on DOR/3TC/TDF had minimal weight gain after W96 (median 0.5 kg) and a small increase overall (median 2.0 kg; Day 1 through W192); participants who switched to DOR/3TC/TDF had a small increase after W96 (median 2.0 kg), similar to median weight gain in the base study (DOR/3TC/TDF 1.2 kg; EFV/FTC/TDF 1.0 kg).
Conclusions: Among participants who continued DOR/3TC/TDF in the open-label extension, high efficacy and favorable safety were maintained for an additional 96 weeks. In participants who switched from EFV/FTC/TDF, DOR/3TC/TDF maintained virologic suppression and demonstrated favorable safety for 96 weeks.

	Randomized to DOR arm and Maintained on DOR/3TC/TDF N = 291	Randomized to EFV arm and Switched to DOR/3TC/TDF N = 269
HIV-1 RNA <50 copies/mL[a] HIV-1 RNA ≥50 copies/mL[a] No data in window[a]	247 (84.9) 13 (4.5) 31 (10.7)	216 (80.3) 23 (8.6) 30 (11.2)
HIV-1 RNA 50 to <200 copies/mL	2 (0.7)	8 (3.0)
Protocol-defined virologic failure[b]	7 (2.4)	13 (4.8)
Genotypic resistance to DOR[c] Genotypic resistance to 3TC/TDF[c]	0 (0.0) 0 (0.0)	3 (1.1) 1 (0.4)
CD4+ T-cell count (cells/mm^3)[d]	Mean change (95% CI) from start of DOR/3TC/TDF[e]	
	304 (278, 330)	74 (49, 99)
Adverse Event (AE) summary	n (%)	n (%)
One or more AE Drug related AE Serious AE Discontinued due to AE Neuropsychiatric AE	213 (73.2) 17 (5.8) 19 (6.5) 1 (0.3) 18 (6.2)	216 (80.3) 16 (5.9) 12 (4.5) 3 (1.1) 25 (9.3)
Fasting lipids (mg/dL)	Mean change (95% CI) from start of DOR/3TC/TDF[e]	
LDL-cholesterol Non-HDL-cholesterol Triglycerides Total cholesterol to HDL-C ratio	-1.2 (-4.2, 1.7) -0.7 (-4.1, 2.6) -0.7 (-10.6, 9.2) -0.15 (-0.30, 0.00)	-10.5 (-13.4, -7.6) -15.5 (-18.5, -12.5) -26.2 (-35.2, -17.1) -0.22 (-0.35, -0.10)
Weight (kg)	Mean change (min,max) from start of DOR/3TC/TDF[e]	
	2.0 (-21.8, 26.0)	2.0 (-12.0, 26.8)

Data shown as n (%), unless otherwise indicated.
[a] FDA Snapshot approach, at Study Week 192
[b] Protocol defined virologic failure (PDVF) is defined as: Confirmed (2 consecutive measures at least 1 week apart) HIV-1 RNA ≥50 copies/mL after initial repsonse of HIV-1 RNA <50 copies/mL at any time during the study.
[c] Resistance was assessed in participants with PDVF and those who discontinued early and had HIV-1 RNA ≥400 copies/mL.
[d] Observed Failure approach for missing data; baseline carried forward for failures, other missing values excluded.
[e] Start = Day 1 for participants maintained on DOR/3TC/TDF; Week 96 for those who switched to DOR/3TC/TDF.

Table. DRIVE-AHEAD efficacy & safetey outcomes, week 192, participants who entered study extension (weeks 96-192)

PEB148

Efficacy and safety of long acting HIV fusion inhibitor albuvirtide in treatment-experienced HIV-1 infected patients: week 48 analysis from the randomized controlled phase 3 TALENT study

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Background: Albuvirtide, a peptide-based and long-acting fusion inhibitor, blocks the HIV-1 Env-mediated cell membrane fusion and virus entry. We present the 48-week analysis of the TALENT study (ClinicalTrials.gov, NCT02369965), that assessed the safety and efficacy of albuvirtide plus lopinavir-ritonavir in antiretroviral-experienced adults with HIV-1.

Methods: TALENT is a phase 3, randomized, controlled, open-label, multicenter non-inferiority study. Eligible subjects failed the WHO first-line ART therapy with plasma viral load > 1000 copies per mL were randomly assigned (1:1) to receive 320 mg albuvirtide (once weekly) plus ritonavir-boosted lopinavir (albuvirtide group) or 2 NRTIs plus ritonavir-boosted lopinavir (2 NRTIs group). The primary endpoint was the proportion of patients with plasma viral load less than 50 copies per mL at 48 weeks by FDA snapshot algorithm. Non-inferiority was pre-specified with a margin of 12%. A modified intention-to-treat analysis was carried out.

Results: A total of 1291 patients were screened and 418 were enrolled. Safety analysis included 401 patients (195 albuvirtide vs. 206 2NRTIs) who received at least one dose of the study drugs. 383 patients (185 albuvirtide vs. 198 2NRTIs) were allocated for the modified intent-to-treat analysis, excluding 18 patients (10 albuvirtide vs. 8 2NRTIs) either for severe protocol violations or without any viral load data. At 48 weeks, 75.7% patients in the albuvirtide group had HIV-1 RNA less than 50 copies per mL versus 77.3% in the 2NRTIs group (difference -1.6%, 95% CI −10.1 to 6.9), meeting the non-inferiority criteria. All patients had good drug adherence of over 90% in both groups. No injection site reactions were observed in albuvirtide group during the 48-week treatment duration. One patient in 2 NRTIs group died during the study, but not related to drugs. Patients in albuvirtide group had no drug-related serious adverse events compared with 2 patients in 2 NRTIs group. Adverse events leading to discontinuation were 2 (1.0%) in both groups. The overall frequencies of drug-related adverse events were similar in both groups, commonly included diarrhea, nausea and triglycerides elevation.

Conclusions: Two-drug regimen of albuvirtide in combination with lopinavir/ritonavir was well tolerated and non-inferior to the standard second-line three-drug regimen at 48 weeks.

PEB149

Week 96 metabolic and bone outcomes of a Phase 2b trial of islatravir and doravirine

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Background: Islatravir (MK-8591) is the first nucleoside reverse transcriptase translocation inhibitor (NRTTI) in development for treatment and prevention of HIV-1 infection. Islatravir+doravirine (ISL+DOR) is well tolerated and effective in maintaining viral suppression through Week 96.

As antiretroviral agents can be associated with weight gain, bone mineral density (BMD) loss, and metabolic abnormalities, this phase 2b trial in treatment-naive adults with HIV-1 examined effects of ISL+DOR on metabolic outcomes and BMD.

Methods: Participants were randomized to ISL (0.25, 0.75, or 2.25 mg) + DOR (100 mg) and lamivudine (3TC; 300 mg) once daily (QD) or fixed-dose combination of DOR, 3TC, and tenofovir disoproxil fumarate (DOR/3TC/TDF) QD. In ISL groups, participants who achieved HIV-1 RNA <50 copies/mL at Week 20 or later stopped 3TC at next study visit. All participants receiving ISL were switched to ISL 0.75 mg between Week 60 and 84. Participant weight, hip/spine BMD, peripheral/trunk fat, and fasting plasma glucose and lipids were assessed.

Results: Participants (N=121) were comparable across groups (93% male; 76% white; mean age 31 years). Mean baseline CD4+ count was 492 cells/mm^3; 22% had HIV-1 RNA >100,000 copies/mL. No statistically significant differences were observed between groups for any metabolic parameter at Week 96 (Table).

Median reduction in BMD from baseline appeared lower in ISL+DOR groups than the DOR/3TC/TDF group. Increases from baseline in both high- (HDL-C) and low-density lipoprotein cholesterol were numerically higher in ISL+DOR groups than the DOR/3TC/TDF group, whereas changes in total cholesterol:HDL-C ratios were similar. Change in weight was modestly higher in ISL+DOR groups, although proportion of participants with ≥10% weight gain was similar.

Parameter	ISL (0.25, 0.75, or 2.25 mg) + DOR QD (n=72)	DOR/3TC/TDF QD (n=24)	Statistically significant difference by overlapping 95% CI or IQR[b]
	Median % change (95% CI) or median change from baseline (Q1, Q3)[a]	Median % change (95% CI) or median change from baseline (Q1, Q3)[a]	
Hip BMD, g/cm^2 [c,d]	−1.07 (−1.82, −0.25)	−3.38 (−4.55, −1.58)	NS
Spine BMD, g/cm^2 [d,e]	−0.51 (−1.98, 0.24)	−1.40 (−2.74, 0.00)	NS
Peripheral fat, g[f,g]	7.50 (−1.12, 13.76)	7.67 (−3.77, 18.94)	NS
Trunk fat, g[f,g]	15.49 (6.75, 22.26)	12.66 (−3.18, 26.91)	NS
Weight, kg[h,i]	3.50 (0.60, 7.00)	2.59 (−0.20, 6.00)	NS
≥10% weight increase, n (%)[h,i]	23.3 (14.2, 34.6)	20.0 (6.8, 40.7)	NS
Fasting plasma			
Glucose, mg/dL	6.32 (2.13, 8.89)	2.97 (0.00, 8.75)	NS
Total cholesterol, mg/dL	8.29 (2.31, 13.59)	−1.56 (−9.40, 12.78)	NS
HDL-C, mg/dL	16.82 (8.16, 21.62)	2.89 (−5.23, 12.12)	NS
LDL-C, mg/dL[e]	3.45 (−0.95, 6.96)	1.72 (−11.41, 20.00)	NS
Triglycerides, mg/dL	1.36 (−9.55, 13.33)	−8.96 (−16.85, 0.00)	NS
TC:HDL-C ratio	−0.27 (−0.83, 0.18)	0.03 (−0.41, 0.12)	NS

[a]Median % change from baseline (95% CI) for all parameters except weight and TC:HDL-C ratio, which are presented as median change from baseline (Quartile 1, Quartile 3)
[b]Statistical significance determined by overlapping 95% CI or IQR; no adjustments for multiplicity were done for these comparisons
[c]ISL+DOR (n=66); [d]DOR/3TC/TDF (n=22); [e]ISL+DOR (n=67); [f]ISL+DOR (n=62); [g]DOR/3TC/TDF (n=21); [h]ISL+DOR (n=73); [i]DOR/3TC/TDF (n=25)
3TC, lamivudine; BMD, bone mineral density; CI, confidence interval; DOR, doravirine; HDL-C, high-density lipoprotein cholesterol; IQR, interquartile range; ISL, islatravir; LDL-C, low-density lipoprotein cholesterol; N/A, not applicable; NS, not significant; QD, once daily; TC, total cholesterol; TDF, tenofovir disoproxil fumarate.

Table. Change in metabolic endpoints at week 96

Conclusions: No unexpected or concerning metabolic or bone effects were observed in treatment-naive adults living with HIV-1 receiving ISL+DOR. Due to small sample size in this trial, clinical significance will be further investigated in phase 3 clinical studies.

PEB150

Achievement of undetectable HIV-1 RNA in the B/F/TAF treatment-naïve clinical trials

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Background: HIV-1 viral loads (VL) that are <50 c/mL but still detectable may be associated with virologic rebound and elevated inflammatory markers. Studies 1489 and 1490 are phase 3, randomized, double-blind, active-controlled studies of initial HIV-1 treatment which demonstrated that bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) was non-inferior to dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) and DTG+F/TAF through 144 weeks. Participants' VL were measured using the COBAS® TaqMan® v2.0 test, which quantitates HIV RNA from 20 to 10,000,000 c/mL and provides qualitative target detected (TD) or target not detected (TND) results for VL <20 c/mL. Here, we assessed achievement of undetectable HIV-1 RNA (TND) in Studies 1489 and 1490.

Methods: Participants with at least one on-treatment post-baseline VL value had treatment efficacy assessed by missing=excluded imputation at each study visit using a range of VL endpoints through Week 144. Predictors of consistent TND (TND at ≥85% of visits between Weeks 48 and 144) were studied using a multivariate logistic regression analysis.

Results: At Week 144, 99% of participants in the B/F/TAF, DTG/ABC/3TC, and DTG+F/TAF groups had VL <50 c/mL. The percentages with undetectable VL <20 c/mL TND at Week 144 were lower for all groups: 71% B/F/TAF, 74% DTG/ABC/3TC, and 72% DTG+F/TAF. Achievement of TND at Week 144 was associated with baseline VL ≤100,000 c/mL, baseline CD4 count ≥200 cells/μL, and adherence by pill count ≥95%. The stringent criteria of ≥85% consistent TND between Weeks 48 and 144 (generally 8-9 of 9 visits) was achieved in 29% to 35% of participants in each treatment group; the pooled participants had a median baseline VL of 11,100 c/mL and CD4 count of 492 cells/μL. By multivariate logistic regression analysis, consistent TND was associated with baseline VL ≤100,000 c/mL, baseline CD4 count ≥200 cells/μL, adherence ≥95%, asymptomatic HIV disease, and no secondary INSTI resistance (p<0.05).

Conclusions: Treatment with B/F/TAF, DTG/ABC/3TC, and DTG+F/TAF achieved similar proportions of VL <20 c/mL TND at all visits through Week 144. Consistent TND was associated with several factors, including lower baseline VL, higher baseline CD4 cell count, and high adherence. These data can be used to design studies with enhanced frequency of TND outcomes, which could aid cure research.

PEB151

Long-term analysis of B/F/TAF in treatment-naïve adults living with HIV through four years of follow-up

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Background: Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) is a guideline-recommended single-tablet regimen for people with HIV-1 (PWH). Week (W) 48 primary and W96 and W144 secondary endpoint results of the blinded phase from two studies established non-inferiority of B/F/TAF to dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) and DTG+F/TAF in treatment-naïve PWH. We present pooled outcomes from an open-label extension (OLE) in participants initially randomized to B/F/TAF through W192.

Methods: We conducted two randomized, double-blind, phase 3 studies in treatment-naïve adult PWH: Study 1489 B/F/TAF vs DTG/ABC/3TC and Study 1490 B/F/TAF vs DTG+F/TAF. Unblinding occurred after all participants completed W144, after which all were offered B/F/TAF in OLE. Participants who were originally randomized to B/F/TAF and entered OLE were pooled into an all-B/F/TAF group.

An analysis at W192 assessed efficacy as the proportion with HIV-1 RNA <50 c/mL using missing=excluded (M=E) and missing=failure analyses; safety was assessed by adverse events (AEs) and laboratory results.

Results: Of 634 participants originally randomized to B/F/TAF, 506 (80%) opted for OLE (89% men, 33% Black, median age 32 years [range 18-71]). An on-treatment analysis at W192 revealed 99.2% of B/F/TAF participants maintained HIV-1 RNA <50 c/mL (M=E) and had a median increase in CD4 count of +289 cells/ml from baseline. No participant on B/F/TAF failed with resistance.

Among the B/F/TAF group through W192, 79% (471/594) of treatment-emergent AEs were Grade 1 or 2, most commonly diarrhea, nasopharyngitis, headache, upper respiratory tract infection and syphilis. AEs led to drug discontinuation in 1% (n=7) of participants. Median (Q1, Q3) weight change from baseline to W192 was 4.9kg (1.3, 9.9), with 3kg (0.3, 5.8) gain occurring in the first year of treatment.

	All-B/F/TAF (N= 634 originally randomized to B/F/TAF, N=506 entered the OLE)*			
	Week 48	Week 96	Week 144	Week 192
HIV-1 RNA <50 c/mL Missing = Excluded – Pooled Data, n/N (%)	585/589 (99.3)	554/557 (99.5)	528/531 (99.4)	476/480 (99.2)
HIV-1 RNA <50 c/mL Missing = Failure – Pooled Data, n/N (%)	585/634 (92.3)	554/634 (87.4)	528/634 (83.3)	476/634 (75.1)
Change from baseline in CD4 cell count cells/mm³, mean (SD)	208 (178), n=584	263 (207), n=546	288 (231), n=517	317 (246), n=475
eGFR [Cockcroft-Gault], change, mL/min, median (Q1, Q3)	-8.8 (-18.4, 0.3)	-7.5 (-16.6, 2.9)	-5.8 (-16, 3.4)	-8 (-19.3, 2.8)
Fasting lipids change, mg/dL, median (Q1, Q3)				
Total cholesterol	12 (-3, 30)	16 (0, 35)	13 (-8, 32)	19 (3, 38)
LDL cholesterol	8 (-5, 22)	18 (3, 35)	20 (2, 40)	22 (6, 39)
HDL cholesterol	5 (-1, 11)	4 (-1, 10)	4 (-2, 10)	6 (0, 12)
Total:HDL cholesterol ratio	-0.1 (0.5, 0.3)	0 (-0.5, 0.5)	0 (-0.6, 0.4)	0 (-0.6, 0.4)
Triglycerides	6 (-21, 32)	7 (-17, 39)	5 (-23, 37)	8 (-21, 37)
Body weight change from baseline, kg, median (Q1, Q3)	(n=588) 3 (0.3, 5.8)	(n=557) 3.5 (0, 8.2)	(n= 533) 4.2 (0.5, 8.9)	(n= 485) 4.9 (1.3, 9.9)

Table 1. Changes from baseline to week 192
*Includes only participants that were initially randomized and treated with B/F/TAF

Conclusions: Through 4 years of follow-up, B/F/TAF resulted in high rates of virologic suppression with no treatment-emergent resistance, and a low frequency of AEs and few drug discontinuations.

ART in highly treatment-experienced people

PEB152

Transition to TLD leads to decreased rates of virologic failure among PLWH in sub-Saharan Africa

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Background: Integrase inhibitors, particularly dolutegravir-based regimens, have a high genetic barrier to resistance and were found in clinical trials to perform better than efavirenz-based regimens in maintaining viral suppression. Subsequently, tenofovir disoproxil fumarate-lamivudine-dolutegravir (TLD) was recommended as preferred first line treatment by the WHO in 2018 and rolled out to President's Emergency Plan for AIDS Relief (PEPFAR) programs late 2018. We examined time to virologic failure across twelve HIV clinic sites in Africa two years after initial TLD rollout.

Methods: We used data from the ongoing African Cohort Study where participants are seen every 6 months at HIV clinics in Kenya, Nigeria, Tanzania, and Uganda. Viral load measurements and extensive medical record reviews are conducted at each visit. Cox proportional hazards modeling estimated time to virologic failure (viral load >1000 copies/mL) comparing participants who switched to TLD and those who remained on non-TLD regimens. We further stratified by TLD transition and viral load status (<200 copies/mL vs ≥ 200 copies/mL) at the visit prior to TLD switch or the first visit after the country transition date among those who did not switch. Only visits occurring after the respective country began transitioning to TLD were included. Models were adjusted for study site, age, sex, and self-reported ART adherence.

Results: As of December 1, 2020, 2,097 ART-experienced participants had at least two visits with viral load data, among whom 115 (5%) experienced virologic failure. At the visit prior to TLD transition, 95% of participants who switched to TLD and 86% of participants who did not switch had a viral load <200 copies/mL (p<0.001). In the adjusted model, participants who did not switch to TLD had a 3.70 increased rate of virologic failure compared to those who switched (95% CI: 2.50-5.48). Even among participants who were virally suppressed, those who did not switch to TLD had a 2.57 increased rate of virologic failure (95% CI:1.47-4.52).

Conclusions: These data provide insight into the real world impact of the TLD transition in Africa, demonstrating that even among PLWH with high rates of viral suppression, TLD provides an additional benefit and can further reduce rates of virologic failure.

PEB153

Long-term (96-week) safety of fostemsavir (FTR) in heavily treatment-experienced (HTE) adults infected with multidrug-resistant (MDR) HIV-1 (BRIGHTE Phase 3 study)

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Background: BRIGHTE is an ongoing study evaluating the gp120 attachment inhibitor FTR in HTE adults with MDR HIV-1.

Methods: Participants assigned to the Randomized Cohort (1-<2 antiretroviral classes remaining) or Non-randomized Cohort (no fully active approved antiretrovirals remaining) received FTR 600mg BID plus optimized background therapy. Frequency of adverse events (AEs), time to onset and duration were analysed.

Results: Most participants (94%, 347/370) experienced ≥1 AE [Table 1] over 96 weeks of FTR exposure [110.4 median weeks (0.1-171.4)]; most AEs were infection-related. Common drug-related AEs were nausea (9%), diarrhoea (5%) and headache (3%). Overall, musculoskeletal and renal AEs occurred in 15% and 14% of participants, respectively. Eight (2%) cases of IRIS occurred. AEs leading to discontinuation were primarily due to complications of advanced AIDS.

38% of participants experienced ≥1 serious AE (SAE) with pneumonia most common. Few SAEs were drug-related (3%). Infection-related SAEs generally occurred in those most immunosuppressed (baseline CD4+ count <20 cells/mm^3). Death occurred for 8% of participants; common causes were acute infections and AIDS-related events. The most severe AEs, including Grade 3-4 AEs, SAEs and deaths, occurred disproportionately in the Non-randomized Cohort and those most immunosuppressed at baseline [Table 1]. Participants with Grade 3-4 liver and renal toxicities [Table 2] had confounding risk factors.

Participants with safety parameter, n (%)	Randomized Cohort FTR 600mg BID (N=271)[a]	Non-randomized Cohort FTR 600mg BID (N=99)	TOTAL (N=370)
Any adverse event (AE)	249 (92)	98 (99)	347 (94)
Any Grade 2-4 drug-related AE	57 (21)	22 (22)	79 (21)
Any Grade 3-4 AE	78 (29)	49 (49)	127 (34)
Any serious AE	92 (34)	48 (48)	140 (38)
Any CDC Class C event	23 (8)	15 (15)	38 (10)
Any death	12 (4)	17 (17)	29 (8)
Any AE leading to discontinuation	14 (5)	12 (12)	26 (7)

a. One participant in the Randomized Cohort discontinued from the study before receiving FTR.

Table 1. Overall summary of cumulative on-treatment adverse events

Clinical chemistry parameter, n (%)	Randomized Cohort FTR 600mg BID (N=271)[a]	Non-randomized Cohort FTR 600mg BID (N=99)	TOTAL (N=370)
Alanine aminotransferase (U/L)	14 (5)	1 (1)	15 (4)
Aspartate aminotransferase (U/L)	10 (4)	2 (2)	12 (3)
Direct bilirubin (µmol/L)	20 (7)	14 (14)	34 (9)
Bilirubin (µmol/L)	7 (3)	6 (6)	13 (4)
Cholesterol (mmol/L)	10 (4)	1 (1)	11 (3)
Creatinine (µmol/L)	52 (19)	23 (23)	75 (20)
Creatine kinase (U/L)	6 (2)	3 (3)	9 (2)

Note: Toxicity grading based on Version 2.0 (November 2014) of the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events.
a. One participant in the Randomized Cohort discontinued from the study before receiving FTR.

Table 2. Summary of maximum post-baseline emergent grade 3-4 (G3-4) clinical chemistry toxicities for selected laboratory parameters

Conclusions: Cumulative safety findings through the 96-week interim analysis of BRIGHTE are consistent with what is expected in an HTE population with high rates of advanced HIV and comorbid disease. The safety and tolerability profile of FTR is favourable in the intended-use population.

PEB154

Weight changes in HIV+ individuals receiving ibalizumab over 96 weeks

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Background: Regimens containing integrase inhibitors (INSTIs) and/or tenofovir alafenamide (TAF) have been associated with weight gain, especially among HIV+ individuals initiating antiretroviral (ART) with high viral load (VL) and low CD4 count. This has raised concern over potential consequences of their long-term use. The impact of extracellular ART on weight has not been previously evaluated. We investigated the impact of the post-attachment inhibitor ibalizumab (IBA) on weight as well as potential risk factors in treatment-experienced patients.

Methods: In TMB-301/TMB-311, 40 viremic patients received a 2000 mg IBA loading dose followed by 800 mg doses every 2 weeks. An optimized background regimen (OBR) with ≥ 1 additional fully active agent(s) was added 7 days after starting IBA. Weight was measured longitudinally through week 96. The impact of baseline CD4 and VL on weight change was measured using multivariate analysis with adjustments for age, sex, and race. Weight change stratified by ARV exposure or suppression status was evaluated by non-parametric Wilcoxon test.

Results: At baseline, median age was 53 years, CD4 count was 73 cells/mm^3, and VL was 35,350 copies/mL. Median weight at baseline was 74.8 kg (IQR: 63.1-85.9). Participants initiating IBA gained an average of 0.64 kg at week 96 (95% CI: -3.28 4.57, p=0.73). Weight gain was neither associated with baseline viral load (p=0.36) nor CD4 count (p=0.57). Twenty-four (60%) and 10 (25%) participants incorporated DTG or TAF in their OBR, respectively. No differences in weight gain were observed between participants on DTG-containing (p=0.65) or TAF-containing (p=0.87) regimens, compared to those without. On average, participants who achieved virologic suppression gained 1.9 kg, while participants who did not lost 4.2 kg; however, this difference was not significant (p=0.48). At each time point, weight changes did not differ by suppression status.

Conclusions: Ibalizumab was not associated with significant weight gain in HIV+ individuals, suggesting its weight neutrality. Moreover, subgroup analyses demonstrated that baseline VL, CD4 count and suppression status did not impact weight changes observed over time. Altogether, despite the limited study size, these data further support the long-term safety profile of ibalizumab.

PEB155

Clinical impact of antiretroviral agents used in optimized background therapy with fostemsavir in heavily treatment-experienced adults with HIV-1: exploratory analyses of the phase 3 BRIGHTE study

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Background: BRIGHTE is an ongoing phase 3 study investigating fostemsavir plus optimized background therapy (OBT) in heavily treatment-experienced (HTE) individuals.

Methods: In the Randomized Cohort (RC; N=272), participants with fully active agents (FAAs) in only 1 or 2 remaining antiretroviral (ARV) classes received fostemsavir 600 mg BID (n=203) or placebo (n=69) for 8 days followed by open-label fostemsavir plus OBT. The Non-randomized Cohort (NRC; N=99), participants with 0 approved FAAs, received fostemsavir 600 mg BID plus OBT from Day 1. This post hoc analysis evaluated most common ARVs and their association with Week 96 virologic response (HIV-1 RNA <40 copies/mL).

Antiretroviral agent, n (%)	RC (N=272)	NRC (N=99)
Dolutegravir QD/BID[a]	58 (21)/171 (63)	6 (6)/68 (69)
Darunavir QD/BID[b]	35 (13)/99 (36)	8 (8)/63 (64)
Emtricitabine or lamivudine[c]	136 (50)	76 (77)
Tenofovir disoproxil fumarate or tenofovir alafenamide[c]	116 (43)	74 (75)
Etravirine[d]	54 (20)	21 (21)
Maraviroc	52 (19)	8 (8)
Ibalizumab[e]	0	15 (15)

ITT-E, intention-to-treat–exposed; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRC, Non-randomized Cohort; NRTI, nucleoside reverse transcriptase inhibitor; OBT, optimized background therapy; RC, Randomized Cohort.
[a]Total dolutegravir use: 229/272 (84%) in the RC and 74/99 (75%) in the NRC; of those using dolutegravir, 171/229 (75%) in the RC and 68/74 (92%) in the NRC were BID. Any integrase inhibitor use: 239/272 (88%) in the RC and 75/99 (76%) in the NRC. [b]Total darunavir use: 134/272 (49%) in the RC and 71/99 (72%) in the NRC; of those using darunavir, 99/134 (74%) in the RC and 63/71 (89%) in the NRC were BID. Any protease inhibitor use: 158/272 (58%) in the RC and 85/99 (86%) in the NRC. [c]Any NRTI use: 154/272 (57%) in the RC and 85/99 (86%) in the NRC. [d]Any NNRTI use: 62/272 (23%) in the RC and 24/99 (24%) in the NRC. [e]Ibalizumab (anti-CD4 monoclonal antibody) was investigational at study enrollment; only the NRC was permitted to include investigational agents in their OBT.

Table 1. Summary of key antiretroviral agents used in initial OBT: ITT-E population

Antiretroviral agent,[a] n/N (%)	Present - Absent	OSR 1.0[b]	OSR-new 1.0[c]
Dolutegravir	146/229 (64) - 17/43 (40)	127/190 (67)	118/167 (71)
Darunavir	83/134 (62) - 80/138 (58)	50/79 (63)	25/31 (81)
Emtricitabine or lamivudine	82/136 (60) - 81/136 (60)	22/36 (61)	8/9 (89)
Tenofovir disoproxil fumarate or tenofovir alafenamide	72/116 (62) - 91/156 (58)	39/68 (57)	4/6 (67)
Etravirine	35/54 (65) - 128/218 (59)	34/48 (71)	29/39 (74)
Maraviroc	25/52 (48) - 138/220 (63)	24/49 (49)	19/36 (53)

ITT-E, intention-to-treat–exposed; OBT, optimized background therapy; OSR, overall susceptibility rating.
[a]OBT agent from one of the following classes: integrase inhibitor, protease inhibitor, nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, or entry inhibitor. [b]Determined by screening resistance testing (Monogram Biosciences PSGT plus Integrase and Trofile testing). [c]OSR-new of 1.0 is suggestive of an antiretroviral agent with fully retained antiviral activity (by overall susceptibility score).

Table 2. Virologic response (HIV-1 RNA <40 c/mL, snapshot analysis) at week 96 by key antiretroviral agent used in initial OBT: ITT-E population, randomized cohort

Results: Most participants were men (289/371; 78%), aged <50 (206/371; 56%), and white (259/371; 70%). RC participants had lower mean number of agents in initial OBT (3.6 vs 4.7, respectively) and higher mean number of FAAs vs the NRC (1.4 vs 0.2, respectively). Across both cohorts, integrase inhibitors (most notably dolutegravir BID) were in-

cluded in OBT (Table 1). Protease inhibitors, particularly darunavir BID, and nucleoside reverse transcriptase inhibitors were more commonly used in the NRC than RC (Table 1). In the RC, Week 96 virologic response rates were comparable regardless of presence or absence of core ARV agent, except for dolutegravir (presence: 64%, absence: 40%; Table 2).

Conclusions: The OBT of HTE participants in BRIGHTE was highly individualized but most commonly included dolutegravir BID. Fostemsavir plus OBT yielded strong rates of virologic response through Week 96 in this population with extensive multidrug-resistant HIV-1 and limited remaining treatment options.

PEB156

Aggregating loss to follow-up behavior in Patients Living with HIV: a cluster analysis using unsupervised machine learning algorithm in R

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Background: Retention of patients in the HIV care continuum is crucial for epidemic control. This study aimed to aggregate loss to follow-up (LTFU) behavior in People Living with HIV (PLHIV) into clusters in order to examine and describe PLHIV clusters having similar characteristics and patterns according to their risk profile.

Methods: This was a retrospective, cross-sectional study that randomly reviewed 11,589 records of LTFU adult patients initiated on first-line ART from 313 USAID/PEPFAR-supported HIV clinics spread across 5 of Nigeria's 6 geographical regions between July 1, 2008 and June 30, 2020. LTFU, was defined as > 28 days without an encounter since the last scheduled appointment. Using the Minkowski method and ward. D2 clustering technique for unsupervised machine learning algorithm "agglomerative hierarchical clustering" in R, we identified 6 clusters associated with patients LTFU behavior.

Results: Within the review period, 497,620 patients were ever enrolled on ART. 324,225 (65.2%) remained on treatment, 101,716 (20.4%) had an LTFU event captured, 36,021 (7.2%) were transferred out to other facilities, 25,633 (5.2%) died and 10,025 (2.0%) self-terminated treatment. Approximately 11% (11,589) of LTFU patients were included. Majority (66.7%) of the clusters consists of female LTFUs. LTFU doubled steadily by age among adolescents (15-19 years) and young people (15-29 years), but as age increased above 40-years the rate of LTFU decreased. High rate of LTFU was reflective of shorter-duration on ART. Patients classified in clusters with shorter-time on ART [8-months (female) vs. 72.6-months (male)] indicated the highest rates of LTFU [31.0% (female) vs. 14.9% (male)]. LTFU varied by region, was highest among clusters confined in the North West (50%) and lowest in the North East (17%). Viral load test was low, with only half (50.0%) of the clusters having a documented viral load test result.

Conclusions: LTFU rates in HIV-positive patients receiving ART in our clinical sites have varied by the duration on ART, with rates declining in recent years. Our study demonstrates that aggregating LTFU behavior among patients on ART offers great benefit for LTFU surveillance in the HIV care continuum. Our findings would inform targeted HIV program interventions for patient-centered care, reduce LTFU and promote optimal retention.

Regimen simplification and switch studies

PEB157

Bictegravir/emtricitabine/tenofovir alafenamide in patients with genotypic NRTI resistance

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Background: Bictegravir/emtricitabine/tenofovir alafenamide (BFT) is approved for treatment of HIV without known resistance to its 3 components. Several studies have demonstrated efficacy of BFT in patients with NRTI resistance associated mutations (RAMs), mainly identified by proviral DNA testing, a technique not available in most of the world. We evaluated the efficacy of BFT in patients with NRTI RAMs identified by routine genotypic resistance testing.

Methods: Retrospective analysis of patients living with HIV receiving BFT. Patients were identified through a search of electronic health records, and eligibility confirmed by review of individual patient records. Included patients were >18 years of age, had genotypically documented 2019 IAS-USA major RAMs affecting NRTIs and at least one HIV viral load (VL) after starting BFT.

Results: 43 patients met study criteria. The mean age was 54 years, the mean proximal CD4 count was 639 cells/mm3, and 28 (65%) were male. 40 were virologically suppressed when BFT was initiated, two were treatment naïve and one had a VL of 961 copies/mL on antiretroviral therapy (ART). 25 had one NRTI RAM (20 were M184V/I), 9 had 2 NRTI RAMs, 3 had 3 NRTI RAMs, 3 had 4 NRTI RAMs, 2 had 5 NRTI RAMs and 1 had 7 NRTI RAMs plus a 69 insertion.

No patient had K65R/E/N. 20 patients also had major NNRTI RAMs and 16 had major protease RAMs, but none had documented integrase resistance. At the last VL measurement on BFT, a mean of 9.6 months after starting BFT, 42 of 43 had VL <40 copies/mL.

One patient who had a VL <40 copies/mL two months after starting BFT, had a VL of 44 copies/mL 16 months after starting BFT. This patient had well documented past history of poor adherence and had no new RAMs identified in the sample 13 months after starting BFT.

Conclusions: BFT was effective in maintaining HIV VL suppression in patients with genotypically documented NRTI RAMs without integrase resistance. Further research is needed to evaluate the efficacy of BFT in viremic patients with NRTI resistance.

PEB158

Switch to BIC/FTC/TAF in virally suppressed PLWH: efficacy and tolerability

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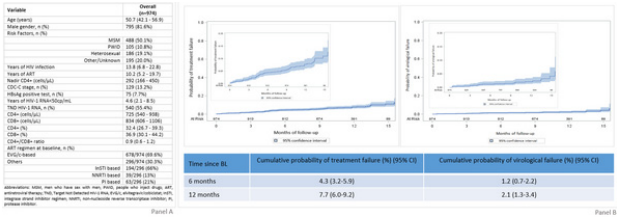
Background: Since bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF) authorization from the Italian Medicines Agency in June 2019, our institute has established a prearranged switch from elvitegravir/cobicistat (EVG/c)-based regimens in virally suppressed PLWH and, based on a case-by-case indication, from other regimens.

The aim of this study was to evaluate the efficacy and tolerability of BIC/FTC/TAF in a real-life setting.

Methods: Retrospective cohort study including PLWH who switched to BIC/FTC/TAF while with HIV-RNA<50 copies/mL and having ≥1 HIV-RNA value within 12 months after switch. Virological failure (VF)= two consecutive HIV-RNA≥50 copies/mL or a single HIV-RNA>400 copies/mL. Treatment failure (TF)= VF or discontinuation. Data are reported as median (IQR). Probabilities of VF or TF were estimated by Kaplan-Meier curves.

Results: Overall, 974 people evaluated (characteristics are reported in Fig.1 Panel A). At availability of BIC/FTC/TAF, all patients on treatment with EVG/c/FTC/TAF were switched [N=678 (69.6%)]. Switches to BIC/FTC/TAF from different regimens [N=296 (30.3%)] were due to: treatment simplification (83.7%), toxicity (9.5%), other causes (6.8%). During 10,249 person-months of follow-up (PMFU), 71 TF occurred for an incidence rate of 6.9 (95% confidence interval (CI) 5.3-8.5) per 1000-PMFU. The estimated 6- and 12-month probabilities of TF were 4.3%(95%CI 3.2-5.9) and 7.7%(95%CI 6.0-9.2) (Fig.1 Panel B). TF occurred after a median of 5.2 months (IQR 3.1-9.6) for: simplification to dual therapy (14%), CNS toxicity (17%, overall incidence 1.2%), other toxicity (24%), other causes (12.7%), death (5.6%), and VF (30.9%, overall incidence 2.3%). VF occurred after a median of 5.8 months (IQR 3.1-11.1) and the median HIV-RNA was 76(63-130) copies/mL. The cumulative probabilities of VF were 1.2% and 2.1% at 6 and 12 months, respectively (Fig.1 Panel B).



Time since BL	Cumulative probability of treatment failure (%) (95% CI)	Cumulative probability of virological failure (%) (95% CI)
6 months	4.3 (3.2-5.9)	1.2 (0.7-2.2)
12 months	7.7 (6.0-9.2)	2.1 (1.3-3.4)

Figure 1. Panel A. Patients' characteristics at baseline.
Panel B. Kaplan-Meier curves and cumulative probabilities of TF and VF.

Conclusions: In a large sample of suppressed PLWH followed in a real-life setting, 1-year TF of BIC/FTC/TAF was low (7%) with 2% of VF, suggesting that the switch is effective and safe.

PEB159

Co-formulated bictegravir, emtricitabine, and tenofovir alafenamide (BIC/F/TAF) for maintenance of viral suppression in adults with historical virological failure and K65N/R mutation

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Background: Real-world experience with co-formulated bictegravir, emtricitabine, and tenofovir alafenamide (BIC/F/TAF) is sparse as a switch regimen among people living with HIV (PLWH) who have achieved viral suppression after prior virologic failures that had resulted in emergence of K65N/R mutation.

Methods: In this multicenter study, PLWH who were aged 20 years or older and had had a history of virologic failure with emergent K65N/R mutation were included for switch to BIC/F/TAF after having achieved viral suppression (PVL <200 copies/mL) with other antiretroviral therapies for 3 months or longer. Patients were excluded if integrase inhibitor strand transfer inhibitor (InSTI) resistance-associated mutations (RAMs) were detected or had had a history of virologic failure to regimens containing an InSTI. Pre-existent RAMs to nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase Inhibitors (NNRTIs), and protease inhibitors (PIs) were allowed. The primary endpoint was virologic non-response (plasma HIV RNA >50 copies/mL) at Week 48 of switch using a modified FDA snapshot analysis algorithm.

Results: A total of 61 PLWH with a history of virologic failure and K65N/R mutation who were switched to BIC/F/TAF after achieving viral suppression with other combination antiretroviral therapies (Table) were identified between Oct. 2019 and Dec. 2020. The other RAMs of HIV-1 included 36 (59.0%) with M184V/I and 7 (11.5%) with 1 TAM, 55 (90.2%) with NNRTI RAMs, and 3 (4.9%) with PI RAMs. The mean duration of viral suppression prior to switch to BIC/F/TAF was 3.9 years and 57 (93.4%) had PVL <50 copies/mL before switch. After a median observation of 41.3 weeks (range, 4.3-61.0), all of the included patients continued to receive BIC/F/TAF. By week 12, all of 56 included PLWH had PVL <50 copies/mL; 1 of 50 (2.0%) had PVL of 68 copies/mL at week 24 and re-achieved viral re-suppression (<50 copies/ml) at week 36; at week 36, none of 33 had PVL >50 copies/mL; and at week 48, the rate of virologic non-response was 0% (0/17).

Conclusions: Despite emergence of K65N/R mutation with or without M184V/I in patients having had virologic failures, BIC/F/TAF could be considered as a therapeutic option for treatment simplification after viral suppression was achieved.

PEB160

Switching to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in adults aged 65 years or older: week 96 results from an international, Phase 3b, open-label trial

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Background: Studies are needed to assess the safety and efficacy of antiretroviral therapy in older individuals. This is the largest, international, Phase 3b study enrolling HIV-1-infected participants ≥65 years. We report the efficacy and safety of switching to B/F/TAF at Week(W) 96.

Methods: Virologically suppressed (VL <50 copies/mL) participants ≥65 years receiving either E/C/F/TAF or a TDF-based regimen at baseline switched to B/F/TAF. W96 VL <50 copies/mL was measured by Snapshot (secondary endpoint) and missing=excluded (M=E) analyses.

Results: 86 participants were enrolled. Median age was 69 years (IQR 67, 72); 13% were female; 99% were white; 92% were receiving E/C/F/TAF at baseline. At W96 (M=E), 100% had VL <50 copies/mL with no virologic failures at W96 by M=E analysis. Snapshot results are presented in the Table. Median CD4 counts were stable. Median changes from baseline in lipid parameters were: total fasting cholesterol (-15 mg/dL), LDL (-10 mg/dL), HDL (-1 mg/dL), triglycerides (-19 mg/dL) and total cholesterol:HDL (-0.2). Median weight change from baseline was 0.0 kg. There were 2 (2.3%) Grade 3-4 study drug-related AEs, 11 (13%) Grade 3-4 laboratory abnormalities and 3 (3.5%) AEs leading to study drug discontinuation (drug-related). There were no discontinuations for renal, bone or hepatic AEs and no study drug-related serious AEs occured. Two deaths occurred that were not attributed to study drug by the site investigator.

	# participants (%)
HIV-1 RNA <50 copies/mL	64/86 (74%)
HIV-1 RNA >50 copies/mL	0
No virologic data in W96 window	22 (26%)
discontinued study drug with last available HIV-1 RNA <50 copies/mL	9
visit after W96 window with HIV-1 RNA <50 copies/mL	2
missed W96 with no RNA assessments after W84 due to COVID-19 restrictions but W84 HIV-1 RNA <50 copies/mL	11

Table 1. Efficacy at W96 (Snapshot)

Conclusions: Through W96, high rates of virologic suppression were maintained in older participants who switched to B/F/TAF. The COVID-19 pandemic affected in-person visits affecting W96 data; however, study teams were able to keep participants in care through telehealth. The safety and efficacy data support the switch to B/F/TAF in virologically suppressed, HIV-infected individuals aged ≥65 years.

PEB161

Week 72 outcomes and COVID-19 impact from The BRAAVE 2020 study: a randomized switch to B/F/TAF in African American adults living with HIV

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Background: Black Americans are disproportionately impacted by HIV. The BRAAVE 2020 study demonstrated that guideline-recommended bictegravir/emtricitabine/tenofovir alafenamide(B/F/TAF) was non-inferior to continuing current HIV treatment in Black adults through week (W) 48. Participants could continue B/F/TAF until W72. We present final W72 results, subgroup analyses, and COVID-19 impact.

Methods: Black American adults living with HIV and virologically suppressed on 2 NRTIs plus a 3rd agent, were randomized (2:1) to switch to open-label B/F/TAF or stay on baseline regimen (SBR). Efficacy and safety at W24&W48 were previously presented. SBR participants switched to B/F/TAF at W24 with follow-up until W72. Virtual visits started after W48 due to COVID-19. Subgroup analyses were performed (age <50& ≥50 and sex at birth [SAB]).

Results:

	B/F/TAF (n=330)	SBR to B/F/TAF (n=163)
Duration of B/F/TAF exposure in weeks, median (Q1, Q3)	72 (71.4, 72.3)	48 (47.3, 48.3)
HIV-1 RNA < 50 copies/mL at Study W72 (Missing = Excluded), n/N (%)	246/248 (99.2)	127/127 (100)
CD4 change from baseline at Study W72, cells/mm^3 mean, (SD)	+28 (205; n= 218)	+7 (174; n=117)
Body weight change from baseline at W72 in kg median (IQR), (n=229 B/F/TAF)	1.8 (-1.4, 4.8)	NA
Body weight change from baseline at W72 in kg (females vs male), median (IQR):		
Female, n (%) (n=79 B/F/TAF)	1.7 (-1.4, 4.6)	NA
Male, n (%) (n=150 B/F/TAF)	1.9 (-1.5, 5.1)	NA
Treatment-emergent AEs by age (< 50 vs ≥ 50 years old), n/N (%)		
< 50 (n=170 B/F/TAF; n = 84 SBR to B/F/TAF)	144/170 (84.7)	61/84 (72.6)
≥ 50 (n=160 B/F/TAF; n=79 SBR to B/F/TAF)	131/160 (81.9)	52/79 (65.8)

Table 1: Duration of Exposure, HIV1 RNA, CD4, Body Weight Changes and Subgroup Analyses

493 were treated with B/F/TAF including 163 of the165 randomized to SBR who switched to B/F/TAF at W24 (SBR to B/F/TAF): 32% female, median age 49y (range 18-79). 124 (25%) participants completed virtual visit(s) in lieu of site visits, 6(1%) missed visits (in person and/or virtual) due to COVID-19-related challenges. The last participant visit was 18-Aug-2020. Five participants were reported to have COVID-19 and two died. 99% were suppressed (HIV-1 RNA <50 c/mL, Missing=Excluded) at W72. No treatment-emergent resistance was detected.

Study drug-related AEs occurred in 10% of participants, mostly grade 1. Twelve (2.4%) participants discontinued due to an AE. One study-drug-related SAE of vomiting occurred (resolved in one day); three participants had grade 3/4 study-drug related AEs. Body weight

change from baseline was similar regardless of SAB. The number of participants experiencing AEs by age group or by SAB were similar regardless of subgroup (table 1). Median study drug adherence was 98%.

Conclusions: Switching to B/F/TAF was highly effective and safe for Black adults regardless of age or SAB. Participants had high study engagement with few missed visits and high adherence despite the COVID-19 pandemic.

PEB162

Successfully (and safely) enrolling a multi-center HIV antiretroviral clinical trial during the COVID-19 pandemic: lessons learned from Kenya

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Background: The Second-line Switch to Dolutegravir (DTG) study is an open-label, randomized, active-controlled, multi-centre, non-inferiority trial conducted in Kenya, evaluating a switch strategy from ritonavir-boosted protease inhibitor (PI/r) to DTG for virally suppressed, treatment experienced, HIV-1 infected adults. Study enrollment began in Feb 2020. Shortly thereafter the first case of COVID-19 was reported in Kenya, followed by containment measures including travel restrictions and stay-at-home orders. An objective became to continue study enrollment and follow-up while ensuring participant and staff safety.

Description: Study participants were recruited from public outpatient HIV clinics at four sites in Kenya. Between Feb 12 and Sep 3 2020, 1,114 adults were screened and 795 were enrolled, including 528 (66%) females. Figure 1 shows enrollment progress along with key COVID-19 events in Kenya.

Important modifications made to study protocol and processes to manage COVID-19-related restrictions included: telephone COVID-19 symptoms and risk screening before in-person appointments; personal protective equipment and hand hygiene measures; telephone visits when travel was restricted; phlebotomy and drug pick-ups closer to participant residence as needed; additional staff training on COVID-19 prevention measures.

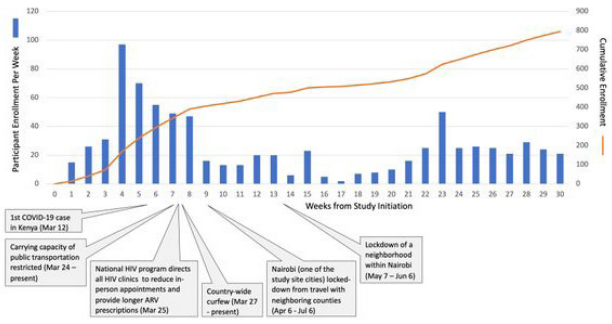

Figure 1. Enrollment rates and COVID-19 events during a multi-centre ARV clinical trial in Kenya

Lessons learned: Safety protocols that surpassed government requirements, and clear communication with staff, participants, and regulators, allowed safe and timely completion of enrollment. Enrollment took 17% longer than anticipated, primarily due to time required to develop and implement safety protocols and adjust study processes to overcome restrictions that came into place during the pandemic. Two study participants and zero staff were diagnosed with COVID-19, however no transmissions were linked to study activities. No participants were lost to follow-up during this period.

Conclusions/Next steps: Protocol modifications to protect participants and staff allowed for timely enrollment into this clinical trial with no identified COVID-19 transmissions related to study activities. Similar measures may allow studies in comparable settings to safely enrol and follow participants in the midst of the COVID-19 pandemic.

PEB163

DTG+3TC in GEMINI-1&-2: HIV-1 replication at <50 c/mL and VL blips through 144 weeks

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Background: The GEMINI-1&-2 studies in treatment-naive adults showed DTG+3TC was non-inferior to DTG+TDF/FTC by FDA Snapshot (HIV-1 RNA <50 c/mL) at Week 144. Abbott's RealTime HIV-1 assay provides viral load (VL) from 40 to 10,000,000 c/mL, and qualitative target detected (TD) or target not detected (TND) for VL <40 c/mL. We assessed low-level viremia and "blips" through Week 144.

Methods: The proportion of participants with VL <40 c/mL and TND status throughout Week 144 is presented based on Snapshot analysis. Participant subgroups assessed included ITT-E population and an Observed subpopulation (ITT-E participants with VL <50 c/mL at Week 144). "Blips" (one VL ≥50 to <200 c/mL bounded by VL <50 c/mL) were assessed from Day 1 after VL suppression to <50 c/mL, and from Weeks 48 through 144.

Results: At Week 144, there were similar proportions of ITT-E participants with TND receiving DTG+3TC vs DTG+TDF/FTC by Snapshot (63% [451/716] vs 65% [465/717]), or for Observed population (77% [451/584] vs 78% [465/599]). Proportions with TND trended upward through ~Week 48 and were similar between arms at all visits (Figure 1a).

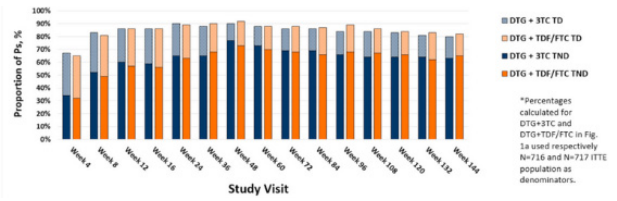

Figure 1a. Participant (Pt) proportions* with TND or TD for DTG+3TC and DTG+TDF/FTC through week 144 by snapshot, ITTE population

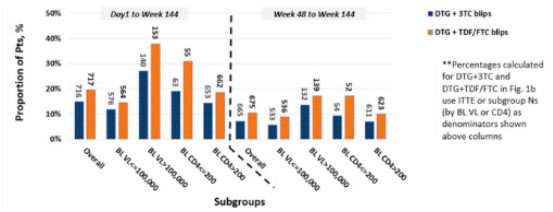

Figure 1b. Pt proportions** with ≥1 'blip' (single VL 50 to 200 c/mL) bounded by VL<50 c/mL) from day 1 or week 48 to week 144 by BL subgroups

Participant proportions with ≥1 "blip" through Week 144 were generally similar across arms (Figure 1b), with higher frequency in DTG+TDF/FTC participants from Day 1 to Week 144 with BL VL >100,000 c/mL or CD4+ ≤200 cells/mm³.

Conclusions: Proportions of participants with TND were similar through Week 144 in the DTG+3TC and DTG+TDF/FTC arms. The frequency of "blips" through Week 144 was generally similar across arms when assessed early from Day 1 or from Week 48. These data continue to demonstrate the efficacy, potency, and durability of DTG+3TC in treatment-naive adults.

PEB164

Metabolic health outcomes at week 96 in the TANGO Study, comparing a switch to DTG/3TC versus maintenance of TAF-based regimens

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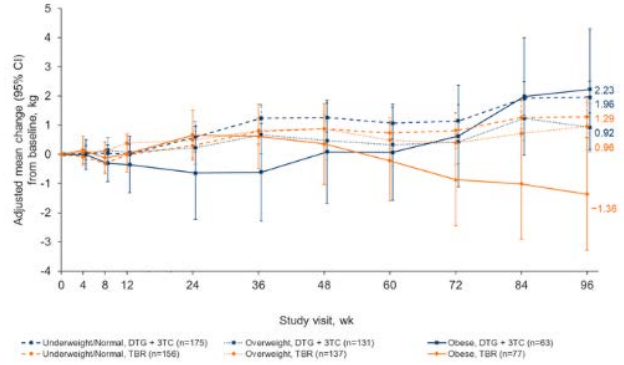
Background: TANGO is a randomised controlled trial assessing the efficacy/safety of switching to the 2-drug regimen DTG/3TC compared with continuation of a 3/4-drug tenofovir alafenamide (TAF)-based regimen (TBR), for the treatment of HIV-1 infection.

Methods: Changes in weight; fasting lipids, insulin, and glucose; HbA_{1c}; FIB-4; and insulin resistance and prevalence of metabolic syndrome were assessed and compared between treatment groups at Week 96. Baseline subgroups of interest included duration of prior TAF use, core agent, boosting status, region, and baseline BMI.

Results: Overall change in adjusted mean weight at Week 96 was +1.64 kg with DTG/3TC vs +0.61 kg with TBR (Figure).

Figure. Adjusted mean change from baseline in weight by visit in participants who were underweight/normal, overweight, or obese at baseline in the DTG/3TC and TBR groups. Adjusted mean is the estimated mean change from baseline at each visit in each group calculated from a repeated measures model adjusting for the following: treatment, visit, baseline third agent class, CD4+ cell count (continuous), age (continuous), sex, race, baseline weight (continuous), treatment-by-visit interaction, and baseline value-by-visit interaction, with visit as the repeated factor. n refers to number of participants in each subgroup randomised to DTG/3TC or TBR from the safety set.



Figure

The proportion of participants who maintained weight (±5%) was 64% in the DTG/3TC group and 65% in the TBR group. More participants lost ≥5%/≥10% weight in the TBR (13%/4%) vs DTG/3TC group (7%/3%), partly due to changes after Week 48 in participants who were obese at baseline. Changes at Week 96 in total cholesterol, LDL-C, and triglycerides favoured the DTG/3TC group; changes in HDL-C favoured the TBR group, resulting in similar mean percent changes in TC:HDL-C ratios (DTG/3TC, −0.5%; TBR, +1.7%). Overall, changes in glucose, insulin resistance, and prevalence of metabolic syndrome were similar between groups.

Conclusions: After 96 weeks of therapy, weight gain in the DTG/3TC group was consistent with that of the general population (0.5-1.0 kg/year); weight gain in the TBR group was lower, partly driven by unexplained weight loss in participants with obese baseline BMI after Week 48. Changes in lipids generally favoured the DTG/3TC group; changes in other metabolic health parameters were generally similar between groups. Long-term follow-up and evaluation of the potential effects of ART and diet/exercise on weight and metabolic outcomes for PLWH remain important.

PEB165

Low risk of losing the undetectable viral load status in people with HIV switching to dual therapy

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Background: No HIV transmission occurs in sero-discordant couples when the HIV-infected partner is undetectable (U), defined as HIV-RNA<200 copies/mL for >6 months. We aimed at estimating the proportion of time in which the U-status was maintained and identifying factors associated with the risk of losing it among people with HIV (PWH) enrolled in a clinical cohort after switching to Dual therapy (DT).

Methods: We included participants in the ICONA cohort who had reached a U status (as of January 2014 while on triple therapy and were subsequently switched to DT regimens (ATV/b+3TC, DRV/b+3TC, DRVb+RPV, DTG+3TC, DTG+RPV). The outcome was the number of person-days-of-follow up (PDFU) above a VL>200 copies/ml, relative to the total number of PDFU observed in follow-up. Participants were defined as losing his/her U status if he/she spent <100% of his/her PDFU on observation with a VL <=200 cp/mL. Logistic regression model was used to identify factors independently associated with the risk of losing the U-status.

Results: Eight hundred fifty-six PWH were included in the analysis. Of these, 156 (18.2%) were female, 436 (50.9%) were men who have sex with men. Overall, during the entire follow-up, 99.3% of PDFU observed were with a VL≤200 copies/ml,meaning that only 0.7% was >200 copies/ml; the median time with VL>200 copies/ml was 1.76 (IQR:0.81-3.88) person-months. The proportion of PDFU with VL>200 copies/ml was higher than average in females (1.2%), unemployed (1.5%), people who inject drugs (1.5%), and in people with>3 previous virological failures (VF, 2.1%).
Overall, only 31 (3.6%, 95% CI:2.5-5.1%) participants spent <100% of PDFU with a VL>200 copies/ml. At logistic regression, higher CD8 cell count (OR 1.10, 95% CI:1.02-1.19) and >3 previous VF (OR 3.54, 95% CI: 1.08-11.65) were independently associated with an increased risk of losing the U-status.

Conclusions: In our cohort of PWH switched to DT with a VL≤200 copies/

ml, the U-status was maintained for > 99% of PDFU. Although DT use appears to be associated with a low risk of VF>200 copies/ml, PWH with a high CD8 count and previous VF should be carefully monitored to minimize the risk of HIV transmission.

PEB166

Transition to DTG in Cote d'Ivoire: are women being left behind?

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Background: Since 2019, the government of Cote d'Ivoire has recommended Dolutegravir (DTG)-based regimen as the preferred first line antiretroviral therapy (ART) regimen for HIV infection. The National AIDS Control Programs and Partners have worked to initiate new patients and transition eligible patients already on ART to this new DTG-based regimen. We assessed clinical and demographic data to describe the characteristics of patients on DTG.

Methods: We enrolled a cohort of patients who were initiating multi-month dispensing of ARV between June-December 2020 in 29 sites across Côte d'Ivoire. 29 Research assistants using tablets collected data on patient socio-demographic and clinical characteristics through short interviews and extracted data from facility records. Study data were entered directly into the ODK2 application on study tablets by each research assistant and uploaded in real time into a central database hosted in a secure server. We conducted descriptive analysis of baseline data on current ART regimen for adolescents and adults (ages 15+) to determine frequencies and performed Chi-Square tests and student's t-tests to assess any association.

Results: A total of 688 participants aged ≥15years were enrolled in the study. Mean age was 41 years and 70% were female. Of those, 387 participants (56%) were on DTG at the time of enrollment; 244 (36%) were on efavirenz-based regimen, and 57 (8%) were on other regimens. Patients aged 55+ years were most likely to be on DTG (95%), compared to 81% among patients ages 45-54, and 34% among patients aged 15-34. Of the men, 90% were on DTG and 5% were on efavirenz compared to 42% of women on DTG and 48% on efavirenz. Men on DTG were significantly younger than men on other regimens (p=0.002). Among women, those aged >45 years were significantly more likely to be initiated on DTG compared to younger women aged 25-44 years (82% vs 24% and p<0.0001).

Conclusions: We found that women were less likely to be initiated on DTG than men.

Women especially younger (<45 years) are still being left behind in the transition to DTG in Cote d'Ivoire. This calls for quick programmatic actions targeting women to address this challenge.

PEB167

Impact of baseline NNRTI pretreatment resistance mutations on risk of virologic failure of RPV-based dual therapies

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Background: Study aim: to assess durability and rate of virologic failure of rilpivirine (RPV)-based dual therapy (RPV plus boosted-darunavir [DRV/b] or dolutegravir [DTG]) among NNRTI-experienced people living with HIV (PLWH) with known NNRTI-drug resistance mutations (DRM).

Methods: Observational, retrospective study on Antiviral Resistance Cohort Analysis (ARCA) database including all PLWH on ART who switched to a dual regimen containing RPV+DTG or DRV/b with available genotypic resistance test (GRT) at baseline. Virological failure was defined as the first of two consecutive episodes with HIV-RNA >50 copies/ml or the first HIV-RNA >200 copies/ml.

Results: 382 PLWH were included. DTG+RPV was the most represented group (223 PLWH), compared to DRV/b+RPV (159) as shown in Figure 1.

	Overall (n. 382)	DTG+RPV (n. 223)	DRV/b+RPV (n. 159)	p value
Median Age (q1-q3) - years	52 (45 - 58)	53 (46 - 59)	50 (42 - 56)	.001
Male sex - n (%)	258 (68)	152 (68)	106 (67)	.776
HIV B subtype - n (%)	302 (79)	173 (78)	129 (81)	.400
Risk factor for HIV infection - n (%)				
Sexual	261 (71)	150 (70)	111 (72)	
PWID	90 (25)	53 (25)	37 (24)	.908
Other	16 (4)	10 (5)	6 (4)	
Previous AIDS-defining event - n (%)	32 (8)	27 (12)	5 (3)	.002
HCV co-infection - n (%)	105 (40)	74 (42)	31 (36)	.502
Number of previous ART regimen - n (%)	5 (3 - 9)	7 (4 - 10)	4 (2 - 7)	<.001
Previous ART regimen - n (%)				
INSTI-based	62 (16)	46 (21)	16 (10)	
PI-based	78 (20)	36 (16)	42 (26)	<.001
NNRTI-based	84 (22)	31 (14)	53 (33)	
Other	158 (42)	110 (49)	48 (30)	
Previous RPV-containing ART - n (%)	127 (33)	59 (26)		0.232
Median (q1-q3) Zenit HIV-RNA - Log10 cp/ml	4.92 (4.08 – 5.49)	5.05 (4.40 – 5.59)	4.65 (3.49 - 5.34)	<.001
Median (q1-q3) Nadir CD4+ T cells count - cell/μL	675 (489 - 917)	682 (499 - 915)	227 (71 - 339)	.089
Median (q1-q3) weeks of virologic suppression before switch	227 (107 - 377)	277 (125 - 420)	177 (89 - 297)	<.001
Unsuppressed at ART switch - n (%)	42 (11)	24 (11)	18 (11)	.836
At least one PDRM at baseline - n (%)	193 (71)	136 (88)	57 (48)	<.001
At least one NRTI-PDRM - n (%)	175 (45)	125 (56)	50 (31)	<.001
At least one NNRTI-PDRM - n (%)	94 (25)	65 (29)	29 (18)	.015
At least one PI-PDRM - n (%)	76 (20)	58 (26)	18 (11)	<.001
At least one INSTI-PDRM - n (%)	12 (3)	4 (2)	8 (5)	.074
Virologic Failures - n (%)	22 (6)	12 (5)	10 (6)	.707

Legend: DTG= dolutegravir; RPV= rilpivirine; DRV/b= darunavir/boosted; q1-q3= first third-quartile; PWID= people who inject drugs; ART= antiretroviral therapy; INSTI=integrase strand transfer inhibitor; PI= protease inhibitors; NNRTI= non-nucleoside reverse transcriptase inhibitors; NRTI= nucleoside reverse transcriptase inhibitors; PDRM= pretreatment drug resistance mutations.

Figure 1. General characteristics of the study population.

The DTG+RPV group had a higher rate of pretreatment drug resistant mutations (PDRMs) (88%) compared to DRV/b+RPV (48%). There were 22 (one occurred in DRV/b group within 1 week from ART-switch and excluded from further analysis) virologic failures (1.4 failures per 100 person-years follow up) [DTG+RPV= 1.3 viral failures per 100 person-years follow-up (95%CI= 0.7 - 2.4); DRV/boosted + RPV= 1.6 viral failures per 100 person-years follow-up (95%CI= 0.8 - 3.0)]. Independent predictors of virologic

failure were failure at ART switch [adjusted Hazard Ratio (aHR)= 9.08, 95% confidence interval (CI)= 3.76 - 21.90, p<.001] and at least one PDRMs for non-nucleos(t)ide reverse-transcriptase inhibitors (NNRTI) at baseline (aHR= 4.34, 95%CI= 1.78 – 10.55, p=.001). Virologic failure at ART switch and at least one PDRMs for NNRTI at baseline were significantly associated with risk of failure (log rank p<.001) by Kaplan-Meier analysis.

Conclusions: RPV-based dual therapies were effective simplification strategies in this cohort. Detectable HIV-RNA and the presence of any NNRTI PDRMs at the time of switch were significantly associated with virologic failure.

Pharmacokinetics, pharmacodynamics, pharmacogenomics and therapeutic drug monitoring

PEB168

Safety and pharmacokinetics of islatravir in study participants with severe renal insufficiency

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Background: Islatravir (MK-8591) is a nucleoside reverse transcriptase translocation inhibitor with high potency and long $t_{1/2}$, currently in development for HIV-1 treatment in daily and weekly dosing regimens, and for prevention as monthly monotherapy. Islatravir has been generally well tolerated at single doses up to 400 mg, and has demonstrated linear pharmacokinetics (PK) over a wide dose range (0.25-400 mg). Preclinical studies and previous clinical trials suggest that islatravir is not a substrate of renal transporters, and ~30-50% of plasma islatravir is excreted renally. This trial was performed to evaluate the safety and PK of islatravir in individuals with severe renal insufficiency.

Methods: In an open-label Phase 1 trial, a single oral dose of 60 mg islatravir was administered to individuals with severe renal insufficiency (eGFR<30 mL/min/1.73 m^2, using CKD-EPI) and in healthy matched control study participants (eGFR ≥ 90 mL/min/1.73 m^2). Safety and tolerability were assessed throughout the trial, and PK was collected from plasma for islatravir parent and major metabolite M4.

Results: Islatravir was generally well tolerated in individuals with severe renal insufficiency. PK parameter values for islatravir (ISL) and major metabolic M4 are depicted in Table 1.

Analyte	Dose (mg)	Impairment Stage	Cmax (µM)	AUC0-∞ (hr*µM)
			Geometric Mean (%GCV)	
ISL	60	Severe Renal Insufficiency	1.23 (14.1)	14.3 (19.2)
		Healthy Matched Controls	1.19 (54.7)	6.49 (32.2)
M4	60	Severe Renal Insufficiency	1.34 (35.7)	10.8 (43.0)
		Healthy Matched Controls	0.737 (85.8)	2.04 (53.0)

Table 1: PK Parameter Values in Participants with Severe Renal Insufficiency and Healthy Matched Controls (N=6 per condition)

Conclusions: A single dose of 60 mg islatravir is generally well tolerated in individuals with severe renal insufficiency. Both ISL and metabolite M4 levels are increased in this group, which is consistent with renal excretion as a relatively major factor in both ISL and M4 elimination. Given prior clinical experience with exposures in this range following administration with doses above 60 mg, no dose adjustment is anticipated.

Drug interactions

PEB169

NNRTI MK-8507 does not alter the pharmacokinetics of the combined oral contraceptive levonorgestrel/ethinyl estradiol

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Background: Every week, ~5500 young women aged 15–24 years become infected with HIV worldwide. Hormonal contraceptives are widely used and highly effective in this population, but many antiretrovirals (ARV) have clinically meaningful drug-drug interactions (DDI) with hormonal contraceptives. MK-8507 is a highly potent oral non-nucleoside reverse transcriptase inhibitor in development for once weekly (QW) administration for treatment of HIV-1 infection. MK-8507 does not inhibit or induce major CYP enzymes and is not expected to alter the pharmacokinetics (PK) of hormonal contraceptives.

This clinical study evaluated the DDI of multiple dose MK-8507 with the combination oral contraceptive levonorgestrel (LNG)/ethinyl estradiol (EE).

Methods: An open-label, 2-period, fixed-sequence DDI study in healthy postmenopausal or oopherectomized females was conducted. In Period 1, a single dose of LNG 0.1 mg/EE 0.02 mg was given followed by a 5-day washout. In Period 2, MK-8507 400 mg was administered once weekly for 3 weeks; a single dose of LNG 0.1 mg/EE 0.02 mg was given concomitantly with the 3rd dose of MK-8507. PK samples were collected for evaluation of LNG, EE, and MK-8507.

Results: Twenty participants aged 47-66 were enrolled; 18 completed. The PK of EE and LNG were not meaningfully altered by co-administration with MK-8507. The geometric mean ratios (GMRs) (90% confidence intervals (CIs)) for LNG AUC0-inf and Cmax of LNG/EE given with MK-8507 compared to LNG/EE alone were 0.88 (0.84, 0.93) and 0.74 (0.66, 0.83), respectively; for EE the GMRs (90% CI) for AUC0-inf and Cmax were 0.85 (0.82, 0.90) and 0.80 (0.74, 0.85), respectively. Co-administration of all three drugs was generally well tolerated.

Conclusions: The results of this study support use of hormonal contraceptives in people living with HIV receiving MK-8507.

PEB170

Persistence of drug-drug interaction problems with contemporary antiretroviral therapy. The case of ergotism

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Background: Drug-drug interaction (DDI) potential of protease inhibitors (PI) based antiretroviral therapy (ART), especially if boosted by ritonavir, became a problem early on after its rollout, with increasing reports of harmful effects, resulting in a large and growing list of drugs and natural substances no to be used concomitantly. Ergotamine derivatives, a frequent component of over-the-counter anti headache combinations was among the firsts in the list. Cobicistat, a more selective inhibitor of the cytochrome P450 isoforms than ritonavir was developed with the aim of decreasing this potential and became the pK booster of newer

integrase inhibitors (II) and more recently of the still used PIs. Despite cobicistat lesser DDI potential, side effects of co-medication are still reported, mostly for physician-prescribed drugs, but only a couple have been found in the medical literature for ergotamine.

Description: We report here the largest series of ergotism (5 cases) due to this association (Table). All cases were with cobicistat boosted elvitegravir. In all, ergotamine containing pills were self-administered and patients were unaware of its presence in the co-formulated medication used. The manifestations ranged from self-limited hands paresthesia and cooling of digits, lasting hours or few days to severe limb ischemia and neurologic symptoms, lasting weeks depending on dose and duration of use; in no case the drugs association and the specific diagnosis were entertained at first medical encounter, delaying proper management in 3.

Age/ Sex	Year	ART regimen†	Analgesic‡	Reason of use	Number of pills	Predominant manifestation	Outcome
45/M	2020	Stribild®	Cefalmin®	Hangover prevention	1/wkly months	Periodic headache, sweating, mialgias	Disappearance upon discontinuation
34/M	2019	Stribild®	Cefalmin®	Undefined pains	2 in 1 day	Hand pain, digital cyanosis, arthralgia	3 days duration
34/M	2019	Genvoya®	Cefalmin®	Headache	3 in 2 days	Paresthesia, lack of pulses	Slow recovery (1 month)
39/M	2019	Genvoya®	Migranol®	Headache	3 in a day	Painful digital ischemia	Short lived
44/M	2020	Stribild®	Migranol®	Headache	1	Fatigue, distal cyanosis	Short, self-limited

Table. Cobicistat and ergotamine interaction: ergotism.

† Stribild® (tenofovir disiproxil fumarate/emtricitabine/elvitegravir/cobicistat), Genvoya® (tenofovir alafenamide/emtricitabine/elvitegravir/cobicistat).
‡ Cefalmin® (ergotamine tartrate/caffeine/metamizole/chlorpheniramine), Migranol® (ergotamine tartrate/caffeine/metamizole).

Lessons learned: These series, from just one center, may indicate a more widespread occurrence, especially with over-the-counter drugs.

Conclusions/Next steps: Adequate identification of ergotamine containing drugs, better counseling of patients and increased awareness in the health care personnel seem necessary to avoid its occurrence in a context of contemporary antiretroviral therapy.

PEB171

No pharmacokinetic interaction between novel NNRTI MK-8507 and Islatravir

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Background: The combination of MK-8507 and islatravir (ISL) is currently in Phase 2 development as a once weekly (QW), complete, oral regimen for treatment of HIV-1 infection. MK-8507 is a potent HIV-1 non-nucleoside reverse transcriptase inhibitor with a t1/2 of 70 hrs. Islatravir (ISL) is a potent, HIV-1 nucleoside reverse transcriptase translocation inhibitor with an intracellular t1/2 of the active triphosphorylated moiety of ~190 hrs. The antiviral activity and long t1/2 make these drugs suitable for QW administration. Neither MK-8507 nor ISL inhibit or induce major CYP enzymes or transporters, and the two drugs are not expected to interact. This clinical study evaluated the two-way drug-drug interaction (DDI) of MK-8507 and ISL to support their combined use in Phase 2.

Methods: This was an open-label, fixed-sequence DDI study in healthy men and women of nonchildbearing potential. A single dose of 20 mg ISL was given followed by a 7-day washout. MK-8507, 400 mg, was then dosed once weekly for 3 weeks; a single dose of 20 mg ISL was given concomitantly with the 3rd dose of MK-8507. PK samples were collected for evaluation of ISL following both doses and for MK-8507 following the second and third doses.

Results: Fourteen participants (5 female) aged 29-59 were enrolled; 13 completed. The PK of MK-8507 and ISL were not meaningfully altered by co-administration. The geometric mean ratios (GMRs) (90% confidence intervals (CIs) for MK-8507 AUC0-168, Cmax and Ctrough given with ISL compared to alone were 1.07 (1.04, 1.11), 1.06 (0.98, 1.15), and 1.08 (1.04, 1.13), respectively; for ISL the GMRs (90% CI) for AUC0-inf and Cmax given with MK-8507 compared to alone were 1.24 (1.14, 1.35) and 1.19 (1.06, 1.33), respectively. The small increase in MK-8507 and ISL exposures is not clinically meaningful. The small increase in MK-8507 PK can be attributed in part to accumulation after weekly dosing as evidenced in the predose concentrations observed prior to co-administration. Co-administration of the two drugs was generally well tolerated.

Conclusions: There was no clinically meaningful interaction between MK-8507 and ISL, supporting further clinical development of this 2-drug, once weekly regimen.

Antiretroviral drug resistance

PEB172

Long-term efficacy among participants switched to bictegravir/emtricitabinetTenofovir alafenamide (B/F/TAF) from dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) with preexisting resistance and viral blips

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Background: Study 1844 demonstrated the safety and noninferior efficacy of switching to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) from dolutegravir/abacavir/lamivudine (DTG/ABC/3TC). Here we present resistance, viral blips, and virologic outcomes through the end of the study.

Methods: Virologically suppressed adults switched to B/F/TAF or continued DTG/ABC/3TC in a double-blind (DB) manner through Week (W) 48; then all remaining participants received B/F/TAF in an open-label (OL) extension. Preexisting HIV-1 drug resistance was determined by cumulative historical genotypes (documented resistance to study drugs was excluded) and retrospective baseline proviral DNA genotyping (participants with resistance to study drugs detected post-switch remained on study). Viral blips (transient HIV-1 RNA ≥50 copies/mL) and outcomes based on last available on-treatment HIV-1 RNA were assessed for all participants with ≥1 on-treatment HIV-1 RNA measurement.

Results: Altogether, 562 randomized and treated participants had HIV-1 RNA data in the DB phase (281 B/F/TAF, 281 DTG/ABC/3TC), and 545 participants received B/F/TAF and had post-switch data in the DB and/or OL phases (B/F/TAF duration median 96 weeks, maximum 168 weeks). Cumulative baseline genotypic data from historical (n=271) and/or pro-

viral DNA (n=499) genotypes were available for 96% (522/545) of B/F/TAF-treated participants: 31% (161/522) had ≥1 preexisting primary resistance substitution (to NRTIs [9%; 48/522], NNRTIs [17%; 88/522], PIs [10%; 54/522], and/or INSTIs [3%; 16/522]).

The average frequency of viral blips was 1% per timepoint with 25 participants (10 B/F/TAF, 15 DTG/ABC/3TC) experiencing ≥1 viral blip through W48 and 9 on B/F/TAF experiencing ≥1 blip after W48. There were 40 total blip events in the DB and OL phases; 85% (34/40) were <200 copies/mL.

Four participants (1 B/F/TAF, 2 DTG/ABC/3TC, 1 both) experienced >1 blip (range 2 – 4 blips). Viral blips were not associated with any baseline characteristic, preexisting resistance, or virologic failure.

Through 168 weeks of B/F/TAF treatment, 98% (535/545) had HIV-1 RNA <50 copies/mL at their last visit, including 99% (159/161) with preexisting resistance. No participant developed drug resistance.

Conclusions: Virologic suppression was maintained for ≥2 years of B/F/TAF treatment, including in those with preexisting resistance or viral blips. Long-term suppression and the absence of treatment-emergent resistance demonstrate the durable efficacy of B/F/TAF.

PEB173

Kinetics of archived M184V mutation in HIV-DNA from highly experienced HIV-infected patients with sustained viral suppression

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Background: The M184V mutation is highly common in viruses of highly pretreated patients. We aimed to assess the kinetics of drug-resistant minority variants (DRVMs) harboring the M184V mutation in long-term virally suppressed patients, as well as factors associated with DRVMs persistence.

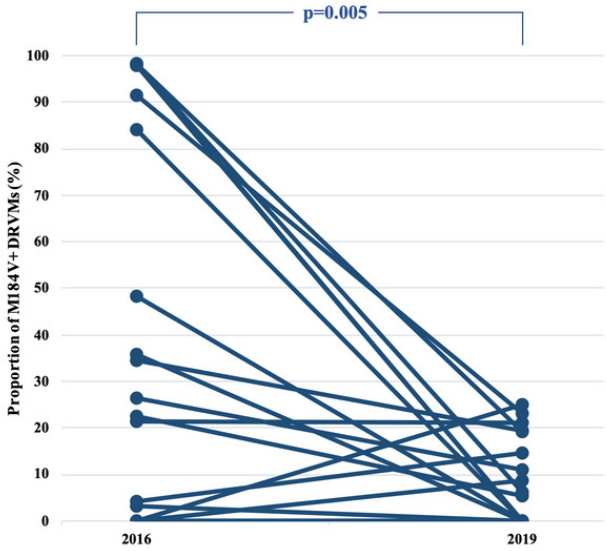
Methods: We enrolled ART treated patients with HIV-RNA <50 copies/mL for at least 5 years, and M184V detected from historical HIV-RNA genotypes. Sanger sequencing (SS) was performed in HIV-DNA from blood cells in 2019. Ultradeep sequencing (UDS, threshold 1%) was performed in 2019 and 2016 in HIV-DNA for M184V- patients using SS, to determine the proportion of M184V+ DRVMs. Factors associated to mutation persistence over time were analyzed.

Results: Samples from 79/110 eligible patients (72%) were successfully amplified for HIV-DNA, of which 53/79 (42 after SS plus 11 after UDS) had persistent M184V in 2019. Patients' characteristics were compared according to M184V presence (Table). Among the 37 patients studied by UDS, M184V mutation detection progressively decreased between 2016 and 2019 (mean difference: -18.5%, 95%CI -31.0 to -6.0, p=0.005) (Figure).

In multivariate analysis, the persistence of the M184V mutation was associated with the duration and the level of HIV-RNA during past viral replication under 3TC/FTC (p<0.001 and p=0.009, respectively).

Conclusions: While decreasing over time in HIV-DNA, the M184V mutation was more frequently persistent in HIV-DNA of the most experienced patients with past longer replication under 3TC/FTC, despite current long-term viral suppression. Randomized clinical trials are needed to assess the efficacy of 3TC-based drug-reduced ART in these patients.

	All patients (n=79)	M184V- (n=26)	M184+ (n=53)	p-value
CD4 nadir, cells/mm^3, median (IQR)	133 (47-257)	228 (131-281)	86 (30-206)	0.002
Pretherapeutic HIV-RNA, log$_{10}$ cp/mL, median (IQR)	5.12 (4.26-5.52)	4.69 (3.90-5.12)	5.29 (4.71-5.68)	0.01
Time on ART, years, median (IQR)	23.8 (20.1-26.8)	21.5 (15.8-24.4)	24.5 (22.2-27.4)	0.038
Previous number of ART, median (IQR)	13 (9-18)	11 (8-14)	15 (10-20)	0.008
Duration of past viral replication under 3TC/FTC, years, median (IQR)	5.6 (2.7-7.9)	2.7 (1.1-5.4)	6.6 (3.7-8.6)	<0.001
Mean HIV-RNA during past viral replication under 3TC/FTC, log$_{10}$ cp/mL, median (IQR)	3.92 (3.26-4.44)	3.30 (2.82-4.06)	4.12 (3.70-4.62)	<0.001
Duration of viral suppression, years, median (IQR)	8.9 (6.8-10.7)	8.4 (6.0-10.0)	9.0 (7.3-10.9)	0.33
HIV-DNA, log$_{10}$ cp/10^6 cells, median (IQR)	3.44 (3.10-3.70)	3.40 (2.90-3.70)	3.49 (3.15-3.70)	0.49
3TC/FTC as part of ongoing ART, n(%)	31 (39)	11 (42)	20 (38)	0.74



PEB174

HIV-1 subtype influences the selection of resistance mutations and the resistance level to integrase inhibitors

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Background: Data on HIV-1 resistance to integrase inhibitors (INIs) is mostly based on subtype B. However, in Western Europe, the proportion of non-subtype B strains is increasing in the last years. The use of INIs in low- and middle-income countries, where non-subtype B are more frequent, is also increasing. Thus, more information regarding resistance to INIs in non-subtype B strains is needed.

Methods: HIV-1 integrase sequences obtained in our laboratory from samples collected between 2008-2020 from 186 HIV-1-infected patients diagnosed in Spain, with at least low-level resistance to any integrase

inhibitor, were included in the study. Resistance to INIs was determined by Stanford University HIV Drug Resistance Database's HIVdb program (version 8.9-1). Classification of sequences in subtypes and recombinant forms was based on clustering with clade references in approximately maximum-likelihood trees with FastTree 2 and subsequently by bootscanning with SimPlot. Differences in drug resistance mutations (DRMs) and the resistance level to different INIs between B and non-subtype B strains were compared.

Results: 24% (44/186) of sequences were classified as non-subtype B, of which CRF02_AG (32%, 14/44) were the most frequent. 61% (114/186) of sequences with resistance to raltegravir (RAL) were still susceptible to dolutegravir (DTG). The percentage of sequences with a high-level resistance to RAL and DTG was higher in subtype B compared to non-subtype B sequences (72% vs 41%, p<0.001, and 13% vs 2%, p<0.03, respectively). The most frequent INI DRMs found were N155H (32%), Q148H/R (32%) and G140S (20%). Q148H (n=29) and G140S (n=37), which are frequently associated and induce resistance to RAL and DTG, were absent in non-subtype B strains (p<0.0001). Q148R was more frequently found among non-subtype B than among subtype B sequences (29% vs 12%; p<0.001).

Conclusions: Non-subtype B strains show a different frequency of resistance mutations and lower resistance level to INIs compared to subtype B strains. DTG is still a therapeutic option for most RAL-resistant HIV-1 strains. Further studies on the influence of HIV-1 subtype on the development of specific INI resistance mutations could have important implications for optimizing the use of INIs in clinical practice.

Adherence measurement

PEB175

Self-reported antiretroviral adherence: association with maternal viral load suppression in HIV-1-infected postpartum women in Promoting Maternal and Infant Survival Everywhere (PROMISE): randomized, open label trial in sub-Saharan Africa and India

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Background: Optimal adherence to antiretroviral therapy (ART) is crucial to promote maternal-infant health. We assessed self-reported adherence to maternal ART (mART) and infant nevirapine (iNVP) and the association of mART adherence with viral load suppression in postpartum women in PROMISE.

Methods: The PROMISE trial enrolled 2431 postpartum, breastfeeding mother-infant pairs between 2011- 2014 in sub-Saharan Africa and India. Randomization was to mART plus 6 weeks iNVP versus iNVP only prophylaxis until breastfeeding cessation or 18 months postpartum, whichever occurred first. Self-reported adherence, measured through 18 months postpartum across all study visits as dichotomous and continuous measures was assessed in a secondary analysis. Among women in the mART arm, longitudinal time-to-event analyses with the adherence measures as predictors for time to first occurrence of maternal viral load (MVL) ≥400 copies/ml and ≥1000 copies/ml were performed.

Results: There were 1220 women in the mART arm with twice daily protease-inhibitor (LPV/r/TDF/FTC) as the preferred regimen and 1211 in the iNVP arm. Baseline median CD4 was 686 (IQR 553-869) and median MVL was 322 copies/mL (IQR 40-1422). Self-reported adherence was lower in the mART arm compared to the iNVP arm (no missed doses within 4 weeks of all study visits: 65.8% vs 83.3%; within 2 weeks: 70.9% vs 85.2%; P<0.0001 comparing mART versus iNVP for both time periods). The self-reported adherence to iNVP at week 6 was high in both arms: 97% in mART arm; 95% in iNVP arm. In time-to-event analyses, the continuous measurement of self-reported maternal adherence to mART was associated with time to first MVL ≥400 copies/ml (P<0.0001). Missing 1 full day of doses over the past 3 days prior to a study visit was associated with a 58% higher risk of having a MVL ≥400 copies/ml (Hazard ratio (HR): 1.58; 95% CI: 1.33, 1.87) and 66% risk of MVL ≥1000 copies/ml (HR: 1.66; 95% CI: 1.37, 1.99).

Conclusions: Our data from the PROMISE trial found that postpartum women were more adherent to providing their infants nevirapine than taking ART for themselves. The self-reported missed mART doses reliably predicted high MVL. Strategies to optimize postpartum maternal ART adherence are urgently needed.

PEB176

Estimating minimum adherence required for plasma HIV-1 RNA viral load suppression among people who use unregulated drugs in Vancouver, Canada

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Background: People living with HIV (PLHIV) must maintain high levels of adherence to experience the clinical benefits of antiretroviral therapy (ART). Advancements in the potency of newer ART regimens have called into question whether adherence levels ≥95% remain necessary to achieve sustained HIV-1 viral load (VL) suppression. We aimed to estimate minimum levels of ART adherence, and whether this differed by ART regimen among PLHIV who use drugs (PLHIV-PWUD).

Methods: We used data from the ACCESS Study, a community-recruited prospective cohort of PLHIV-PWUD in Vancouver, Canada, linked to comprehensive pharmacy dispensation records and HIV VL monitoring. Among individuals with ≥1 day(s) of ART dispensation during the study period (1996-2017), we included VL measures taken >360 days after the earliest date of ART dispensation. We calculated ART adherence levels using the proportion of days of dispensed ART in the 360 days before each VL. We used generalized linear mixed models to identify adherence- and ART regimen- correlates of VL suppression (<200 copies/mL), and stratified probit regression models (by ART regimen) to plot dose-response curves to estimate the minimum ART adherence level needed to produce HIV VL suppression in 90% of tests.

Results: Among 837 PLHIV-PWUD contributing 38,815 HIV VL records between 1996 to 2017, the overall estimated adherence level necessary to achieve VL suppression in 90% of VL measures was 93% and varied by ART

regimen: 69% for integrase inhibitor (InSTI)-, 96% for boosted protease inhibitor (PI)-, and 98% for non-nucleoside reverse transcriptase inhibitor-based regimens. Not-boosted PIs and "other" ART regimens were not able to reach the 90% VL suppression benchmark even with perfect adherence levels. In multivariable analysis, compared to boosted PIs, InSTI-based regimens were positively associated with VL suppression, while not-boosted PIs and "other" ART regimens were negatively associated. Similarly, adherence levels <95% were associated with lower odds of VL suppression in a dose-response fashion.

Conclusions: ART adherence levels necessary to achieve VL suppression among PLHIV-PWUD in this study was high. InSTI-based regimens may represent an advantage for this group. These results underline the need for innovative interventions to support ART adherence among this key affected population.

PEB177

Utilization of antiretroviral refill histories as a predictor of future HIV viremia

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Background: Various adherence measures have assessed associations with HIV viral suppression. However, the assessment of these markers for viral failure (VF) is less described. While tenofovir diphosphate in dried blood spots demonstrated predictability of future VF, its utility outside of research settings has been limited and does not encompass all ART regimens. Refill histories (RH) are readily accessible and can be quantified to an adherence level. However, little is known about their utility for predicting VF.

Methods: Participants from a US, academic HIV clinic were evaluated from 2018-2020. RH and last HIV RNA (VL) for each participant were collected for each study year. RH were quantified as a percentage of days covered (PDC) and VF was defined as VL >200 copies/mL. PDC values were matched with the following year's VL (matched case). Sample t-test was used to compare mean PDC between years and Generalized Estimating Equation approach was used to determine the predictability of PDC on the following year's VL. Optimal PDC threshold for VF was predicted by receiver operating characteristic curve by the Youden index. Regression analyses evaluated predictive factors for PDC under the optimal threshold.

Results: 1056 participants contributed to 1987 matched cases (PDC/VL); mean age was 48.3 years, 24% women, and 30.6% Black. PDC levels differed significantly based on dichotomized VL (2018-2019: VL>200 – 0.40, VL≤200 – 0.85, p<0.0001; 2019-2020: VL>200 – 0.45, VL≤200 – 0.87, p<0.0001). Based on the highest Youden's J value of 0.658 (sensitivity 0.767, specificity 0.891), the optimal PDC threshold predictive of VF was 0.52. Black (odds ratio [OR] 2.04) and other race (combined variable: Asian, American Indian/Pacific Islander, OR 2.66) vs Caucasian, single (OR 1.86) vs committed relationship, homelessness (OR 3.84) vs stable and government-based (OR 1.72) and uninsured status (OR 9.85) vs commercially insured were significantly associated with PDC≤0.52.

Conclusions: Lower ART adherence levels were predictive of future VF when PDC≤0.52. Patients of Black, Asians or American Indian/Pacific Islander race, single, homeless, uninsured or supported by government-based insurance where identified as potential risk factors for PDC≤0.52. Thus, these populations may benefit from enhanced services to improve adherence and prevent future VF.

Ethical issues in clinical trials and treatment strategies

PEB178

Region-specific laboratory reference intervals are important: a review of the data from Africa

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Background: Region-specific laboratory reference intervals (RIs) are important to guide design, enrollment, and patient management for clinical trials and these data are often sparse in high priority areas for prevention research, including Africa. We review published data on RIs from Africa.

Methods: We conducted a systematic review of PubMed and supplemental searches of African Journals Online, Google Scholar, Dimensions, and Project Smile for RI studies from Africa published ≥2010. Search focus included clinical analytic chemistry, hematology, metabolism, immunological parameters and RIs. We excluded persons with conditions that might preclude clinical trial participation of healthy volunteers; we included healthy people living with HIV.

Results: Of 144 identified manuscripts, 62 were included in this review, covering 18 countries with the largest number of studies in Ethiopia (n=16, 26%); one study included more than one country (Malawi and Uganda). Most studies considered healthy, nonpregnant adults (n=37, 60%). Six (10%) studies included pregnant women, 12 (19%) included adolescents and 20 (32%) included children (<12 years old). No manuscripts included RIs for people living with HIV. Recruitment, screening and enrollment procedures varied significantly across studies.

Nineteen (31%) studies included RIs for both hematology and clinical chemistry parameters, 34 (55%) exclusively characterized hematology RIs (including immunology/lymphocyte subset studies), 9 (14%) characterized exclusively clinical chemistries. The number of parameters characterized ranged from only one (two studies each characterized CD4+ counts or hemoglobin), to as many as 40. Statistical methods for calculating RIs varied.

While all studies noted the importance of regionally appropriate RIs, 41 (66%) studies explicitly compared their results to other international RI databases. Nearly all found significant deviation from values in Europe or North America, with up to half of otherwise healthy participants having an "abnormal / out of range" result; Only one study from South Africa found that the hematological parameters measured did not vary meaningfully from international RIs. Not all studies presented clear methods for these comparisons.

Conclusions: There is a paucity of RI data available from Africa. Studies to fill this gap are warranted including efforts to standardize statistical methods to derive RIs, methods to compare with other RIs, and participant selection.

New strategies (2DR, rapid start)

PEB179

Five years durability of dolutegravir + lamivudine in patients with suppressed HIV-RNA

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Background: Availability of new potent drugs allows to explore the feasibility of less-drug regimens but their long-term durability is unknown.
Methods: Prospective, multi-center, cohort study in patients on stable cART , with a confirmed (>6 months) viremia <50 copies/ml, absence of M184V mutation or HBsAg. Patients were switched to DTG+3TC and prospectively monitored. Kaplan-Meier curves, Cox-regression analysis and general linear model for repeated measures were used in the analysis.
Results: 218 patients, 75.2% males, median age 52 years (IQR 12) were enrolled. At switch patients were on ARV drugs for a median of 10.2 years (IQR 13) and virologically suppressed for a median of 75 (IQR 217) months. Most patients presented with a non-infectious chronic co-morbidity (median 2; IQR 1) because of which, beside ARV drugs, they were taking a median of 2 other drugs (IQR 11). Over 959 patient/years of follow-up treatment was discontinued in 50 (22.9%) subjects. Eleven subjects stopped therapy because of death (occurring at a median age of 61 years), further 13 subjects because of intolerance; 20 because of other causes mostly related to losses at follow-up (10), patients' decision (7) or transfer to other Center (3), while 4 patients were re-shifted to a 3 drugs regimen. Mean KM estimate of treatment duration was 64.3 months (95% CI 61.3-67.3) (figure); only female gender (P=0.043) and lower baseline CD4 levels (P=0.023) were negatively associated to treatment durability in the Cox-regression model.
For the whole follow-up no virological failure and only 15 isolated viral-blips in 15 different patients were recorded. Over time CD4 median increment was of 251 cells/mcL (P<0.0001), while CD8 cells decreased of a median of 126 cells/mcL (P=0.189) with a significant (+0.21; P<0.0001) change in CD4/CD8 ratio.

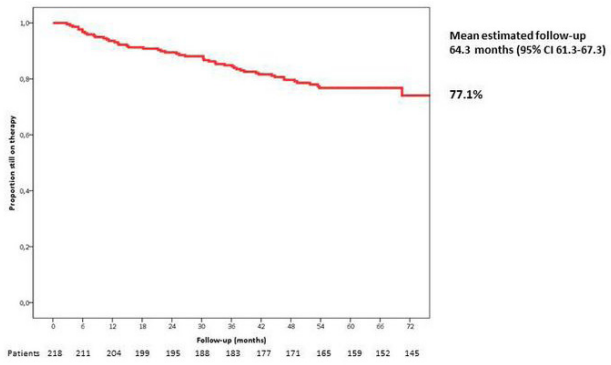

Figure. Prospective cohort of 218 patients

Conclusions: DTG-3TC dual ART is a durable, effective and well tolerated alternative to standard three drug regimens in virologically controlled patients.

PEB180

Immediate versus delayed antiretroviral treatment in hospitalized persons with AIDS-defining opportunistic disease: a randomized clinical trial

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Background: According to international recommendations, antiretroviral therapy (ART) is delayed in persons living with HIV with AIDS-defining opportunistic disease (OD), until the OD has been stabilized. We studied the possible benefits of immediate ART initiation in comparison with conventional delayed ART, using currently recommended ART regimens.
Methods: This is an open label, randomized controlled trial to assess survival in subjects hospitalized by an AIDS-defining OD at a tertiary referral institution at 360 days, comparing immediate (maximum 48 hours after admission), versus delayed (after OD stabilization) ART. Secondary outcomes were days of hospitalization, and immune reconstitution inflammatory syndrome (IRIS) incidence.
We included adults admitted to the emergency department with an OD, documented HIV infection, ART-naïve, or with ART suspension for at least 3 months.
Participants underwent stratified randomization by CD4+ T cell count (<50 or ≥50 cells/mm^3) into the two study groups. Statistical analyses were performed with SPSS v24.
Results: A total of 58 participants were included, 51 male (87.5%); mean age 36.4 (SD 9.3) years. Baseline viral load was 419,450 (SD 684,519) copies/mL, and baseline CD4+ T cell count was 55.8 (SD 49.4) cells/mm^3. The initial ART regimen was TAF/FTC/BIC (or TDF/FTC+DTG if clinical suspicion of tuberculosis existed).
Time to ART initiation was 2 (SD 0.9) days in the immediate vs. 11.8 (SD 9.0) in the delayed ART arm. No difference in IRIS incidence (n=5, 17.8% vs. n=4, 13.3%; p=0.77) or time for clinical presentation of IRIS (59.9, SD 20.0, vs. 104.5, SD 60.4 days; p=0.14) was observed in the immediate vs. delayed ART arm. A trend toward shorter hospital stay in the immediate ART group was observed (14.1, SD 6.1 vs. 18.8, SD 17.0 days; p=0.07).
Mortality (n=2, 7.1% vs. n=5, 16.6%; p=0.28), as well as ART withdrawal (n=4, 14.3% vs. n=4, 13.3%; p=0.87) were similar in the in the immediate vs. delayed ART arm.
Conclusions: A trend toward shorter hospital stay was observed in the immediate ART arm, with similar IRIS incidence in the study groups. No additional benefits of immediate ART initiation were evident, although a possible effect on mortality could be confirmed increasing the sample size.

PEB181

Largely increasing amounts of patients under dual ART due to new therapeutic regimens: dual therapy regimens 2016-2020 in the German North Rhine Cohort

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Background: The focus of this retrospective cohort analysis was to assess the proportion and treatment success of diverse dual treatment strategies between 2016 and 2020.

Methods: Within the German North Rhine cohort, records of therapy-experienced patients from 16-19 centers were collected annually between 2016 (n=2247) and 2020 (n=4137). Data on therapy and virological response were documented for the 1st quarter of each year. Treatment success was determined as the proportion of patients with suppressed viral load <50 copies/mL. Conversion to dual therapies (2DR) occurred mostly with prior successful viral suppression.

Results: The overall proportion of 2DRs remained nearly constant until 2019. The proportion of patients on 2DR was 7.4% in 2016, 6.9% in 2017, 6.3% in 2018, and 6.6 % in 2019. However, a significant increase in patients on 2DRs was seen 2020, when the proportion increased to 14.2% (n=588). The treatment success of dual regimens in therapy-experienced patients in 2016-2020 was 89.7%, 90.7%, 95.4%, 92.8%, and 94.3%, respectively, and was comparable to the treatment success in the entire cohort (91.2%-96.4%). The proportion of patients on protease inhibitor (PI) + integrase inhibitor (INI) decreased from 64% to 41% in 2019 and to 20.1% in 2020. A similar trend was seen for the combination of NRTI+PI (18% to 9% and 2.4%, respectively). In contrast, combinations of NRTI+INI, on the other hand, increased from 4% to 63.1% (mainly 3TC+DTG) and combination of one NNRTI + INI from 6% to eventually 11.1%. In 2020, the most frequently documented combinations consisted of 3TC+DTG (62%), DRV/r+DTG (12.4%), RPV+DTG (10.2%), and DRV/r+RAL (4.6%).

Conclusions: The proportion of patients on dual ART 2020 was more than double the proportion within the same period 2019. During the previous years, the proportion had remained largely constant. Approximately 94% of all patients on dual therapy in 2020 showed a sustained viral load below the detection limit which was comparable to the treatment success in the overall population.

PEB182

Feasibility, efficacy, and safety of Dolutegravir/Lamivudine (DTG/3TC) as a first-line regimen in a test-and-treat setting for newly diagnosed people living with HIV (PLWH): 48-week results of the STAT study

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Background: Dolutegravir/Lamivudine (DTG/3TC) is indicated for treatment-naive and treatment-experienced people living with HIV (PLWH); however, questions remain about its utility in a test-and-treat setting because of potential transmitted resistance and baseline hepatitis B virus (HBV) co-infection. The STAT study evaluated the feasibility of using DTG/3TC as a first-line regimen in a test-and-treat setting in the United States. Here we present the 48-week end-of-study results.

Methods: STAT is a single-arm study in adults who initiated DTG/3TC ≤14 days after HIV-1 diagnosis without availability of screening/baseline laboratory results. If baseline testing indicated DTG or 3TC resistance, HBV co-infection, or creatinine clearance <30 mL/min/1.73 m^2, participants had their antiretroviral therapy (ART) adjusted and remained on study. Efficacy analyses included proportion of participants with HIV-1 RNA <50 c/mL, regardless of ART received at Week 48, among all participants (ITT-E missing = failure analysis), and among those with available HIV-1 RNA data at Week 48 (observed analysis).

Results: Overall, 131 participants were enrolled in the study. By Week 48, treatment was modified in 10 participants: 5 due to baseline HBV, 1 due to baseline M184V, 1 due to an adverse event (AE; grade 2 rash), 1 due to first-trimester pregnancy, and 2 withdrew consent. After the Week 48 assessment, 1 participant modified ART due to lack of efficacy. At Week 48, 82% (107/131) of all participants and 97% (107/110) of those with available data achieved HIV-1 RNA <50 c/mL (Table). Two participants (2%) met confirmed virologic failure criteria; no treatment-emergent resistance-associated mutations were observed, and both remained on DTG/3TC. Incidence of drug-related AEs was low (8%); no drug-related SAEs occurred.

		DTG/3TC (N=131)	
Analysis	**Outcomes, n/N (%)**	**Week 24[a]**	**Week 48**
Observed analysis	HIV-1 RNA <50 c/mL	102/111 (92%)	107/110 (97%)[b]
ITT-E missing = failure analysis[c]	HIV-1 RNA <50 c/mL	102/131 (78%)	107/131 (82%)
	Data in window and HIV-1 RNA ≥50 c/mL	9/131 (7%)	3/131 (2%)
	On study but missing data in window	5/131 (4%)	3/131 (2%)[d]
	Discontinued from study	15/131 (11%)	18/131 (14%)[e]

ART, antiretroviral therapy; DTG/3TC, dolutegravir/lamivudine; ITT-E, intention-to-treat–exposed.
[a]Detailed outcomes from the efficacy analyses at Week 24 have been presented at ACTHIV 2020; Virtual; Poster. [b]Of the 107 participants with HIV-1 RNA <50 c/mL at Week 48, 100 were on DTG/3TC; the 3 participants with HIV-1 RNA ≥50 c/mL were on DTG/3TC. All 17 participants with HIV-1 RNA ≥500,000 c/mL at baseline and available data at Week 48 achieved HIV-1 RNA <50 c/mL at Week 48. [c]Of the 10 participants who modified ART before the Week 48 visit, 7 achieved HIV-1 RNA <50 c/mL at Week 48, 2 discontinued from study, and 1 was on study but missed HIV-1 RNA assessment at Week 48. [d]1 participant missed HIV-1 RNA assessment at Week 48 because of COVID-19. [e]8 (6%) participants discontinued due to being lost to follow-up, 6 (5%) due to withdrawal of consent, 4 (3%) for other non–treatment-related reasons.

Table. Proportion of participants with HIV-1 RNA <50 c/mL at week 24 and week 48 in the observed and ITT-E missing = failure analyses

Conclusions: These data further support the feasibility of rapid DTG/3TC initiation and demonstrate that appropriate ART adjustments can be performed safely via routine clinical care in the presence of baseline resistance or HBV co-infection.

PEB183

48 weeks efficacy and tolerability of dolutegravir (DTG) + lamivudine (3TC) in adult HIV naïve patients. A multicenter real life cohort

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Background: DTG / 3TC therapy is indicated as one of the preferred treatments for HIV patients in the main international guidelines[1, 2], due to the efficacy observed in randomized clinical trials[3, 4]. However, information in real-life cohorts is still scarce.
Methods: A multicentre study of HIV-patients, with DTG+3TC as first line regimen starting before January 31th 2020. Virological failure (VF) was defined as 2 consecutive HIV RNA >50 c/mL or a single value >200 c/mL.
Results: 135 patients were included. The baseline characteristics are described in Figure 1. Treatment was started without the results of the baseline drug resistance testing (bDRT) results in 71.9% of cases, which subsequently confirmed baseline resistance mutations in 17 patients (12.6%). Two of them needed to change HAART due to the presence of M184V mutation.

Baseline characteristics			Patients (p) (N = 135)	
Age (years) (median – IQR)			32 (27-39)	
Gender	Male		90.4%	
	Female		9.6%	
HIV transmission	MSM		83%	
	MSW		14.8%	
	IDU		2.2%	
Country – region	Spain		51.1%	
	Latinamerican		39.3%	
	Europe		4.4%	
	Others		5.2%	
CDC stage	A		92.6%	
	B		5.2%	
	C		2.2%	
CD4 cells/mm^3 (median – IQR)	Basal CD4 cells/mm^3		469 (347-650)	
	CD4 < 200 cells/mm^3		2.2%	
HIV-1 VL (c/mL)	> 100000 c/mL		17%	
	< 100000 c/mL		83%	
Hepatitis B co-infection	AgSHBV +		0%	
	AcCHBV +		23.7%	
	AcSHBV +		64.2%	
Hepatitis C co-infection (IgG HCV +)			5.2%	
HLAB5701 positive			8.5%	
Median time from diagnosis to start of treatment			6 weeks (IQR: 3-14)	
Major mutations in Baseline drug resistance testing (bDRT)	17 p (12.6%)	INSTIs	1 p (0.7%)	G163K
		PIs	1 p (0.7%)	V82C
		NNRTIs	12 p (8.9%)	E138A(3), K103N(6), V106I(3), V108Vi, E138EG, E138E, G190A
		NRTIs	5 p (3.7%)	M184V(2), M14L, E44D, T215D, T215C, 210W,215S

Figure 1. Baseline patients' characteristics

In the intention to treat (ITT) analysis (missed patients=failures), efficacy at week 48 was 85.2%, however in the treatment-related discontinuation equals failure (TRDF) analysis, it was 99.3%. Six patients (4.4%) discontinued treatment. One developed VF after discontinuing treatment due to poor adherence, non related with the treatment; no resistance-associated mutations (RAM) emerged. Three patients discontinued treatment due to CNS side effects (2.2%). Two patients due to a medical decision after determining the M184V mutation in bDRT; one of them reached CV <50 cop/mL in week 4. Finally, 14 patients (10.4%) were lost for follow-up, most of them due to COVID-19 pandemic. At week 4 and 12, 92% and 100% of patients with available information respectively, had <200 c/mL (78% y 98% <50 c/mL).
Conclusions: In a real-life cohort of naïve HIV-patients starting ART with DTG + 3TC shows similar results in efficacy and security of those obtained in randomized clinical trials. Starting the treatment without knowing results of the baseline drug resistance test did not impact in the efficacy of the regimen.

PEB184

Immediate ART is feasible during the COVID-19 pandemic

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Background: Immediate antiretroviral therapy (ART), within seven days of HIV diagnosis, has been introduced as a strategy to improve clinical outcomes and reduce barriers to ART for people living with HIV (PLWH). The impact of the COVID-19 pandemic on these pathways is unknown. We describe an outpatient immediate ART pathway in a cohort with a high proportion of late HIV diagnosis, female, heterosexual and Black, Asian and minority ethnic (BAME) PLWH and present the outcomes for this cohort pre- and post the COVID pandemic.
Methods: Clinical data were collected for users of the immediate ART pathway during 2019 (pre-COVID) and 2020 (COVID). Late presentation defined as new HIV with a CD4 count <350 cells/mm3. Time to immediate ART was defined as the time from confirmed HIV diagnosis to ART initiation. Cox regression analysis was used to compare time to viral load <50copies/ml (VL<50) between groups.
Results: One hundred and eighty indiviudal were diagnosed with HIV during the study period, of these 123 were eligible for the Immediate ART pathway, 87% opted for Immediate ART. Primary infection accounted for 19%. The proportion of new HIV diagnoses using the Immediate ART pathway was similar pre-COVID (66%) and during COVID (70%). Median (IQR) time to ART initiation was 7 (2,14) days and time to VL<50 was 49 days (26,103). The proportion of Late HIV diagnosis was similar pre-COVID and during COVID (41% & 31%, P=0.3), as were the rates of disengagment with HIV care (2.8 and 3.8% respectively, P=0.8). Higher Baseline HIV viral load (HR -0.56, P<0.001) was associated with longer time to VL<50, while CD4/CD8 ratio (HR=0.47, P=0.005) Clade B virus (HR=0.53, P=0.01) and INSTI use (HR=0.59) were associated with shorter time to VL<50. Late HIV diagnosis and Use of Immediate ART during the COVID pandemic did not impact the time to HIV VL<50.
Conclusions: Immediate ART was feasible and acceptable in our clinical setting. ART uptake and the proportions achieving virological suppression were similar in both Pre-and during the COVID-19 pandemic. These data support the use of outpatient immediate ART during the COVID pandemic at all CD4 counts and in groups beyond MSM.

Nutrition

PEB185

Food rescue programs in food-insecure PWLH in Baylor Mwanza-Tanzania: a descriptive study

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Background: Food rescue is a program issued at Baylor to help PLWH food insecurity, because food insecurity is a disorder of HIV care. Food rescue based to supports the nutritional advancement of malnourished children who suffered with food Insecurity. Through the provision of essential foods and supportive education, the program helps caregivers understand the value of a healthy diet, and teaches them how to obtain and prepare foods.

Food rescue aimed to improve the nutritional status, swallowing ARTs properly because of the presence of food, retain client in care, start home garden and entrepreneurship skills in order to generate their own family income.

Description: This was a retrospective cohort study. The study period was from July 2019 to Jan 2020. 19 samples were taken. Data was obtained from nutrition daily Attendance book, food donation database and electronic medical record (EMR). Assed families with food insecurity were enrolled. STATA program used to analyze the data.

Lessons learned: A total of 19 families with food insecurity were enrolled. Nutrition education and counseling on feeding practices were provided.8(36.8%) client had severe acute malnutrition,9(47.4%) client had moderate acute malnutrition, all of them had improved on nutrition status at six months of the program and 3(15.8%)client had good nutrition status before the program. All clients had increased body weight by average of 3. 51kg.Only 11(57.9%) families started home garden.18(94.7%) families adhered well on ART and on program visit.6(31.6%) successes on starting a small business and 13(68.4%) increased their abilities through entrepreneurship skills.

Conclusions/Next steps: The food rescue program is impressive, especially to help PLWH's life, in this review has showed that, there are clear association between food insecurity and malnutrition. During the program client's body weight were increased, malnutrition clients had improved. Food availability is a successful key of health status to PLHIV.

Pregnancy (Blinical management issues and pharmacokinetics)

PEB186

Prevalence of depression among postpartum women on Isoniazid-Preventive Therapy and Efavirenz-based treatment for HIV—an exploratory objective of the IMPAACT P1078 randomized trial

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Background: In response to a concern for Isoniazid-Preventive Therapy (IPT)/efavirenz (EFV) interaction, we conducted an exploratory analysis of IMPAACT P1078 to investigate possible neurocognitive toxicity in postpartum women on HIV treatment.

Methods: Pregnant women on HIV treatment from 8 high-incidence tuberculosis countries were randomized in IMPAACT P1078 to 28 weeks of IPT started during pregnancy or 12 weeks postpartum and followed monthly until 48 weeks postpartum. Partway through study implementation, the Patient Health Questionnaire 9 (PHQ-9) was added to systematically evaluate depression symptoms at entry, quarterly antepartum, and postpartum weeks 4, 12, 24, 36, and 48. We summarized percentages of women with depression symptoms at postpartum visits and assessed the association of 11 risk factors of probable depression (PHQ-9 ≥10) at 36 weeks postpartum using exact logistic regression, adjusted for gestational age stratum. Week 36 was selected *post-hoc* because it had a high prevalence. Study arm effect modification by EFV use was also evaluated.

Results: Of 956 women enrolled, 749 (78%) women had ≥1 PHQ-9 evaluation(s). At study entry, 691/749 (92%) women were Black African/Black of African origin, with median (Q1, Q3) age of 29 years (24, 33) and gestational age of 26 weeks (22, 30). Most women were at WHO Clinical Stage I (88%), on an EFV-containing regimen (85%), and had undetectable HIV RNA levels (63%), with median CD4 count of 499 cells/mm^3 (355, 689). Across postpartum visits, probable depression was reported in 0.7-2.2% of women (Table).

Postpartum Study Visit Week	Number of Women Evaluated	Depression Symptoms				Probable Depression (PHQ-9 ≥ 10)	
		Minimal (PHQ-9: 1-4)	Mild (PHQ-9: 5-9)	Moderate (PHQ-9: 10-14)	Moderately severe, severe (PHQ-9: 15-27)	IPT initiated in pregnancy (Immediate)	IPT initiated postpartum (Deferred)
4	136	28 (20.6%)	8 (5.9%)	0 (0%)	2 (0.7%)	0/64 (0%)	2/72 (2.8%)
12	229	57 (24.9%)	24 (10.5%)	4 (1.7%)	1 (0.4%)	2/111 (1.8%)	3/118 (2.5%)
24	378	91 (24.1%)	29 (7.7%)	3 (0.8%)	3 (0.8%)	3/186 (1.6%)	3/192 (1.6%)
36	539	117 (21.7%)	26 (4.8%)	9 (1.7%)	2 (0.4%)	7/270 (2.6%)	4/269 (1.5%)
48	689	127 (18.4%)	25 (3.6%)	4 (0.6%)	1 (0.1%)	3/342 (0.9%)	2/347 (0.6%)

Cotrimoxazole use was associated with increased odds of probable depression at Week 36 [adjusted odds ratio (95% confidence interval): 3.1 (1.1, 20.3)]. There was no evidence of study arm differences in odds of probable depression, nor treatment effect modification by EFV use.

Conclusions: Timing of IPT initiation was not associated with probable depression. Further study is advised to formally assess associations of risk factors with probable depression.

PEB187

Adverse perinatal outcomes associated with timing of initiation of antiretroviral therapy: systematic review and meta-analysis

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Background: An increasing number of HIV-positive women conceive while taking ART, the vast majority of whom reside in low- and middle-income countries (LMICs). We aimed to assess the association between timing of antiretroviral therapy (ART) initiation and perinatal outcomes.

Methods: We conducted a systematic literature review by searching PubMed, CINAHL, Global Health, EMBASE, and five clinical trial databases from 1 January 1980 to 28 April 2018. We included studies reporting specific perinatal outcomes among HIV-positive pregnant women according to timing of ART initiation. Perinatal outcomes assessed were preterm birth, very preterm birth, low birthweight, very low birthweight, small-for-gestational-age, very small-for-gestational-age, and neonatal death. Random-effects meta-analyses examined perinatal outcomes associated with preconception and antenatal ART initiation, including trimesters of antenatal initiation. Quality assessments, subgroup and sensitivity analyses were performed, and the effect of adjustment for confounders assessed.

Results: Of 51,874 unique citations, 25 studies (8 prospective and 17 retrospective cohort studies) were eligible for analysis, including 40,920 women. No associations with perinatal outcomes were found in the comparison of preconception and antenatal ART initiation, except an increased risk of preterm birth associated with preconception ART initiation (relative risk 1.16, 95% CI 1.03-1.31). First trimester exposure (i.e. preconception or first trimester initiation) was not associated with any increased risk of adverse perinatal outcomes. No association between timing of ART initiation and adverse perinatal outcomes was found in the studies of higher quality and those conducted in LMICs.

Conclusions: Preconception initiation of ART is associated with preterm birth, but no other adverse perinatal outcomes. Our findings support the WHO recommendation for immediate ART initiation in all HIV-positive individuals, including pregnant women and those of childbearing potential.

PEB188

Comparable pregnancy outcomes for HIV-uninfected and HIV-infected women on antiretroviral treatment in Kenya

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Background: The impact of HIV on pregnancy outcomes for HIV-infected women on antiretroviral therapy (ART) in sub-Saharan Africa (SSA) remains unclear. We compared adverse pregnancy outcomes between HIV-uninfected and HIV-infected women on ART and assessed associations between HIV status and other potential causes of adverse pregnancy outcomes in Kenya.

Methods: During 2017-2019, pregnant women aged ≥15 years in the second trimester were enrolled from three facilities in Coastal Kenya. Study nurses administered a questionnaire including socio-demographics, obstetric history, anthropometric measurements, and abstracted baseline laboratory records. Participants were followed-up monthly until delivery. Pregnancy loss was defined as any miscarriage or stillbirth; low birthweight (LBW) as birthweight <2500g; and prematurity as gestation at delivery <37 weeks. Using multiple logistic regression, we compared pregnancy loss, LBW, and prematurity among HIV-uninfected and HIV-infected women on ART, adjusting for socio-demographic and obstetric factors. We used similar procedures to determine correlates of HIV-positive status. We reported risk ratios (RR), prevalence ratios (PR), 95% confidence intervals (95%CI) and p values.

Results: Of the 2,113 enrolled participants, median age was 28 years (IQR: 24-32), 311 (15%) were HIV-infected and on ART, 633 (30%) had no previous pregnancy, 549 (26%) had anemia, 69 (5%) developed pre-eclampsia and 28 (1%) had syphilis. Ninety-one (5%) experienced a pregnancy loss, 169 (10%) a premature birth, and 74 (6%) had a LBW newborn.

There was no evidence of an association between treated HIV and pregnancy loss (RR: 1.20 [0.67-2.12], p=0.54), prematurity (1.07 [0.69-1.65], p=0.77) and LBW (1.36 [0.77-2.40], p=0.29). Age (PR: 1.04 for each year older [95%CI: 1.02-1.06]), low SES (1.51 [1.22-1.87]) and anemia (1.54 [1.27-1.87]) were independently associated with HIV-positive status. Higher gestational age at first antenatal clinic (ANC) (0.95 [0.94-0.97]), higher BMI (0.95 (0.94-0.97)), and being primigravid (0.45 [0.33-0.65]) were inversely associated with HIV-positive status.

Conclusions: This study demonstrated that when treated with ART, HIV infection was not significantly associated with adverse pregnancy outcomes. Women living with HIV, however, may still have higher rates of pregnancy loss than their uninfected counterparts due to higher prevalence of anemia, poorer nutritional status, higher parity and low SES. Longer monitoring in ANC maybe a mitigating factor.

PEB189

A comparative multi-country analysis of the impact of COVID-19 on HIV services for pregnant and breastfeeding women and their infants

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Background: HIV service delivery adaptations during the COVID-19 pandemic ensure timely prevention of mother-to-child HIV transmission (PMTCT) services. This analysis updates a 2020 International Pediatrics Workshop oral presentation and compares USAID PEPFAR PMTCT program data from 12 countries before and during COVID-19.

Methods: Quarterly (Q) PMTCT program data was collected (October 1, 2019 and September 30, 2020). Chi-squared tests and percent change compared results on HIV testing and treatment before (average of Q1 and Q2 data [Q1/2]) and during COVID-19 (Q3 and Q4).

Results: Women attending and tested at ANC1 decreased from Q1/2 to Q3 by 3.4% and 3.8%, respectively. From Q3 to Q4, attendance and testing increased by 5.5% and 4.4%, respectively. Testing coverage was similar in Q3 as Q1/2, but decreased by 1% in Q4 (p<0.001). PWLHIV identified and on ART decreased from Q1/2 to Q3 by 4.5% and 4.9%, then increased from Q3 to Q4 by 6.7% and 7.4%, respectively. Positivity decreased from 8.0% in Q1/2 to 7.9% in Q3, then increased to 8.1% in Q4 (Q3 vs. Q4 p<0.001). ART coverage for PWLHIV was stable during FY20.

HEI tested ≤2 months and testing coverage was similar in Q3 vs Q1/2, then decreased by 4.7% and 10.6% in Q4 (Q3 vs. Q4, p<0.001) respectively. HEI tested at 2-12 months decreased by 5% between Q1/2 and Q3 while testing coverage was stable; both increased in Q4 by 9% and 2.2% (Q3 vs. Q4, 2.2%, p<0.001), respectively. Table 1 summarizes absolute numbers, positivity rates, and proxy coverage.

FY20 Quarters	ANC1 Attendance	ANC1 HIV Tests	ANC1 Testing Coverage	ANC1 Positive Tests	ANC1 Test Positivity	ART Coverage	Current on ART	EID ≤2mo (% coverage)	EID 2-12mo (% coverage)
FY20Q1	796,859	778,782	97.7%	61,313	7.9%	98.9%	60,624	54,494 (88.9)	30,167 (49.2)
FY20Q2	915,905	885,078	96.6%	71,925	8.1%	100.0%	71,944	57,282 (79.6)	30,489 (42.4)
FY20 Q1/Q2 (avg)	856,382	831,930	97.2%	66,619	8.0%	99.5%	66,284	55,888 (84.3)	30,328 (45.5)
FY20Q3	827,299	800,353	96.7%	63,626	7.9%	99.1%	63,029	56,117 (88.2)	28,827 (45.3)
FY20Q4	872,760	835,452	95.7%	67,877	8.1%	99.7%	67,676	53,471 (78.8)	31,440 (46.3)

Table 1. HIV services among PW and HEI across 12 PEPFAR-supported countries, October 2019 - September 2020

Conclusions: During COVID-19, there were decreases in ANC1 testing coverage, HEI tested ≤2 months, and testing coverage. As COVID-19 restrictions lessened in Q4, ANC1 positivity, ART coverage and HEI 2-12 month testing coverage increased. PMTCT services should continue to be adapted to serve mothers and infants during the COVID-19 pandemic to ensure continuity of treatment.

Contraception

PEB190

Hormonal contraception is associated with increased risk of cardiometabolic disease in women living with HIV

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Background: Women living with HIV (WLWH) have a high incidence of cardiometabolic disease. Hormonal contraception (HC) can affect cardiometabolic risk in women but has not been studied in WLWH.

Methods: Observational clinical cohort included cis-female WLWH aged 18-45 years in Nashville, Tennessee, between 1998-2018. Women with breast/ovarian cancer, hysterectomy, or bilateral tubal ligation at/before clinic entry were excluded. Person-time during pregnancies was censored. Outcomes included incident clinical or laboratory diagnoses of cardiovascular/thrombotic disease (CVD) (hypertension, atherosclerotic disease, heart failure, and deep venous thrombosis) and metabolic disease (diabetes, dyslipidemia, obesity, and non-alcoholic steatohepatitis). Multivariable marginal structural models examined time-varying current and cumulative HC use and cardiometabolic outcomes, adjusting for age, race, smoking, prevalent cardiometabolic comorbidities, and CD4 count at clinic entry. WLWH with prevalent CVD were excluded from analyses evaluating incident CVD; WLWH with prevalent metabolic disease were excluded from analyses evaluating incident metabolic disease. Comparator groups included WLWH on other contraception or none.

Results: Of 729 women included, median age was 31 years (IQR 26-37), median CD4 count was 442 cells/μL (IQR 232-678), 111 (15%) women had CVD, and 350 (48%) women had a metabolic disorder at baseline. During follow-up, 235 (32%) women used HC (median duration 1.65 years (IQR 0.61-3.61)). CVD analyses included 618 women and 117 events; metabolic analyses included 379 women and 172 events. Current and cumulative HC use increased risk of CVD, particularly oral HC (Figure). HC use was less associated with incident metabolic disorders. Metabolic disorder risk increased with cumulative oral HC use and decreased with cumulative DMPA use. Non-white race, smoking, prevalent comorbidities, time from baseline, and older age also increased risk of cardiometabolic disease.

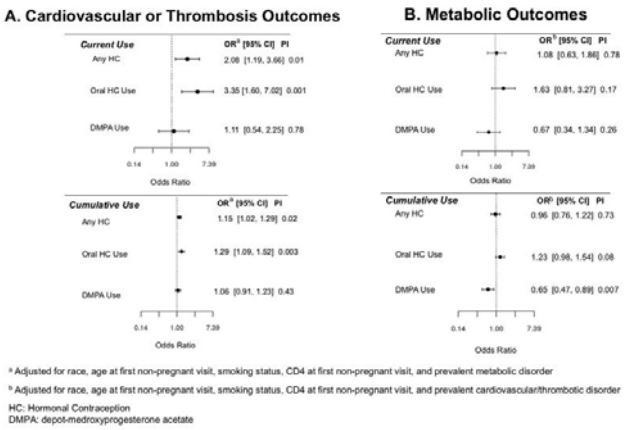

Figure.

Conclusions: Current and cumulative HC use was independently associated with cardiometabolic disease risk, particularly CVD, among WLWH. Cardiometabolic risk should be considered when selecting contraception for WLWH.

Other sex- or gender-specific issues

PEB191

Retention on antiretroviral treatment (ART) six and 18 months after delivery in women living with HIV (WL-HIV), in Brazil, 2010-2017

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Background: Monitoring the cascade care for WL-HIV identifies gaps and possibilities to adjust policies in place. WL-HIV lose more follow-up than men and puerperium is a critical moment in their life cycle. The aim of this study is to assess trends in the retention on ART of WL-HIV at puerperium, in Brazil, stratified by sociodemographic data.
Methods: We analyzed data from laboratory exams and ART prescriptions national systems to identify pregnant women living with HIV, from 2010-2018. We calculated ART retention: six months after delivery for those with at least one antiretroviral dispensation between 150-270 days after pregnancy delivery date (DD); and 18 months after delivery for those with at least one antiretroviral dispensation between 510-620 days after DD. We fitted generalized additive models to assess trends in both indicators.
Results: There is statistically significant growth trend in the proportion of WL-HIV retained on ART six and 18 months after delivery (figure 1).

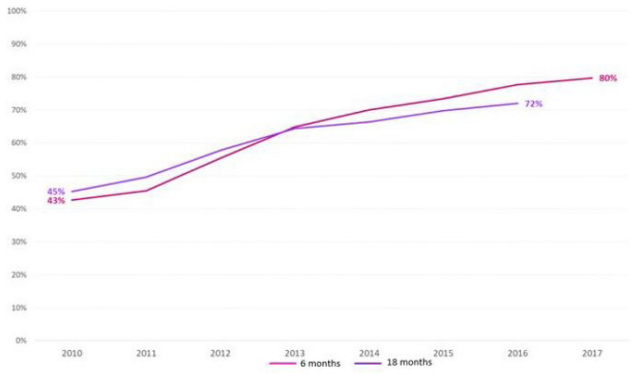

Figure 1. Proportion of PW-HIV identified in HIV systems(1) and which were retained in art six and 18 months after delivery, by year of beginning of pregnancy, brazil, 2010-2017.
(1) Siscel, siclom and sisgeno.
(2) PW-HIV on art at pregnancy and that have at least one dispensation between 150 and 270 days after DD, and 18 months that have dispensation between 510 and 620 days after DD.

Retention six months after delivery increased from 43% to 80% and retention 18 months after delivery increased from 45% to 72%, between 2010-2017 and 2010-2016, respectively. The analysis of retention in both moments stratified by race/color (white/yellow, black, indigenous), education (in years of study: 0-7, 8-11, ≥12), age (<19, 20-24, 24-29, 30-39, ≥40), region of residence (North, Northeast, South, Southeast, Midwest) showed significant trends of increase (p-value <0,05 in all categories).

The greatest increases in retention were observed among indigenous WL-HIV, aged up to 24 years and those residing in the Northeast, South and Midwest regions.
Conclusions: Trends improvements in ART retention of WL-HIV during puerperium represents both a reflection of investments in public policies and a goal to achieve better outcomes. It is necessary to intensify actions to support WL-HIV's social network and adapt all levels of healthcare services to WL-HIV's needs in this particular moment of life.

Diagnosis of HIV disease in paediatric and adolescent populations

PEB193

Plasma IP-10 concentrations show no correlation with HIV infection in children attending hospitals in Blantyre and Mulanje, Malawi

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Background: Timely diagnosis of HIV in children ≤ 2 years (Early Infant Diagnosis group [EID]) and viral load (VL) monitoring using nucleic-acid-tests (NATs) such as polymerase-chain-reaction (PCR) and Cepheid Xpert HIV-1 Qual assay (XpertHIV) remains a challenge in resource-limited settings. These NATs are not readily available due to cost and infrastructure constraints. As such, identifying other biomarkers for EID to screen and detect HIV infection early is still a priority. CXCL10/IP-10 is a proinflammatory chemokine which has been suggested as a potential screening tool for detection of HIV infection in adults in resource-limited-settings. In this study, we assessed whether measuring IP-10 levels can be used as an initial screening tool to identify potential HIV infected children in Malawi, who will then undergo a confirmatory NAT test.
Methods: We prospectively recruited children aged 0-14 years attending Queen Elizabeth Central and Mulanje District Hospitals, Malawi from July 2018-August 2019. We quantified plasma IP-10 using the Human CXCL10/IP-10 DuoSet ELISA kit, detected HIV infection using the XpertHIV and PCR tests, and determined HIV VL of all samples using Abbot M2000 system. Logistic regression was used to assess differences in IP-10 and HIV infection.
We calculated correlation between IP-10 levels and age, stratified by HIV status using Spearman rank correlation. Accuracy of IP-10 in predicting HIV infection was assessed using area under the curve (AUC).
Results: Of the 216 participants recruited (65/216 (30%) were aged <=2 years), 95/216 (44%) were female. Most participants, 135/216 (62.5%), were HIV-uninfected. IP-10 was not associated with HIV infection (OR 1:00; 95% confidence interval (1.00-1.01). Correlation between IP-10 and age were -0.2796 and -0.1039 among HIV-infected and HIV-uninfected, respectively. IP-10 was not associated with sex (p= 0.917). Correlation between IP-10 and VL was -0.2796. Children aged <=2 years had higher IP-10 levels

than >2-14 years (median 1,229 versus 324 pg/ml). Performance of IP-10 as a screening test was poorer among >2-14-years (AUC 0.58) versus <=2 years (AUC 0.86).

Conclusions: Unlike in adults, IP-10 does not seem to be an accurate screening marker for HIV in children. Rapid screening tests for HIV infection remain a priority to address key infrastructural challenges in EID in resource-limited-settings.

Pharmacokinetics, pharmacodynamics, pharmacogenomics and therapeutic drug monitoring in paediatric and adolescent populations

PEB194

No age-related difference in dolutegravir metabolic glucuronidation ratio in children between 3 months and 18 years old in the ODYSSEY trial

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Background: ODYSSEY and IMPAACT-P1093 found lower and more variable dolutegravir (DTG) exposure in children compared to adults based on mg/kg dose. Investigating the main metabolic pathway (UGT1A1) for DTG could help to explain these findings.

Estimates of DTG glucuronide/DTG molar metabolic ratio (DTG-MR) are 0.05-0.08 in adults but this has not been studied in children.

Methods: A subset of children was selected from PK substudies within the ODYSSEY trial, including all children aged <2 years and a random sample of older children receiving DTG film-coated tablets (FCT; >=20kg) or dispersible tablets (DT; 3-<25kg). DTG and DTG-glucuronide concentrations were measured with a validated UPLC-MS/MS assay and geometric mean (GM) DTG-MR was determined using 3 plasma samples per PK curve (t=2, 6 and 24h).

We assessed correlation between DTG-MR and DTG clearance in children, as clearance adjusted for formulation is independent of DTG dose, and it is associated with DTG exposure.

Pearson's correlation coefficient was used on log-transformed data to assess the relationships between DTG-MR and DTG clearance/kg (corrected for higher bioavailability of DT), and DTG-MR and age (not log-transformed).

Results: In total, 37 children (age 3 months – 18 years) were included in this study. There was positive relationship between DTG-MR and DTG clearance/kg in children (r(37)=0.64, p<.001) (Figure).

No association was found between DTG-MR and age (r(37)=-0.12, p=0.50). GM(CV%) DTG-MR in children was 0.051(66%), in line with adult values.

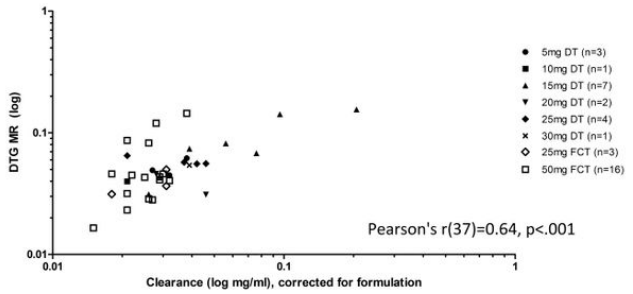

Figure. DTG metabolic glucuronidation ration by DTG clearance

Conclusions: Intersubject variability in DTG-MR was high in children and as the ratio correlates with clearance, this may explain high variability of DTG exposure between children. DTG-MR was similar to adult values and did not change with age, hence increased glucuronidation does not appear to explain the relatively low DTG exposure observed in children aged >3 months. Further studies are needed to assess the role other factors contributing to differences in DTG exposure in children.

PEB195

Expected impact of malnutrition on first-line antiretroviral drug exposure in a global population of children in countries with highest child mortality: a quantitative modeling and simulation study

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Background: HIV/AIDS is one of the top killers of children under 5 years of age. Among children receiving antiretroviral therapy (ART), malnutrition is associated with higher mortality. Low ART exposure may contribute to mortality in malnourished children with HIV. We simulate pharmacokinetics (PK) for dolutegravir, abacavir, and lamivudine using a real-world global population of children under 5 years of age.

Methods: Anthropometric data from 30 countries with highest under-5 mortality were acquired from demographic health surveys (n=450000). Published and in-house pediatric PK models were used to simulate drug exposures. Guideline dosing was used for all drugs. Child PK was compared to the adults receiving standard doses. Given typically higher PK variability in children, we set the minimum target to be the 25th percentile (P_{25}) of adults.

Results: In the anthropometric sample of 450,000 children aged 0-5 years from 30 countries included, 30% were stunted, 30% were underweight, and 5% had severe acute malnutrition (weight-for-height z-score [WHZ] < -3). Abacavir exposures were higher in children than adults. Dolutegravir median C_{24} was > 500 ng/mL in children and adults, but 39% of children fell below the minimum P_{25} target. Similarly, 33% of children fell below the lamivudine minimum P_{25} target. Malnutrition resulted in lower dolutegravir and lamivudine exposures: among children with WHZ<-3, 43% and 73% fell below the adult P25 for dolutegravir and lamivudine, respectively. Among children with WHZ<-2, 42% and 45% fell below the adult P25 for dolutegravir and lamivudine, respectively.

	PK Metric	25th Percentile (Adult)	25th Percentile (Child)	25th Percentile (Malnourished Child)
Dolutegravir	C_{24}	753 mg/L	531 mg/L	481 mg/L
Abacavir	AUC_{0-12}	3.33 mg*h/L	5.11 mg*h/L	5.21 mg*h/L
Lamivudine	AUC_{0-24}	9.23 mg*h/L	8.33 mg*h/L	5.15 mg*h/L

Table.

Conclusions: Current guideline dosing, which is weight-based, may need to account for nutritional status to prevent under-exposure of first-line ARTs and improve outcomes in young, malnourished children with HIV.

Drug formulations for infants and children

PEB196

Assessing parental choice of lopinavir/ritonavir granules intake to improve child adherence at Baylor-Mwanza, Tanzania

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Background: Drugs formulations are one of the main obstacles to achieving viral suppression in children. A new policy introduced in 2020 by the Tanzania Ministry of Health included Lopinavir/ritonavir (LPV/r) in granules. This new formulation allows new and more attractive routes of administering medication to children older than three years. During counselling, different options were advised: to mix granules with soft food, to blend with liquids such as water or milk, or to pour directly into the child's tongue. This study's objective was to assess administration practices, challenges, and acceptability among caregivers whose children are on LPV/r granules.

Description: The study was conducted at Baylor Clinic in Mwanza, Tanzania between September and October 2020. Caregivers whose children were on LPV/r granules for at least two weeks were sampled and interviewed. Data on administration practices, challenges encountered during administration and acceptability of LPV/r granules were collected.

Lessons learned: Out of the 72 caregivers interviewed, 52 (72%) and 44 (61%) were aware of the three options to administer the dose and found the process of mixing granules prior easier, respectively. Offering the granules with water was the preferable route for 52 caregivers (72%). Interestingly, 69% of caregivers who started by mixing granules with soft food had changed to water. At least three sachets per dose were prescribed for 94% of the children, and 72% (52) of the caregivers admitted administering it at once. Although 64% (46) have not claimed any problem while administering the granules, 25% (18) described vomiting and 11% (8) complained of the number of sachets per dose. More than half of the caregivers (57%) preferred to continue with LPV/r granules as it was easy to administer.

Conclusions/Next steps: Although the suggested first option was mixing with food, the preferred option of administering LPV/r granules was with water. The majority of the caregivers well accepted the new administration route, being vomiting and dose size the biggest challenges observed.

PEB197

Acceleration of pediatric ART regimen optimization during COVID-19 epidemic using self-learning for health care workers in Malawi

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Background: Transitioning children and adolescents to more effective ART regimens and drug formulations is required to achieve the third 95 for this important population. In Malawi, ART switches can be difficult for providers due to an increasing number of standardized regimens, newly introduced drugs and blurring of the traditional distinction between 1st and 2nd line regimens, since dolutegravir is used in both. In the setting of cancelled provider trainings due to Covid-19 restrictions in April 2020, we sought to develop, implement, and evaluate a self-learning training program for pediatric ART optimization.

Description: Partners in Hope Malawi (PIH) is a local non-governmental organization supporting HIV care in 8 districts. PIH developed a self-learning package for pediatric ART regimen optimization, including slide-set, video, standard operating procedures, quiz and case scenarios. The curriculum included the rationale of transitioning away from nevirapine, the importance of correctly prescribing lopinavir formulations and how to support caregivers of children on ART. We implemented and evaluated this at 48 health facilities, with PIH staff providing monthly on-site support. Health Care Workers (HCWs) attached individual optimization recommendations to patients' treatment cards and followed each child and adolescent actively through to optimization of the ART regimen.

Lessons learned: In an evaluation of the self-learning process with semi-structured questionnaires, HCWs indicated that they had acquired sufficient knowledge to implement pediatric ART optimization. Prior to the intervention (March 2020), the distribution on NNRTI, PI and DTG-based regimens was 45%, 46% and 9% respectively. Six months after the intervention, this had improved to 2%, 24% and 74%. Although viral load suppression rates increased (from 74% in May to 78% in November among children 1-19 years), they remained unsatisfactory, especially in the lowest age group (0-4 years) and among children on PI-based regimens.

Conclusions/Next steps: A pediatric ART provider self-learning program with subsequent on-site mentoring was successful and is a low cost option, which can be used for future public health programming. Pediatric ART regimen optimization was achieved after six months, however further efforts are needed to understand and improve VL suppression among children and adolescents, including more individually tailored longitudinal care delivery approaches.

PEB198

Proof of principle oral dissolvable strip formulation for pediatric ARV prophylaxis

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Background: Current formulations of pediatric HIV prophylaxis pose barriers to administration and adherence due to regimen complexity, reliance on liquid formulations, and conspicuous administration in settings with HIV high stigma. Oral dissolvable strips (ODS) are alternative formulations that can simplify administration for infants and have generated interest for other pediatric formulations.

Methods: We conducted a preclinical pilot study to formulate and evaluate a single mucoadhesive and rapidly dissolving ODS for pediatric HIV prophylaxis containing 60 mg zidovudine (AZT) and 10mg nevirapine (NVP); the prophylactic regimen for infants >12 weeks of age in Kenya. For strip formulation, AZT was encapsulated for taste masking; NVP – with a more neutral flavor - was not. ODS were evaluated on the following key properties: AZT encapsulation, active ingredient degradation at 72-hours (40*C, 80% humidity) and after 6 months (20°C, 30% humidity), taste, and dissolution. A three-stage in vitro bioavailability study mimicked the varied pH environments of the oral administration pathway (oral cavity [pH 6.8], stomach [pH 2], intestine [pH 6.5]) to quantify active pharmaceutical ingredients (API) released from the ODS compared with non-formulated bulk drug powder. Table 1 details the targeted versus actual results for each ODS formulation characteristic and quantified levels of released API.

Results: ODS characteristics met or exceeded targeted criteria, see table. Taste needs to be formally evaluated, but investigators indicated that taste was mild and not bitter. The values of API released at the intestinal stage were 97.5% (±4.4%) of AZT and 107.6% (±4.6%) of NVP.

ODS Formulation Characteristics	Measurement technique	Target range	Observed value
Encapsulation (AZT, only)	HPLC	>50%	72%
Degradation during encapsulation (AZT, only)	HPLC	<10%	None detected
72 hour degradation	HPLC	<10%	None detected
6 month degradation	HPLC	<10%	None detected
Taste	Qualitative only	Mild	Mild
ODS Disintegration Study Results	Visual observation	<1 min	<30 sec
Availability in "intestine" (AZT)	Assayed by HPLC	80-125%	97.5% (±4.4%)
Availability in "intestine" (NVP)	Assayed by HPLC	80-125%	107.6% (±4.6%)

Table.

Conclusions: These preliminary in vitro bioavailability data indicate non-inferiority of ODS (AZT + NVP) compared to bulk drug standards, indicating proof of principle that formulation of ODS for pediatric dual ARV prophylactic is feasible. These formulations have the potential to mitigate many of the barriers to pediatric ARV adherence.

PEB199

Caregivers perception on paedriatic lopinavir/ritonavir formulations for HIV-infected children at Baylor Clinic, Mwanza, Tanzania

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Background: In 2015 and 2017, Tanzania introduced and updated Lopinavir/ritonavir (LPV/r) based regimen as the first line regimen for children < 3 and < 15 years old respectively; tablet and solution were the only formulations available. LPV/r tablets were prescribed for children able to swallow tablets.

However, most children were unable to swallow tablets which led to the introduction of LPV/r granules in 2019. Over a span of 5 years, there are children who have used different LPV/r formulations during the course of their treatment depending on age, weight, availability, ability to swallow tablets and caregivers' preferences. The objective of this study was to assess caregiver's perception regarding the different formulations administered.

Description: This was a cross sectional study conducted at Baylor Clinic-Mwanza between September and October 2020. Participants were caregivers whose children were < 25kg and on LPV/r pediatric regimen for ≥ 2 weeks. Structured questionnaire was administered to assess information on types of LPV/r formulations administered over the course of treatment between 2015 and 2020, reasons for change and caregiver preference on the LPV/r formulation administered.

Lessons learned: Of the 330 caregivers assessed, (56%) were children < 5 years old. Majority (52%) of caregivers had administered two, (34%) administered one and (14%) administered all three of LPV/r formulations throughout their children therapy. Half (50%) of caregivers mentioned stock out as a reason that led to change of LPV/r formulation. Furthermore, (30%) and (20%) of caregivers cited weight gain and inability to swallow tablets as reason for change respectively. Of 46 caregivers who had used all three LPV/r formulations; (50%) preferred solution, (28%) tablets and (22%) granules. Those who had administered one formulation, (25%) administered LPV/r granules of which (50%) of them preferred to continue with the formulation.

Conclusions/Next steps: LPV/r solution was most preferred formulation by majority of caregivers who has experience in administering all formulations and main reason for formulation change was stock out. Further studies with large sample size to assess perception and reasons for preference of LPV/r formulations. Strengthen supply chain management for child- friendly pediatric formulations to avoid stock out and unnecessary changing of formulations in future.

PEB200

Low viral suppression in children < 3 years old on two protease inhibitor formulations in Kenya, 2015-2019

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Background: Kenya's preferred first-line antiretroviral therapy (ART) for HIV-infected children aged 0-3 years is a protease inhibitor (PI) based regimens specifically Lopinavir/Ritonavir (LPV/r). Children 0-3 years are either given LPV/r syrup or pellets. There has been substantial scale-up of use of LPV/r pellets, which are heat-stable. We report scale-up of LPVr pellets and viral load suppression rates among children 0-3 years on LPV/r syrup amd pellets from 2015 to 2019.

Methods: We analyzed routine HIV program data from 4 CDC implementing partners in supported sites providing ART for children aged 0-3years from 2015-2019. We described the distribution of data for continuous variables using interquartile ranges (IQR) and categorical variables using proportions. We used Pearson's chi-squared statistics to test for independence of proportions and the extended Cochran-Mantel-Haenszel stratified test of association to test for trends of rates over time.

Results: Over the five years, 1446 children were newly initiated on a PI-based ART regimen and had complete data for both initial and current ART. Males were 45%, and the median age at enrollment was 1.01 years(IQR was 0.43-1.79). At baseline, 150 and 1296 children were initiated on pellets and Syrup formulations respectively. The use of LPVr pellets as an initial regimen improved from 2.1% in 2015 to 24.3% in 2019, p<0.001, while the use of pellets as a current regimen improved from 29.1% in 2015 to 53.0% in 2019, p<0.001. Over a third (38.0%), of children started on LPV/r syrup at baseline were switched to LPVr pellets. Overall viral load suppression (VLS) was 64.6%; VLS among those on syrup was higher at 65.6% compared to those on pellets 50.94% p=0.032.

Conclusions: There has been moderate scale-up of LPVr pellets use among children. However, younger children < 3 years have sub-optimal VLS regardless of LPV/r pellets or syrup use. Findings call for use of optimal regimens and strengthening key interventions and strategies such as enhanced adherence counseling and psychosocial support for caregivers to improve VLS in younger children which are easier to administer and more palatable for this age group.

Clinical trials in paediatric and adolescent populations

PEB201

Once-daily integrase inhibitor (INSTI) with boosted darunavir is non-inferior to standard of care in virologically suppressed children, Week 48 results of the SMILE PENTA-17 TRIAL

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Background: INSTI+Darunavir/r, a regimen with a high-resistance barrier, avoiding NRTI toxicities, might be a switching option in children LWHIV.

Methods: SMILE is a randomised non-inferiority trial evaluating safety and antiviral effect of once-daily INSTI+Darunavir/r versus standard-of-care (SOC) in HIV-1 infected, virologically-suppressed children 6-<18 years. The primary outcome is the proportion with confirmed HIV-RNA≥50c/mL up to week 48. Analyses were intention-to-treat, using Kaplan-Meier method (10% non-inferiority margin).

Results: 318 participants were randomised (Africa 53%, Europe 24%, Thailand 15%, Latin America 8%), INSTI+DRV/r:158(DTG: 153, EVG: 5); SOC:160. Median (range) age was 14.7years (7.6-18.0); weight 47.8kg (22.1-96.3); CD4 count 782cells/mm3 (227-1647); 61% female; 59% NNRTI; 41% PI.

Median follow-up was 64.3 weeks with no loss to follow-up. By 48 weeks, 8 INSTI+DRV/r vs 12 SOC had confirmed HIV-RNA≥50c/mL; difference (INSTI+DRV/r-SOC) -2.5% (95% CI: -7.7, 2.6), showing non-inferiority. No major PI (0/11) or INSTI (0/6) resistance mutations were observed. There was 1 new severe CDC stage B event in INSTI+DRV/r and none in SOC. There were 4 SAEs (4 participants) in INSTI+DRV/r vs 5(4) in SOC (p=0.986); 13 grade 3/4 AEs (13 participants) in INSTI+DRV/r vs 25(19) in SOC (p=0.280). Self-reported mood/sleep disorders were infrequent and similar between arms.

By week 48, difference between arms (INSTI+DRV/r-SOC) in mean CD4 count change from baseline was 48.3cells/mm3 (95% CI: -93.4,-3.2; p=0.036); numbers with CD4 count ≤500cells/mm3 were low and similar between arms [21(14%) INSTI+DRV/r vs 15(10%) SOC; p=0.234]; no significant differences were observed for CD8%, CD8 count and CD4%/CD8% ratio. Difference between arms (INSTI+DRV/r-SOC) in mean LDL and HDL change from baseline was +4.7mg/dL (95% CI: -0.7, 10; p=0.088)

and -4.1mg/dL (95% CI: -6.7,-1.4; p=0.003), respectively. Weight and BMI increased more in INSTI+DRV/r than SOC [difference: 1.97kg (95% CI: 1.1, 2.9; p<0.001), 0.66kg/m² (95% CI: 0.3, 1.0; p<0.001)].

Conclusions: In virologically-suppressed children, switching to INSTI+DRV/r was non-inferior virologically, with similar safety profile, to continuing SOC. Changes in CD4%, CD4 count, HDL-cholesterol, weight and BMI were slightly different in INSTI+DRV/r vs SOC although clinical relevance needs further investigation. SMILE data corroborate adult findings and provide evidence for an alternative NRTI-sparing regimen for children and adolescents.

PEB202

Weight gain in children and adolescents on dolutegravir vs standard of care in the ODYSSEY trial

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Background: Dolutegravir is associated with excessive weight gain in adults. We present the first randomised data in children and adolescents.

Methods: ODYSSEY is a randomised multi-country trial evaluating dolutegravir + 2NRTIs (DTG) versus standard-of-care (SOC) in children starting first-line or second-line ART. We compared weight, height and BMI-for-age Z-scores (BAZ) between treatment arms using normal regression models adjusting for first-/second-line, randomisation stratification factors and baseline measurements. Proportions becoming newly overweight (BAZ>1-≤2) or newly obese (BAZ>2) are described.

Results: 707 children were randomised (sub Saharan Africa 88%, Thailand 9%, Europe 4%); 311 started first-line (80% ABC/3TC, 19% TDF/3TC(FTC); 92% efavirenz-based in SOC); 396 second-line (54% ABC/3TC, 26% TDF/3TC(FTC); 72% lopinavir/ritonavir in SOC); 49% were female. At baseline, median age (IQR; range) was 12.2 (9.1, 14.9; 2.9-18.0) years; weight (IQR) 31 (23, 43) kg, height 138 (125, 153) cm, BMI 16.3 (14.9, 18.5) kg/m², BAZ -0.6 (-1.4, 0.1); 11% had WHO-defined severe thinness/thinness, 5% were overweight, 1% obese; 50% were pubertal/postpubertal. Median follow-up was 142 (124, 159) weeks.

Weight, height and BAZ increased more in DTG than SOC with adjusted difference in means (DTG-SOC) at 96 weeks of 1kg (95%CI 0.3, 1.7; p=0.004), 0.8cm (95%CI 0.2, 1.4; p=0.007) and 0.14 Z-score (95%CI 0.02, 0.26; p=0.018) respectively. Differences between groups emerged early and stabilised (Figure).Treatment differences at 96 weeks in BAZ were similar in males and females (heterogeneity p=0.42), children aged <12 and ≥12 years (p=0.95), prepubertal and pubertal/postpubertal participants (p=0.54), participants starting first- and second-line ART (p=0.746), and those starting TDF vs not(p=0.61). Findings were similar for weight, height and BMI.

Overall, 14 (4%) children/adolescents in DTG and 9 (3%) in SOC were newly overweight or obese at 96 weeks (p=0.29).

Conclusions: Children grew better after starting DTG. Differences between arms in weight, height and BMI were small and stabilized before 2 years, with few becoming newly overweight or obese in either arm. DTG-based ART was not associated with excessive weight gain in children and adolescents.

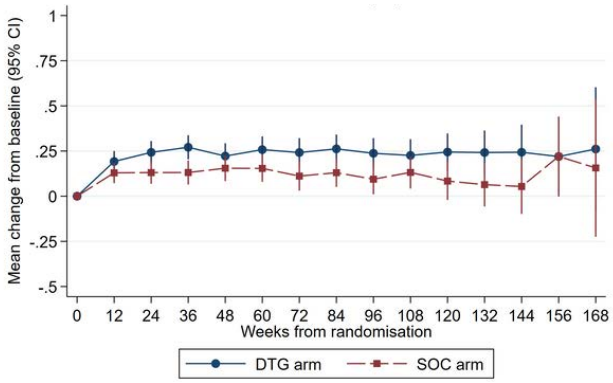

Figure. Mean change in BMI-for-age Z-score from baseline: total ODYSSEY population

PEB203

Effect of dolutegravir on folate and vitamin B12 status among HIV-infected children and adolescents in the ODYSSEY trial

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Background: Neural tube defects (NTDs) are known to be associated with maternal folate and vitamin B12 deficiency, and initial surveillance studies suggested an increased risk of NTDs among infants conceived by women taking dolutegravir (DTG). We, therefore, compared folate and vitamin B12 levels among HIV-infected children aged 6-<18 years starting first- or second-line DTG-based antiretroviral treatment (ART) versus Standard of Care (SOC) at 3 Ugandan sites in the ODYSSEY trial.

Methods: Plasma folate was measured on stored samples at baseline and 4 weeks. Red blood cell (RBC) folate and vitamin B12 levels were measured using samples collected prospectively at ≥96 weeks. Samples were analysed in one laboratory using Elecys assays. Normal regression was used to compare change in plasma folate from baseline to 4

weeks (adjusted for baseline) and cross-sectional RBC folate and vitamin B12 between randomised arms, adjusting for site, sample date, first-/second-line ART and randomisation stratification factors.

Results: 229 children ≥6 years were randomised; 51% female, median(IQR) age was 12.3 years (9.0,14.7), CD4 501cells/mm^3 (228,795); 67% started second-line ART; 114 started DTG, 115 started SOC (40% lopinavir/ritonavir-, 37% efavarinez-, 23% atazanavir/ritonavir-based ART). By 4 weeks, mean plasma folate was higher in DTG arm versus SOC (difference (DTG-SOC) 1.6 ng/mL; 95%CI 0.8, 2.3; p<0.01). At week ≥96, mean RBC folate was higher in the DTG arm vs SOC (difference 73 ng/mL; 95%CI 3, 143; p=0.04). Plasma and RBC folate levels varied by site, but there was no evidence for heterogeneity of treatment effects (Table). Vitamin B12 levels were similar between arms (p=0.42).

Measure	DTG arm			SOC arm			Adjusted difference (DTG-SOC)*			Arm x site interaction**
	n	mean	SE	n	mean	SE	mean	95% CI	p	p
Change in plasma folate from baseline to week 4, ng/ml	110	0.4	0.3	107	-1.1	0.3	1.6	0.8, 2.3	<0.01	0.66
RBC folate at week ≥96, ng/ml	109	822	29	105	808	28	73	3.0, 143	0.04	0.82
Vitamin B12 at week ≥96, pg/ml	109	478	21	105	504	26	-26	-91, 39	0.42	0.57

*Adjusted for site, date of sample, first- vs. second-line, availability of routine resistance testing, NRTI backbone, and baseline value (for change in plasma folate only); **Test for heterogeneity of treatment effect by site.
Presenting mean change in plasma folate from a baseline of 6.1 ng/ml.

Table. Difference in change in plasma folate from baseline to week 4, and cross-sectional red blood cell folate and serum vitamin B12 at ≥96 weeks in DTG-arm compared to SOC-arm

Conclusions: We found no evidence that DTG-based ART was associated with decreased levels of plasma folate or RBC folate; levels were higher than on NNRTI-/PI-based ART though the mechanism is unclear. Vitamin B12 levels were similar in both arms. These results suggest any increased risk of NTDs in infants conceived on DTG is unlikely to be due to DTG causing decreased folate and vitamin B12 levels.

ARV management strategies in paediatric and adolescent populations

PEB204

There is no substitute for hard work(ing dolutegravir): outcomes of single drug substitutions among CALHIV shifted to a dolutegravir antiretroviral regimen in Mbeya and Mwanza, Tanzania

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Background: As dolutegravir (DTG) is being rolled out globally for CALHIV, many questions remain on the effectiveness of a single ARV drug substitution when shifting patients to DTG-containing regimen, especially in countries where the NRTI backbone ARV options are limited. We report the virologic suppression rates of CALHIV shifted to DTG regimens using only a single drug substitution (SDS) from the Baylor Tanzania HIV clinics in Mbeya and Mwanza, Tanzania.

Methods: Retrospective chart review was conducted to assess the clinical characteristics of CALHIV who received DTG as part of their ART at the Baylor College of Medicine Children's Foundation – Tanzania Centres of Excellence (COEs) in Mbeya and Mwanza, Tanzania between 1 March 2019 (when DTG became available) and 30 November 2020. HIV viral load(VL) suppression was defined as VL<1000 copies/mL. The SDS cohort was defined those CALHIV who kept the same two NRTIs backbone (i.e. ABC or AZT or TDF + 3TC) when shifting to a DTG regimen (e.g. TLE-to-TLD).

Results: Of the 1703 total CALHIV received DTG, there were 634 (37.2%) involved SDS changes. Among the SDS cohort with pre- and post-DTG viral loads, viral suppression rates improved from 86.8% (547/630) pre-DTG to 92.9% (409/440) post-DTG overall. Of the SDS patients were previously unsuppressed (n=75), 84.0% (63/75) were able to become virally suppressed on a DTG regimen.

When analyzing the TLE-to-TLD cohort alone, 91.7% (11/12) of previously unsuppressed CALHIV became suppressed with the SDS of DTG via TLD, and 92.7% (76/82) of those previously suppressed (or unknown VL) remained suppressed on TLD.

The cohort also included 48 patients on TDF-3TC-Protease Inhibitor (PI) regimens, of which only 54.2% (26/48) were suppressed on a PI regimen. After a SDS to TLD, 92.3% (41/45) successfully became suppressed, including 90.9% (20/22) of those previously unsuppressed.

Conclusions: Single drug substitutions with DTG alone was highly effective in virally suppressing our cohort of CALHIV in Tanzania. A large majority of CALHIV previously non-suppressed while on NNRTI or PI-based regimens subsequently became suppressed with SDS of DTG. These results are especially encouraging in settings where NRTI backbone ARV options and/or HIV resistance testing is limited.

PEB205

High levels of drug-resistant HIV-1 among newly diagnosed antiretroviral treatment naïve infants in Uganda

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Background: Scale-up of prevention of mother-to-child transmission (PMTCT) services has resulted in an increase of HIV drug resistance (HIVDR) among children born to HIV-infected mothers through exposure to anti-retrovirals (ARVs) perinatally. This study determined the prevalence and factors associated with HIVDR among treatment-naïve children newly diagnosed with HIV in Uganda.

Methods: This was a retrospective cross-sectional survey in which stored dried blood spot specimens for children ages 0–18 months collected from 1st January – 31st August 2017 for early infant diagnosis were tested for HIVDR. The protease and reverse transcriptase regions of the HIV-1 *pol* gene were genotyped and analyzed using the Stanford HIVDR database. Weighted prevalence of HIVDR with 95% confidence intervals

(CI) were calculated, factors associated with HIVDR were determined using survey-adjusted logistic regression. PMTCT exposure was defined as having received prophylactic ARVs categorized as maternal, neonatal or both.

Results: Of the 494 specimens retrieved, 417 (84.4%) had PMTCT exposure, 147 (29.8%) were successfully genotyped of which 111 (75.5%) had PMTCT exposure. The prevalence of HIVDR regardless of PMTCT exposure to any drug class, non-nucleoside reverse transcriptase inhibitors (NNRTIs) and nucleoside reverse transcriptase inhibitors (NRTIs), was 67.4%(CI: 59.3 – 74.5), 63.3%(CI: 59.3 – 74.5); and 25.9%(CI: 19.4 – 33.6), respectively. Only one patient had a mutation to protease inhibitors (PI). The most common NNRTI mutations were K103N/S (47.3%) and Y181C/Y (27.9%), whereas MI84I/V (44.7%) was the most common NRTI mutation. Thymidine analogue mutations were more common among children with PMTCT exposure (38.7% compared to 3.2%). Children who were aged 4-6 months had over 4 times higher odds of having HIVDR compared to those aged >12 months (adjusted odds ratio [AOR]:4.4,CI(1.1 – 18.3, p=0.04). Children whose mothers were on lifelong ART had nearly 3 times the odds of having mutations to NNRTIs, compared to those whose mothers were not on any ARVs (AOR:2.8,CI:1.0 – 7.6, p=0.04).

Conclusions: The high levels of resistance to NNRTIs support the current WHO recommendation of initiating all HIV-infected children on dolutegravir (DTG) or PI-based regimens, regardless of PMTCT exposure. There is therefore need to fast-track the availability of DTG formulations for infants in order to improve their viral suppression.

PEB206

HIV minority resistance variants partially explain genotypic-phenotypic discordance

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Background: Extent and etiology of discordance between genotypic and phenotypic drug resistance (DR) are existing knowledge gaps, especially in children and adolescents with HIV (CAWH) and dominant non-B subtypes, and might impact clinical care. We examined discordance in perinatally-infected Kenyan CAWH.

Methods: CAWH were enrolled at AMPATH clinics in Kenya. Samples with viral load >500 copies/mL were genotyped with next generation sequencing (NGS; Illumina), interpreted with Stanford Database tools and phenotyped with Monogram Phenosense. Discordance was defined as pheno-resistant/geno-sensitive (PR-GS) or pheno-sensitive/geno-resistant (PS-GR), and evaluated for NNRTIs efavirenz (EFV), nevirapine (NVP), rilpivirine (RPV), etravirine (ETV), doravirine (DOR); NRTIs abacavir (ABC), tenofovir (TDF), zidovudine (AZT), lamivudine (3TC); and PIs lopinavir, atazanavir (ATV), darunavir. Fisher Exact Tests were used to examine associations between minority DR variants and discordance.

Results: Data were available in 56 CAWH: 45% female; median age 15 years, CD4% 19; 7.7 years on therapy; 73% subtype A, 13%-D, 7%-C, 7%-other. Any genotypic DR (NGS 20% threshold) was in 96%; 84% NRTI, 96% NNRTI, 84% dual-class, 2% PI. Discordance to ≥1 drug was in 45/56 (80%; 28/45 PS_GR only; 6/45 PR_GS only; 11/45 both); NNRTI discordance in 34, highest for DOR (n=22; 18 PS_GR; 4 PR_GS) and RPV (n=18; 15 PS_GR; 3 PR_GS); NRTI discordance in 33, highest for ABC (n=15; 15 PS_GR; 0 GR_PS) and TDF (n=9; 7 PS_GR; 2 PR_GS); and PI discordance in only 1 (ATV; PS_GR). NGS minority DR variants (1-20%) potentially explaining discordance for ≥1 examined drugs were seen in 16/45 (36%) CAWH, mostly driven by F227L (DOR, p<0.05) and V179D (ETV, p<0.05). For example, a 16-year-old with subtype A, 'fully sensitive' genotype and 'fully resistant' phenotype to DOR, had F227L at 2.7%, a 50-point genotypic penalty score mutation, that would lead to a 'fully resistant' genotypic score if included.

Conclusions: In Kenyan CAWH with extensive DR, genotype-phenotype discordance was high for reverse transcriptase inhibitors and low for PIs. Discordance, mostly represented by genotypic DR overestimation, was partially explained by NGS minority DR variants. This suggests that minority DR variants might help refine genotypic interpretation algorithms to avoid inappropriate choice of drugs; but also, existence of alternative explanations.

PEB207

Pediatric ART regimen optimization in the midst of global supply chain challenges: lessons from implementation in Uganda

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Background: In 2018, the Ministry of Health Uganda revised the national ART guidelines in line with WHO recommendations to optimize children aged 3-10 years solid dosage formulations of LPV/r based regimens to achieve better viral load suppression. However, a global shortage of LPV/r 100/25mg tablets compromised the transition.

Description: We describe how supply chain lessons learned from implementing pediatric ART regimen optimization in Uganda ensured that children already taking LPV/r 100/25mg did not experience interruptions during the transition period. A phased approach was used to roll out pediatric regimen optimization with each subsequent phase being informed by stock levels at the central warehouses through supply planning and stock status monitoring by the central Quantification and Procurement Planning Unit (QPPU).

This article is based on the analysis of reports and discussions with stakeholders involved in implementing pediatric ART regimen optimization.

Lessons learned: Nationally, pediatric regimen optimization for children living with HIV increased from 59% in May 2020 to 78% in October 2020. The performance across the 14 regions of Uganda varied due to the phased nature of implementation, some regions gradually increased from 70% to 95% with the highest optimization rates reported in central and east-central regions, while some areas remained between 50% and 60%. Treatment interruption was averted for children who were already on ART. Optimal stocks were maintained at the three central warehouses that serve the entire country. The continued use of sub-optimal regimens in the face of high levels of HIV resistance to non-nucleoside reverse transcriptase inhibitors (NNRTIs) contributed to lower virology suppression in children as compared to adults.

Conclusions/Next steps: For any regimen transition and optimization to be successful, the supply chain coordination mechanism needs to be well coordinated and should lead clinical programming. The Quantification and Procurement Planning Unit of the MOH Pharmacy Department, through meticulous supply planning and coordination of supply

chain actors ensured that treatment was not interrupted despite glaring global challenges. The need for centralized supply chain coordination cannot be overemphasized during implementation of regimen transitions.

PEB208

HIV drug resistance patterns among highly treatment-experienced children, adolescents and young adults in sub-Saharan Africa

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Background: There are limited studies of drug resistance among children, adolescents, and young adults failing antiretroviral treatment (ART) in sub-Saharan Africa (SSA). We evaluated baseline drug resistance patterns in children, adolescents, and young adults enrolled in the New Horizon's study, which provides darunavir (DRV) and/or etravirine (ETR) to children failing second-line ART.
Methods: From November 2018 to October 2020, we collected data from Eswatini, Kenya, Lesotho, Rwanda, Uganda, Zambia, and Zimbabwe among patients aged 0-24 years initiated on DRV and/or ETR. Data were abstracted from medical records at baseline and approximately every six months thereafter. Susceptibility to various drugs was determined using the genotypic susceptibility score (GSS) using the Stanford University HIV drug resistance database version 8.9.1 portal (hivdb.stanford.edu) and was classified as susceptible, intermediate-level, and high-level resistance.
Results: A total of 233 patients aged 0-24 years were enrolled and the median age at switch to DRV or ETR was 12.9 years. Immediately prior to DRV or ETR initiation, 80.1% had viral failure while receiving LPV/r plus dual NRTIs. Of those enrolled, 128 (55%) had documented baseline resistance results (Figure).

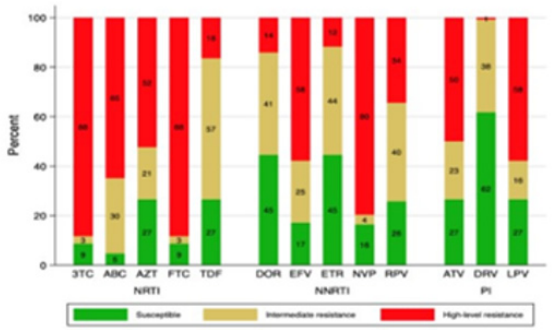

Figure. HIV drug susceptibility among participants at baseline (N=128)

Only 27% were susceptible to TDF or AZT and 82 (64.1%) were not susceptible to any NRTI. For NNRTIs, high-level resistance was found for NVP in 80%, EFV in 58%, while 45% remained susceptible to second-generation NNRTIs, doravirine (DOR) and ETR. Among PIs, high resistance was found for both LPV (58%) and ATV (50%), with 71% having cross-resistance, however, 62% remained susceptible to DRV with only 1% having high-level DRV resistance. Compared to adolescents and children under five years, PI resistance was higher in 5-9-year-olds (80.8% vs 60% vs 44.4%).
Conclusions: Highly treatment-experienced children/adolescents in SSA have accumulated high-level of resistance to NRTI, NNRTI, and commonly used PIs, but susceptibility to DRV and second generation NNRTI was retained in most.

PEB209

The impact of the COVID-19 pandemic on uptake of multi-month dispensing (MMD) of antiretroviral therapy for children living with HIV: a multicountry analysis

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Background: Uptake of multi-month dispensing (MMD) of antiretroviral therapy (ART) for stable children (<15 years old (y/o)) living with HIV (CLHIV) varied widely across countries prior to the COVID-19 pandemic. COVID-19 prompted efforts to rapidly decongest health facilities to prevent transmission. This analysis updates a 2020 International Pediatrics Workshop oral presentation on MMD services changes for CLHIV during COVID-19.
Methods: MMD uptake among CLHIV in 12 USAID/PEPFAR-supported countries from October 1, 2019 to September 30, 2020 (Fiscal Year 20 quarter (Q) 1 to Q4) was analyzed using implementing partner and program data. Q1 and Q2 data was averaged (Q1/2) to represent pre-COVID-19 results; Q3 and Q4 data represented results during quarters with COVID-19-related-restrictions. Chi-square tests compared results from pre-COVID-19 to during COVID-19 (Q1/2 to Q3; Q1/2 to Q4), and compared changes during COVID-19 (Q3 to Q4). MMD was defined as dispensing ART at intervals of <3 months (<3MMD), 3-5 months (3-5MMD), or ≧6 months (6MMD).
Results: From Q1/2 to Q4, the total number of CLHIV on treatment increased from 178,820 to 185,357 (Table 1). The percentage of CLHIV receiving any MMD (3-5MMD or 6MMD) increased from 36.9% (Q1/2) to 54.8% (Q4). The percentage of CLHIV receiving <3MMD decreased from 63.1% (Q1/2) to 45.2% (Q4). The 3-5MMD coverage increased from 34.2% (Q1/2) to 47.6% (Q3); despite a slight decrease to 45.9% in Q4 there remained an overall increase from Q1/2 to Q4. The percentage of CLHIV receiving 6MMD increased steadily from 2.7% in Q1/2 to 6.1% in Q3 to 9.0% in Q4. All changes from Q1/2 to Q3 and Q4, and Q3 to Q4 were statistically significant (p<0.001).

FY20 Quarters	CLHIV on Treatment[1]	<3MMD (%)	3-5MMD (%)	6MMD (%)
FY20Q1	176,516	108,210 (65.6%)	52,769 (32.0%)	3,919 (2.4%)
FY20Q2	181,123	109,186 (60.6%)	65,510 (36.4%)	5,453 (3.0%)
FY20Q1/Q2 (avg)	178,820	108,698 (63.1%)	59,140 (34.2%)	4,686 (2.7%)
FY20Q3	182,914	82,304 (46.3%)	84,725 (47.6%)	10,869 (6.1%)
FY20Q4	185,357	7,944 (45.2%)	80,673 (45.9%)	15,774 (9.0%)

[1]Number of CLHIV on treatment may not equal the total number of children <3MMD, 3-5MMD and 6MMD due to differences in data completeness.

Table 1. MMD among <15y/o across 12 PEPFAR-supported countries, October 2019 - September 2020

Conclusions: MMD uptake among CLHIV on ART increased significantly during the COVID-19 pandemic. Continued expansion of MMD policies and uptake, even as COVID-19-related restrictions relax, will strengthen access to ART for CLHIV.

PEB210

Impact of ARV optimization on HIV viral load suppression among children in Tanzania

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Background: Tanzania adopted the WHO recommendation to optimize pediatric antiretroviral therapy (ART) using a lopinavir-boosted ritonavir (LPV/r)-based or a dolutegravir (DTG)-based regimen. The Elizabeth Glaser Pediatric AIDS Foundation supported the transition to optimized regimen by using pediatric mentors to build capacity of multi-disciplinary teams to conduct routine pediatric case file reviews and we evaluated the impact on HIV viral load suppression.

Methods: A retrospective cross-sectional review of program data from five supported regions was conducted to analyze the progress of transition to optimal ART regimens and HVL suppression in children aged 0-14 years, over a three-year period, January 2018-December 2020. Export for analysis data were extracted from electronic care and treatment (CTC2) databases across 325 health facilities from five supported regions. HVL suppression was determined using the latest HVL measure within the calendar year.

Results: The number and proportion of children on optimal regimen increased from 392 children (9%) by June 2018 to 4,052 children (87%) by June 2020, including 1,350 children (29%) who are on LPV/r-based regimen. Within the same period, the HVL suppression rate among children increased from 60% to 83%, whereby an improvement is seen across all regimens, including the sub-optimal NVP and EFV-based regimens. However, the HVL suppression rate among children using LPV/r-based regimen had a relatively low increase from 66% to 76%, compared to 89% among children on DTG based regimen, as shown in the figure below.

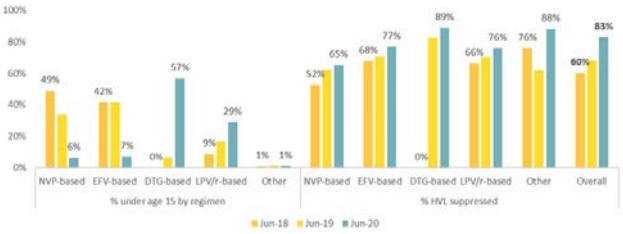

Figure. Trends in proportion of children on ART by regimen and HVL suppresion by regimen

Conclusions: While the transition to optimal pediatric ART regimens is making progress, and subsequently resulting in a steady increase of HVL suppression among children, there are concerns with the low HVL suppression among children using LPV/r-based regimen, which till date does not yet outperform the sub-optimal EFV-based regimen. There is need to assess the availability and administration of pediatric formulations of LPV/r-based regimen to ensure children reach viral suppression.

PEB211

What are the drivers of improved viral suppression among HIV infected children (0-14 years)? Results from the national data warehouse in Kenya 2020

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Background: Of the estimated 105,000 children living with HIV (CALHIV) in Kenya, 68,611 are currently on antiretroviral therapy (ART). Although viral suppression (VS) is lower in children compared to adults; there has been a 25% increase in VS among CALHIV from 2016 to 2020. We investigated the drivers of improved VS among CALHIV in Kenya.

Methods: Using the national HIV data warehouse, we sampled 81 nationally representative HIV clinics in 41 of 47 counties through stratified random sampling. Stratification was based on counties and facility volume, with high volume being ≥100 active CALHIV. VS was defined as viral load (VL) <1000 copies/milliliter. After bivariate analysis, multilevel mixed effects logistic regression modeling was used to control for confounding variables and random effects at county and facilities.

Results: Of the 6,559 CALHIV, 5,319 (81.1%) had valid VL. Median age was 11 (interquartile range (IQR) 7-13) years and males were 3,242(49.4%). Overall VS was 86.1% with 19 (23.5%) clinics having VS >90% (range 38.5% - 100%). Children 5-9 years were twice as likely to be suppressed compared to <5 years, adjusted odds ratio (aOR) 2.0(95% confidence interval [CI] 1.20 - 3.16, p=0.007. Every extra year on ART improved the odds of VS by 10% (aOR 1.1, 95%CI (1.01-1.1), p=0.012). Children on dolutegravir had a 3-fold odds of VS, aOR 3.2, 95%CI (2.15-4.61) compared to those on efavirenz, p<0.0001. Documented satisfactory adherence was associated with nearly 5 times more likely to be suppressed compared to unsatisfactory adherence, aOR 4.9, 95%CI (2.37-10.11), p<0.0001. CALHIV with initial VS after ART initiation were 3 times more likely to be suppressed, aOR 3.1 95% CI (2.42-4.04) p<0.0001. Tertiary facilities had better VS than health centres, aOR 1.9, 95% CI (1.03-3.43) p=0.04. There were no differences in VS by sex, orphan status, treatment supporter, age at ART start and baseline CD4 (p>0.05).

Conclusions: Older children, longer duration of ART use, being enrolled in a tertiary level facility, being dolutegravir-based regimen and satisfactory adherence are key drivers of high VS among CALHIV. Strategies are needed to improve VS among younger CALHIV < 5 years.

Adherence in paediatric and adolescent populations

PEB212

Impact of enhanced adherence counselling on viral re-suppression among adolescents and young persons with persistent high viremia in selected health facilities in Kisii and Migori county, Western Kenya

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Background: Globally, adolescents and young persons (AYP; 10-24yrs) on antiretroviral therapy (ART) experience suboptimal ART adherence and viral suppression (VS). In 2017, VS among adolescents (10-19yrs) was 61.4% compared to adults at 71.6% in Kenya. Kenya ART guidelines recommend 3 sessions of Enhanced Adherence Counselling (EAC) following detectable Viral Load (VL). We assessed completion of EAC and factors associated with viral re-suppression amongst AYPs with persistent viremia in western Kenya.

Methods: This was a retrospective analysis of routinely collected data abstracted from electronic medical records in 20 high volume facilities supported by University of Maryland, Baltimore. AYP with persistent viremia (>1,000 copies/ul) between October 2017 to September 2019 were followed for 12 months; those with ≧ one follow-up VL test were included in the analysis. Persistent viremia referred to non-VS of > 1 consecutive VL tests. EAC sessions were "satisfactory" if ≧3 sessions were conducted and barriers successfully identified or "unsatisfactory" if otherwise. Medication adherence (MA) was assessed using the standard Morisky MA score (≥1 considered sub-optimal, 0 considered optimal adherence). Bivariate logistic regression model was used to assess predictors of VS at 95% confidence interval (CI).

Results: Of 124 AYPs with persistent viremia, 118 (95.2%) had a documented follow up VL and were included in the analysis. The median age was 15.9 years (interquartile range14.0 – 18.0) and 52.5% (62) were male. Overall, 39.8% (47) of patients re-suppressed during the study period. In total 54.2% (64) had satisfactory EAC sessions and 50.8% (60) had optimal adherence. AYPs who had satisfactory EAC sessions were four times more likely to have VS (odds ratio [OR] 3.92, 95% confidence interval [CI]: 1.70 – 8.99). AYPs with an optimal adherence score were six times (OR 6.4, 95% CI: 2.8-14.8) more likely to have VS, and those who were suppressed at 6 months post ART initiation were three times (OR 2.7, 95% CI:1.1.-6.8) more likely to have VS.

Conclusions: Completion of the recommended 3 EAC sessions with optimal ART adherence were strongly associated with viral re-suppression among AYPs with persistent viremia. Strategies to improve EAC completion with ART adherence could improve viral re-suppression and outcomes among AYP living with HIV.

PEB213

High rates of acceptance and viral re-suppression among children and adolescents (0-19 years) receiving virtual enhanced adherence counselling and synchronous medication reminders in Nairobi, Kenya

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Background: Emergence of the COVID-19 pandemic with guidelines for social distancing posed unprecedented challenges to HIV service delivery. Face-to-face directly observed therapy (DOT), for children and adolescents living with HIV (CALHIV) with high viral loads (HVL) could not be achieved. As an adaptation measure, we adopted phone based virtual enhanced adherence counselling (VEAC) and daily medication intake reminders for CALHIV with HVL in Nairobi. We describe program level experience, acceptability and re-suppression rates among CALHIV receiving VEAC and daily reminders between May-September 2020.

Description: We implemented VEAC and daily medication reminders in 18 University of Maryland supported government facilities in Nairobi. We developed standard operating procedures, trained healthcare workers on VEAC implementation and provided phones to facilitate this process. We sought written consent from caregivers and allowed them to participate in choosing their preferred case-managers. Phone alarms were aligned for clients and case-managers to the time of taking medication. Case-managers conducted daily calls at the time of medication intake to confirm drug intake. Adherence counsellors called caregivers 2 weekly for VEAC. We evaluated their viral load outcomes as at the end of 3 months of VEAC.

Lessons learned: We conducted a retrospective analysis of children and adolescents (0 -19years) with HVL between May and September 2020 in 18 facilities in Nairobi who had been initiated on VEAC. Among 152, 121 (80%) accepted and were offered 2 weekly VEAC and daily medication intake reminders. All the 121 (100%) were active by month 3 of follow up. 93 (77%) had completed 3 months, 68 (73%) had a repeat viral load and 58 (85%) had viral load results documented. Two-thirds (67%) re-suppressed without regimen switch (54% among the 0-4,71% 5-9,75% 10-14 and 67% 15-19). Re-suppression was lowest among the 0-5. The primary problems encountered were unresolved client adherence challenges, inconsistent reach over the phone & delay in viral load results.

Conclusions/Next steps: There is high acceptability of VEAC and daily phone- based reminders. Implementation of this strategy resulted in high re-suppression and retention of CALHIV with HVL. HIV programs need to consider implementation and scale-up of this strategy in order to fast-track achievement of the 95-95-95 targets for CALHIV.

PEB214

High loss to follow up among young people living with HIV on antiretroviral therapy in Mozambique, 2017-2019

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Background: In 2019, 2.2 million people were living with HIV (PLHIV) in Mozambique, of which 60% were receiving antiretroviral therapy (ART). Young people often experience ART interruption. We assessed the ART status of patients between 10 and 24 years of age who initiated ART in 2017 to ascertain specific populations of young PLHIV in Mozambique that require focused attention.

Methods: Data were analyzed from a national patient-level database derived from the Electronic Patient Tracking System (EPTS), which covered 85% of new ART patients in 2017. The cohort was composed of 67,809 new patients between the ages of 10 and 24 years who performed at least one ART pick-up in the first 6 months, representing 24% of all patients who initiated ART in 2017. The cohort was 82% female. ART pick-ups and consults were used to determine ART status at three evaluation points: 6, 12, and 18 months after initiation. The relationship between initiation age and lost to follow-up (LTFU) patients was assessed by Spearman correlation.

Results: Among the cohort, 78%, 81%, and 81% were LTFU at each evaluation point, respectively. There is a strong, positive correlation between the proportion of LTFU patients in the cohort and initiation age (6 months: rho = 0.93, p <0.001; 12 months: rho = 0.94, p <0.001; 18 months: rho = 0.96, p <0.001). By 18 months after initiation, 40% of patients aged 15-19 years were LTFU. The proportion of LTFU patients increased at initiation ages of 18 for males and 15 for females.

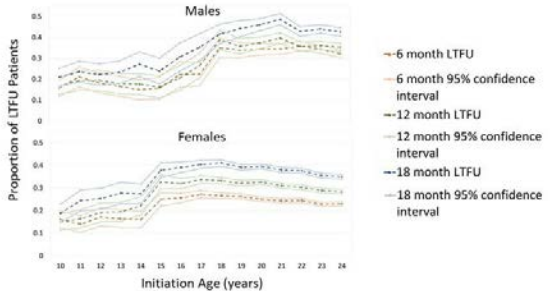

Figure. The proportion of LTFU patients increased at certain initiation ages for each sex, across the three evaluation points, with 95% confidence intervals, Mozambique, 2017-2019

Conclusions: Focused study of the reasons for LTFU, including undocumented deaths, silent transfers, and client-specific reasons for suspending ART is needed. Understanding the causes of LTFU status among young people, particularly among 18-year-old males and 15-year-old females, may inform adherence counseling, patient support, and transitioning young people to adult care.

PEB215

"Who am I going to stay with? Who will accept me?" A qualitative study of family-level factors underlying disengagement from HIV care among Kenyan adolescents

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Background: Adolescents living with HIV (ALHIV, ages 10-19) have lower retention in care compared to other age groups. Adolescents rely on family support in their transition to autonomy. We investigated family-level factors underlying disengagement from HIV care among adolescents who were lost to program (LTP).

Methods: Semi-structured interviews were performed with ALHIV LTP, their caregivers, and healthcare workers (HCW) in the Academic Model Providing Access to Healthcare (AMPATH) program in western Kenya, from 2018-2020. Criteria for ALHIV LTP were ≥1 visit within the 18 months prior to data collection at one of two clinical sites and nonattendance ≥60 days following their last scheduled appointment. HCW were recruited from 10 clinics. Transcripts were coded using an adapted socioecological model, and family-level factors underlying disengagement were elucidated through thematic analysis.

Results: Interviews included 42 ALHIV LTP, 32 caregivers, and 28 HCW. ALHIV were 67% orphaned, 62% female, 60% food-insecure, and average age 17.0 (range 12.9-20.9). Family-level factors were central to disengagement. Orphaned ALHIV experienced challenges when new caregivers or unstable living situations limited support for HIV care. These challenges were compounded by anticipated stigma ("Who am I going to stay with? Who will accept me?"); resultant non-disclosure of HIV status to household members ("I feared telling people at home; I hid it completely"); enacted stigma in the household, with overwhelming effects on adolescents ("If we are at the table eating, they should not discriminate against him. Let us just sit all of us together"); or experiences of multiple forms of trauma. These challenges directly undermined HIV care engagement. Some caregivers lacked finances or social support to facilitate care. Others did not feel equipped to support adolescent engagement or adherence. Regarding facilitators to re-engagement, participants described roles for household disclosure ("Since they know, at least I have the courage I can come"); and supportive caregivers, especially those also living with HIV ("We understand her situation, and we do things as a team").

Conclusions: Family support is integral to adolescent retention in HIV care. Interventions targeting household relationships, disclosure, HIV stigma, and care resources may promote adolescent retention.

HIV complications and co-morbidities in paediatric and adolescent populations

PEB216

A tool to predict the individual risk of mortality in early treated infants with HIV

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Background: The rate of early childhood mortality is still too high during the first months after ART initiation in Sub-Saharan Africa. There are no tools to evaluate early the individual risk for each infant. We aimed to create an online tool to predict the individual risk of mortality or progression to AIDS in early-treated infants with HIV during the first year of life, using machine-learning (ML).

Methods: A total of 100 infants born with HIV and treated before 90 days of life in South Africa and Mozambique were included in the prospective cohort study Early ART in HIV (EARTH-EPIICAL Consortium). The combined outcome was mortality or clinical progression to AIDS 12-months after enrolment. A ML (random-forest) model was built using age at recruitment, sex, weight-for-age z-score, preterm birth, age at HIV diagnosis, age at ART initiation, initiation ART regimen, pre-ART viral load, baseline CD4%, mother severe life events or health issues, mother's adherence to ART at enrolment, and mother's last CD4 count and VL measurements. The set of participants was randomly divided into a training dataset used to generate the model (70%), and a validation dataset used to assess performance (30%).

Results: An online tool was created with the ML model. The online tool permits entering the sociodemographic, virological, immunological and maternal information at any moment after ART initiation. Upon entrance of data, a pop-up window appears with the probability of death or clinical progression to AIDS 12 months after enrolment.

The model had 82.2% accuracy, 78% sensitivity, 85% specificity, and an area under the curve of 0.73 (95% CI, 0.67-0.79). In the validation set of participants, the model classified most of the patients correctly. The probability of death or progression that the model predicted for the children who actually died/progressed was different (p=0.002) to the children who did not die/progress.

The web-app is freely available in https://rserver.h12o.es/pediatria/MAGPIE/ (u:user, password:0000)

Conclusions: The outcome of early-treated infants with HIV can be predicted using an ML model, which integrates standard clinical, virological, and immunological data. The online tool can be useful for health workers to identify children with high risk and implement appropriate countermeasures

PEB217

Daily ferrous sulfate supplementation for three months improved iron status in South African schoolchildren living with HIV

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Background: Fifty-two percent of African children are considered iron deficient. Oral iron supplementation in individuals living with HIV (HIV+) remains controversial. Persistent subclinical inflammation despite antiretroviral therapy may decrease intestinal iron absorption and render oral interventions less effective. Unabsorbed iron reaching the colon may increase gut inflammation and pathogen growth. We aimed to compare the effect of daily oral iron supplementation on iron status and gut inflammation between virally suppressed HIV+ children and children without HIV (HIV-ve).

Methods: In this controlled trial, we provided 50 mg elemental iron from ferrous sulfate daily for three months to 8 to 13-year-old virally suppressed (<50 HIV RNA copies/mL plasma) HIV+ and HIV-ve children with inflammation-unadjusted ferritin ≤35 µg/L. At start and endpoint, we measured hemoglobin (Hb), plasma ferritin (PF), soluble transferrin receptor (sTfR), C-reactive protein, and α-1-acid glycoprotein in blood, and calprotectin in fecal samples. We adjusted PF for inflammation using the BRINDA regression correction approach. For continuous variables, we assessed within-group changes with paired sample t-tests or Wilcoxon signed-rank tests, and between-group comparisons at endpoint using analysis of covariance (ANCOVA), adjusting for respective baseline values, age, and sex.

Results: We included 64 children, 52% (*n*=33) HIV+. Mean (SD) age and sex were 11.3y (1.8) with 46% (*n*=15) male in HIV+ and 11.1y (1.7) with 52% (*n*=16) male in HIV-ve children. Hb increased from 118 to 124 g/L (*P*=0.003) in HIV+ and from 120 to 124 g/L (*P*=0.003) in HIV-ve children. Inflammation-adjusted PF increased from 15.0 to 33.8 µg/L (*P*<0.001) in HIV+ and from 17.8 to 37.3 µg/L (*P*<0.001) in HIV-ve children. sTfR decreased from 7.1 to 5.9 mg/L (*P*<0.001) in HIV+, and from 6.6 to 5.7 mg/L (*P*<0.001) in HIV-ve children. Calprotectin concentrations did not change significantly in either group. At endpoint, there were no significant differences in Hb, PF, sTfR or calprotectin between groups.

Conclusions: Daily ferrous sulfate supplementation for three months improved iron status in virally suppressed HIV+ and HIV-ve schoolchildren with no significant effects on gut inflammation. Iron status and gut inflammation did not differ significantly between the groups at endpoint. Thus, iron supplementation appears effective in virally suppressed HIV+ schoolchildren.

HIV-associated co-infections and malignancies in paediatric and adolescent populations

PEB218

Follow-up evaluation for anal HPV infection among men who have sex with men and transgender women with HIV in Atlanta

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Background: Men who have sex with men (MSM) and transgender women (TW) with HIV are disproportionately affected by anogenital human papillomavirus (HPV) infection and remain the highest risk group for developing anal cancer. However, there are no national guidelines for anal cancer screening in this population. While some perform anal cytology with confirmatory high-resolution anoscopy (HRA) as a common screening method, this has not been widely adopted among youth younger than age 25. In this study, we aimed to determine the prevalence of abnormal anal cytology and histology, in addition to follow-up evaluation, among young MSM and TW with HIV in Atlanta, GA.

Methods: Retrospective chart review was conducted for all patients aged 13-24 at Grady Ponce and Family Youth Clinic in Atlanta, GA from 2009-2020. Data were collected on patient demographics, sexual history, anal cytology, and treatment received (surgical evaluation, HRA, and anal biopsy). Data were analyzed using descriptive statistics.

Results: 466 sexually active MSM and TW with HIV were included. The mean age at first observation was 19.9 (SD: ±2.1) years. 415 patients (93%) were Black and 442 patients (99%) were horizontally infected. 332 patients (74%) had at least one anal cytology with 99% of those (327/332) having an abnormal result over the study period. Of those with an abnormal anal cytology, 139/327 patients (43%) were referred for surgical evaluation and 77/139 (55%) underwent evaluation. 142/332 patients (43%) were referred for HRA and 41/142 (29%) completed the visit. Of those who underwent surgical evaluation or HRA, 104/118 patients (88%) had an anal biopsy with the following distribution of pathology results: 65 patients (63%) had high-grade disease, 29 patients (28%) had low-grade disease, 9 patients (9%) had no evidence of disease, and 1 patient (1%) had an inadequate specimen.

Conclusions: Our study showed disproportionately high rates of anogenital HPV infection among young MSM and TW with HIV, with nearly 100% of individuals having at least one abnormal anal cytology over the study period. For those who underwent anal biopsy, the majority had high-grade disease. Our data support the need for national screening guidelines for anal cancer among young MSM and TW with HIV.

Behavioural health outcomes in paediatric and adolescent populations

PEB219

A randomized trial of a standardized patient actor training intervention to improve adolescent engagement in HIV care in Kenya

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Background: Adolescents and young adults living with HIV (ALHIV) report that negative interactions with health care workers (HCWS) affected their willingness to return to care. We evaluated effectiveness of a standardized patient actor (SP) HCW training intervention on adolescent engagement in care.

Methods: We conducted a stepped wedge randomized trial of the SP intervention during 2016-2020. HCWs caring for ALHIV at 24 clinics in Kenya received training in adolescent care, values clarification, communication skills, and motivational interviewing, then rotated through seven SP encounters, followed by individual feedback and group debriefing. Facilities were randomized to four waves of timing of the intervention. The primary outcome, early engagement, was abstracted from electronic medical records and defined as return after first visit within 3 months among newly enrolled ALHIV, or ALHIV who returned after >3 months out of care. Generalized linear mixed models adjusted for time, newly enrolled, with clustering by facility calculated adjusted odds ratios (aORs).

Results: Overall, 139 HCWs were trained. HCWs reported significant improvement in competence in communication, empathy, clinical skills, and overall confidence comparing pre-and post-training (all p<0.001). Medical records were abstracted for 4,645 ALHIV with 45,422 visits. Most ALHIV (64%) were age 20-24, 25% were 15-19, and 11% were 10-14; 82% were female, 76% were newly enrolled in care, and 75% returned for care within 3 months of their first visit. Across all sites, ALHIV engagement significantly improved over time (global Wald test=0.05). In adjusted models, the intervention showed no significant effect on engagement [aOR=0.81, 95% Confidence Interval (CI): 0.59-1.12]. There was high turnover of trained HCWs: 58% of wave 1 providers were in their position 9-months post-training. Newly enrolled ALHIV had significantly higher engagement than those with prior lapses in care (aOR=1.80, 95%CI: 1.19-2.71).

Conclusions: SP training resulted in higher confidence of HCWs providing ALHIV care. However, there was no statistically significant effect of SP training on ALHIV care engagement, likely due to high diffusion of the trained workforce and temporal improvements in engagement in care, reflecting program efforts. Strategies to retain SP-training benefits need to address HCW turnover. ALHIV with prior gaps in care may need more intensive support.

HIV-exposed uninfected children

PEB220

Risk of hospitalization among children who were HIV exposed and uninfected (cHEU) in Montreal, Canada

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Background: While a number of studies have demonstrated increased risk of morbidity and mortality among children who were HIV-exposed and uninfected (cHEU) in resource-limited settings, the specific causes of this, and the role of underlying socio-economic factors, including access to care, remain unclear.
The objective of this study was to determine risk factors for hospitalization among cHEU living in a well-resourced setting with universal health care coverage.
Methods: Longitudinal cohort study linking patient level data from the Centre maternel et infantile sur le SIDA (CMIS) cohort (1988-2015) to provincial (Quebec) administrative data from the Régie de l'assurance maladie du Québec (RAMQ) (1988-2016), a universal provincial health plan that covers all residents in the province of Quebec through a single patient identifier. Kaplan-Meier curves were constructed to determine risk of hospitalization over time, and risk factors for hospitalization determined using Cox proportional hazards models.
Results: Between Jan 1st 1988 and Dec 31st 2015, 847 children were enrolled in the CMIS cohort; 726 were successfully linked to the RAMQ database. Children ranged in age from 1-25 years at the end of the follow-up period (10.4% between 20-25, 46.5% between 10-20, 26.7% between 5-10, and 16.2% between 1-5 years). A total of 647 hospitalizations were captured (excluding birth hospitalization).
Cumulative risk of hospitalization was 29.6% within the first year of life (95% CI 27.9-31.3%), 42.5% in the first 5 years (95% CI 40.6-44.3%), and 48.7% within the first 10 years (95% CI 46.7-50.7%). Significant risk factors for hospitalization on multivariate analysis were gestational age <=37 weeks vs >37 weeks (HR 2.60, 95% CI 1.97-3.42), and detectable (VL>500 copies/ml) vs. undetectable maternal viral load at delivery (1.44, 95% 1.03-2.02), after adjusting for maternal age, race, CD4 count at delivery, class of antiretrovirals used during pregnancy, and year of birth.
Conclusions: In this cohort of cHEU children from the province of Quebec, significant risk factors for hospitalization included prematurity and detectable maternal viral load at time of delivery. Further work needs to be done to understand risk factors for elevated maternal viral load at the time of delivery and the potential long-term effects on cHEU health.

PEB221

Increased infectious-cause hospitalization among infants who are HIV-exposed uninfected compared to HIV-unexposed

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Background: Increased risk of morbidity and hospitalization has been observed in children who are HIV-exposed but uninfected (HEU) compared to HIV-unexposed and uninfected (HUU), although studies in the era of universal maternal ART are limited.
Methods: We investigated hospitalization between 29 days and 12 months of life in a prospective South African cohort of infants born between February 2017 and January 2019 (HEU=455; HUU=458). All mothers known with HIV during pregnancy received ART.
We reviewed infant hospital records and classified and graded infectious diagnoses using a standardized tool. We examined factors associated with infectious-cause hospitalization using mixed-effects Poisson regression.
Results: Infants HEU vs. HUU had higher all-cause and infectious-cause hospitalization (13% vs. 7%, p=0.004 and 10% vs. 6%, p=0.014 respectively). Infectious causes accounted for most hospitalizations (77%). More infants HEU were hospitalized with severe or very severe infections than those HUU (3% vs. 4% severe; 3% vs. 6% very severe; p=0.041). Mortality (<1%) did not differ between groups. HIV exposure was a significant risk factor for infectious-cause hospitalization (aIRR=2.8; 95% CI 1.5-5.4).
Although increased incidence of preterm birth (14% vs. 10%; p<0.05) and shorter duration of breastfeeding among infants HEU vs. HUU (44% vs. 68% breastfed for ≥3 months, p<0.001) contributed to increased hospitalization, they did not account for all the increased risk.

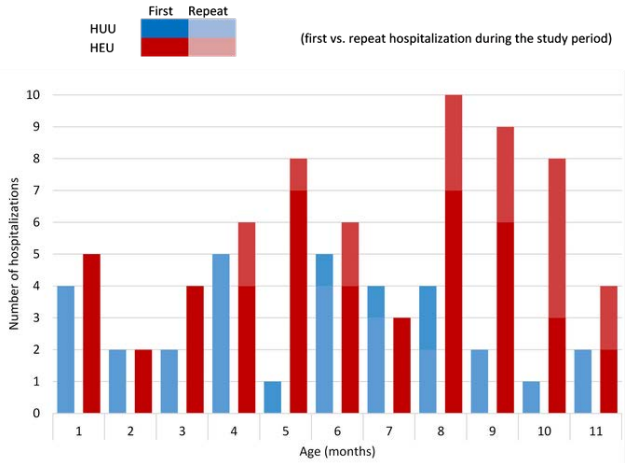

Figure 1. Number of infection-related hospitalizations at different ages in infants, age 29 to 365 days, who were HIV exposed uninfected (HEU; n=455) and HIV unexposed uninfected (HUU) (N=458) (<1% infants censored during the study period)

	Unadjusted IRR (incidence rate ratio; 95% confidence interval)	Model A: Adjusted IRR (n=625)	Model B: Adjusted IRR (n=613)
HIV exposure (vs. HIV unexposed)	1.76 (1.05-2.93)	2.84 (1.49-5.39)	1.95 (1.01-3.79)
Maternal education (secondary schooling completed vs. not completed)	0.76 (0.44-1.32)	0.70 (0.37-1.34)	0.67 (0.35-1.26)
Maternal age at delivery (per year increase)	0.96 (0.92-1.00)	0.94 (0.89-0.99)	0.94 (0.89-0.99)
Reside in formal housing (vs. informal dwelling)	0.68 (0.41-1.14)	0.78 (0.44-1.41)	0.85 (0.48-1.52)
Male sex of infant (vs. female)	1.31 (0.79-2.17)	1.44 (0.80-2.60)	1.46 (0.83-2.59)
All vaccinations up-to-date (vs. incomplete)	0.52 (0.29-0.95)	0.52 (0.29-0.95)	0.61 (0.34-1.10)
Preterm birth (<37 weeks gestation)	2.35 (1.24-4.45)		2.20 (1.06-4.56)
Breastfeeding duration (per month increase)	0.90 (0.84-0.96)		0.90 (0.84-0.98)
Variance of random effect (95% CI)		1.42 (0.65-3.11)	1.07 (0.42-2.72)

Table 1: Poisson regression models assessing associations with infectious-cause hospitalization in HIV uninfected infants between 29 days and 12 months of age (n=891)
(Note: Second-born twins and infants with high-risk congenital anomalies were excluded. Model A includes possible confounders; Model B also includes mediators.)

Conclusions: Infectious-cause hospitalization incidence was higher among infants HEU vs. HUU, likely partly due to lower breastfeeding rates among infants HEU. The increased infectious disease burden in HEU infants has important implications for health services in sub-Saharan Africa.

Transition of adolescents into adult care

PEB222

Viral suppression among adolescents and young adults on ART before and after structured transition to adult care in rural Western Kenya

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Background: Kenya 2018 national HIV treatment guidelines recommend structured transition of adolescents (10–19 years) living with HIV (ALHIV) to adult care. In 2018, viral suppression among ALHIV was 61.4% compared to 71.6% among adults—a continued gap among transitioned ALHIV. We evaluated viral suppression (VS) before and after transition to adult care among ALHIV following implementation of adolescent package of care (APOC) and transition guidelines.
Methods: This retrospective cohort analysis included young people living with HIV (YPLHIV) aged 19-24 years who transitioned to adult care. The sample included people active on ART in October 2018 in 37 facilities in Kisii and Migori counties Viral load results recorded before and after age 19 years were defined as pre- and post- transition respectively. Routinely collected demographic and clinical data were abstracted from electronic medical records. Proportion of VS [viral load (VL) <1000c/ml] among AYHIV with paired VL data was calculated before and after transition and compared using chi square tests. Multivariable alternate logistic regression was used to assess factors associated with VL suppression including age, gender and duration on ART in the pre- and post-transition periods.
Results: Paired VL data from a total of 527 individuals were analyzed. The median age was 21 years [interquartile range (IQR): 20–22] and median duration on ART was 7 years [IQR:4.3–9.1]. Overall, there was a statistically significant difference in viral suppression before and after transition [76.3% (n=402) vs. 81.4% (n=429) p <.0001]. Those on ART > 7 years were more likely to have VS before and after transition compared to those on ART for < 7 years, [OR=2.06; 95% confidence interval (CI) 1.58-2.55] and [OR=1.97; 95%CI 1.44- 2.50]. Young women were more likely to be suppressed before and after transitioning [OR=2.10; 95%CI 1.64-2.56] and [OR=2.10; 95%CI 1.54- 2.63] respectively.
Conclusions: These findings demonstrate better VS rates after ALHIV transition to adult HIV care. Although implementation of the APOC and transition guidelines may enhance VS among YPLHIV, additional strategies are needed after transitioning for young men and patients on ART < 7 years.

PEB223

Development of a risk score for adolescents living with perinatally-acquired HIV and transitioning to adult care

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Background: Adolescents living with perinatally-acquired HIV (ALHIV) have poor viral suppression and retention in care after transition from pediatric to adult based care. Optimal timing and readiness for transition to adult care are not currently known.
Methods: We prospectively enrolled 199 ALHIV prior to transition from pediatric to adult care in South Africa. At enrollment, adolescents completed a questionnaire asking about alcohol/substance use, depression, stigma, self-esteem (Rosenberg self-esteem scale), social support (Adolescent social support scale), and transition readiness (HIV Adolescent Readiness for Transition Scale (HARTS)). Additional demographic and clinical data were extracted from medical records. Adolescents were followed for 12 months after transition to adult care to determine viral suppression (viral load <200 copies/ml). We used factors associated with viral failure in the bivariable and multivariable logistic regression models to calculate a transition risk score using a point scoring system based on the regression coefficients. We used the Homer-Lemeshow Goodness of fit test for calibration and calculated the Area Under the Curve to determine the model's discrimination.
Results: Of the 199 adolescents who transitioned to adult care, 84 (43%) maintained viral suppression one year after transition. Factors associated with a higher odds of viral failure are located in the table below. Transition risk scores were divided into tertials of low, intermediate, and high risk for viral failure after transition. The discrimination performance was good with an area under the curve of 0.85 (95% CI 0.79-0.90).
Conclusions: This risk score can be used to identify adolescents who are ready to transition to adult care. For adolescents with higher transition risk scores, it may identify additional areas for intervention to prepare adolescents for transition to adult care.

COVARIATE	OR	Bivariate Analysis 95%CI	p-value	AOR	Multivariate Analysis 95% CI	p-value
First line ART	0.10	0.04, 0.25	<0.001	0.07	0.02, 0.24	<0.001
Disclosed of HIV status	0.67	0.38, 1.18	0.16	0.36	0.16, 0.82	0.015
HARTS score‡ (per unit score)	0.98	0.96, 1.01	0.15	0.95*	0.92, 0.98	0.004
Lifetime alcohol use	2.91	1.53, 5.54	0.001	3.43	1.51, 7.80	0.003
Age at ART initiation	1.22	1.09, 1.36	<0.001	1.23	1.07, 1.42	0.004
Drug use	2.26	0.78, 6.55	0.13	0.05†	0.00, 2.22	0.123
Female	1.30	0.74, 2.30	0.37	2.58	1.21, 5.10	0.014
Peer Support	0.99	0.96, 1.03	0.58	1.02	0.98, 1.05	0.41
Self- Esteem	0.94	0.87, 1.00	0.057	0.96	0.88, 1.04	0.301

Table.
* Coefficient for HARTS score among persons not taking drugs
† Coefficient for drug use among persons scoring 0 on HARTS

Clinical issues in people who use drugs

PEB224

Correlates of medication for opioid use disorder treatment retention in patients with HIV and opioid use disorder in Northern Viet Nam

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Background: In Viet Nam, over 50% of new HIV infections are attributed to injection drug use. Medications for opioid use disorder (MOUD) are effective in improving both HIV and opioid use disorder (OUD) outcomes, but treatment adherence is low. This study aimed to investigate factors associated with improved MOUD treatment retention.

Methods: From 2015 to 2019, patients in Viet Nam with HIV and OUD were randomized to receive HIV clinic-based buprenorphine or referral for methadone maintenance therapy (MMT) and followed for 12 months. Buprenorphine and MMT doses were directly observed per national guidelines. The primary outcome was MOUD retention, defined as days of MOUD exposure over one year, abstracted from dosing logs. Negative binomial regression was used to model associations between demographics, pain, and social support and MOUD retention.

Results: Of the 281 enrolled participants, 264 (94%) completed all study follow-up visits. Participants were primarily male (97%), unmarried (61%), employed (54%), previously arrested (83%), and previously detained in a compulsory rehabilitation 06 center (59.5%). At baseline, 69% of participants were prescribed antiretroviral therapy, with a mean CD4 count of 408 cells per µL (standard deviation [SD] 221). Participants received a mean 187 (SD 150) days of MOUD with 134 (50.8%) receiving at least 180 days of MOUD in one year. In bivariate analyses, age (incidence rate ratio [IRR]: 1.02, 95% Confidence Interval [CI] 1.01-1.04), income (millions of đồng) (IRR 0.97, 95% CI 0.94-1.00), baseline pain with activities of daily living (IRR 1.35, 95% CI 1.07-1.72), MMT (compared to buprenorphine) (IRR 1.79, 95% CI 1.45-2.21), years since HIV diagnosis (IRR 1.02, 95% CI 1.01-1.04), family support score (IRR 1.14, 95% CI 1.01-1.27), and significant other support score (IRR 1.11, 95% CI 1.01-1.22) were associated with greater MOUD retention. Multivariate models identified age (IRR 1.02, 95% CI 1.00-1.05), income (IRR 0.96, 95% CI 0.93-0.99), and MMT (IRR 1.89, 95% CI 1.49-2.38).

Conclusions: MOUD retention was suboptimal among patients with HIV and OUD. MMT (compared to buprenorphine), age, and social support were associated with greater retention. Countries seeking to expand access to MOUD for people with HIV should consider interventions to support MOUD adherence and retention.

Clinical issues in other vulnerable populations

PEB225

Cardiometabolic risk factor comparison between foreign and native born African American persons with HIV infection in a U.S. urban healthcare setting

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Background: Persons living with HIV infection (PLHIV) are at increased risk for cardiovascular disease, and traditional risk factors are known to differ between racial groups. We aimed to determine whether cardiometabolic risk factors differ between foreign born African Americans (FBAA) and native born African Americans (NBAA), given important social and behavioral differences.

Methods: PLHIV with ≥2 HIV clinic visits between 2010-2017 were included in this retrospective cohort. Data were collected for at least 2 years once patients had HIV RNA <200 cp/mL and prescribed antiretroviral therapy. Clinical characteristics (Table) were collected from the electronic medical record. FBAA was defined as AA race with country of origin anywhere other than the United States. Descriptive statistics were performed, and conditional prevalence was adjusted for age and gender. Adjusted values were compared between racial groups by Chi Square test using Stata 16.

Results: Among 2271 patients, 872 (38%) were White non-Hispanic (W), 639 (28%) NBAA, 17% were FBAA, and 381 (17%) were of other races. Gender distribution differed substantially (Table). Current smoking status was highest among NBAA at 66%, W at 53%, and then FBAA at 11% (p<0.01). Crude prevalence of hypertension and hyperlipidemia are presented in Table. After adjusting for age and gender, hypertension prevalence among NBAA was 37%, compared to FBAA at 25%, and W at 20% (p<0.01). In contrast, adjusted prevalence for hyperlipidemia was lowest among NBAA at 18%, when compared to W (23%; p=0.02), but was not statistically independent from FBAA (20%; p=0.52). Among the proportion of patients on antihypertensives prescribed within 2 years was prescribed to 84% of NBAA, compared to 83% of FBAA (0.7 vs NBAA), and 76% of W (P=0.02 vs NBAA). There was no statistical independence in rates of lipid lowering treatment among those with hyperlipidemia.

Conclusions: In an urban U.S. setting, we describe differences in the prevalence of smoking, hypertension, and hyperlipidemia between FBAA and NBAA. Treatment of hypertension was more common than hyperlipidemia in all racial groups. Distinguishing FBAA and NBAA populations may be important for understanding disparities and optimizing CVD prevention strategies for PLHIV.

COVID-19 morbidity and mortality in PLWH

PEB226

Progression risk in people with HIV and COVID-19: predictive performance of current risk scores

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Background: People living with HIV (PWH) might have a higher risk of adverse coronavirus disease 2019 (COVID-19) outcomes. Several scores were developed to predict COVID-19 progression to critical disease and are often used among PWH. We estimated the rate of progression to critical disease in a multicenter cohort of PWH and COVID-19 and we assessed the performance of two web-based COVID-19 risk equations. Secondarily, we investigated whether we could improve the performance of the risk equations by assigning PWH with low nadir CD4 counts an adjusted score value.

Methods: Participants were identified from a multicenter cohort of 6,361 PWH on regular follow-up at two university hospitals. Of 99 HIV-infected individuals with confirmed SARS-CoV-2 infection during 2020, 63 had complete data and were included in this analysis. CALL and COVID-GRAM scores were calculated and participants were stratified into low, intermediate, and high-risk for each. Discrimination was assessed using receiver operating characteristic curves. Calibration was evaluated using observed-versus-expected ratios and Hosmer–Lemeshow X^2 goodness of fit statistic. Scores were adjusted by increasing one category level in individuals with nadir CD4 lymphocyte count <200/µL.

Results: Participants were predominantly male (87%), Caucasic (73%), with a mean age of 52 (range, 19-77) years. The median nadir and current CD4 counts were 207 (interquartile range, IQR, 119-345) and 440 (IQR 280-719) cells/µL, respectively. Ten (16%) individuals progressed to critical disease and 4 (6%) died. Assessed scores showed acceptable discrimination (area under the curve, 0.701-0.771) and were overall calibrated (observed-versus-expected ratio, O:E, 1.01). However, both overestimated the risk of progression among individuals in the low and high-risk categories (O:E 0.01-0.94), whereas they underestimated the risk in the intermediate category (O:E 1.20-1.21). Thus, 50% of critically ill individuals were not identified as high-risk. Assigning PWH with low nadir CD4 count a higher risk of progression reduced the proportion of individuals not identified to 20%.

Conclusions: COVID-19 risk scores had lower performance in PWH compared to that described in the general population and failed to adequately identify individuals who progressed to critical disease. Adjustment for nadir CD4 partially improved their accuracy. Risk equations incorporating HIV-related factors are needed.

PEB227

Characterizing the impact of COVID-19 among female sex workers living with HIV in Durban, South Africa

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Background: The COVID-19 pandemic reinforces vulnerabilities among those most marginalized, including female sex workers (FSW). FSW living with HIV face multi-level barriers to access and adherence to antiretrovirals and have potentially increased COVID-19 risks due to housing, work environments and TB/HIV history, and are highly vulnerable to socioeconomic impacts of lockdowns. We aim to study COVID-19-related impacts on health and behavior among FSW living with HIV.

Methods: Data were collected among FSW participating in the Siyaphambili trial to optimize ART in Durban, South Africa. FSW were trial-eligible if: >18 years, diagnosed with HIV ≥6 months and non-virally suppressed. An interviewer-administered questionnaire assessed COVID-19-related impacts to health and behavior during a study or intervention visit. Engagement in the trial during the pandemic and COVID-19 impacts were described among those responding to the COVID-19 questionnaire.

Results: Among 777 trial participants, 601 (77.3%) were seen during the pandemic March 27-January 26, 2021; there were no clear associations between trial engagement and housing/venue type, behavioral or socioeconomic factors. Among the 210 FSW completing COVID-19 questionnaires from October 1, 2020–January 26, 2021, the median age was 29 [IQR:27-34] years, 73/210 (34.8%) had been SARS-CoV-2 tested, 3/210 (1.4%) diagnosed, and 2/210 (1.0%) hospitalized due to COVID-19. Almost half (100/210) reported a decreased quality of life due to COVID-19. The majority of participants reported occupational and socioeconomic impacts of COVID-19, including decreases in the number of sexual partners and clients (Figure 1). Access to healthcare and treatment declined among some due to COVID-19, but was accompanied by reduced substance use.

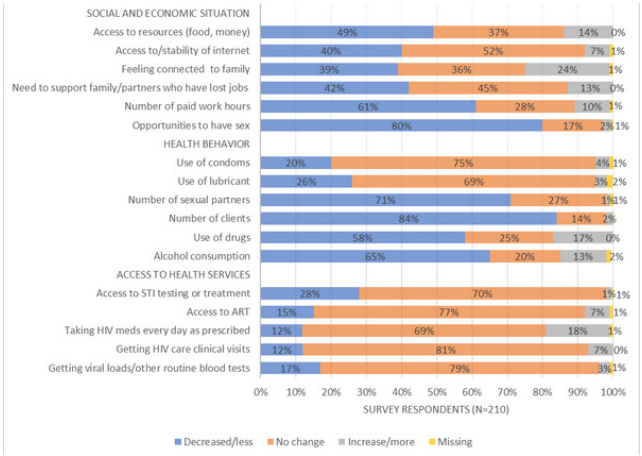

Figure 1. Covid-19 impacts among female sex workers living with HIV in Durban, South Africa

Conclusions: Many FSW are experiencing COVID-19 impacts related to their general wellbeing, occupation, and access to resources. One-third of FSW had been tested for SARS-CoV-2 and a greater understanding of the epidemiology of HIV and COVID-19 among FSW remains to avoid exacerbating health disparities and ensure continued HIV care.

PEB228

Seroprevalence and risk factors of SARS-CoV-2 infection in people living with HIV

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Background: The objective of the study was to describe seroprevalence and risk factors of SARS-CoV-2 infection in people living with HIV (PLWH), in comparison to the general population.
Methods: Consecutive serological assays for SARS-CoV-2 were performed in two large public microbiology laboratories which collect blood samples from the province of Modena, Italy, that comprises 700 000 habitants and 7 hospitals, from 4 May to 30 July 2020. PLWH were offered serological screening for SARS-CoV-2 as a part of the HIV blood test routine including CD4 count and HIV viral load, performed at Modena HIV clinic. The outcome was a positive serology for SARS-CoV-2 defined as IgM and/or IgG positivity in the last blood sample available per each individual.
Results: 57794 serological assays were performed in 37259 people. The overall seroprevalence for SARS-CoV-2 was 5% (1869/35390): 2.9% in PLWH and 5.1% in the general population respectively (p=0.003) (Table 1). In the logistic multivariable model, SARS-CoV-2 seroprevalence was positively associated with migrant status vs Italians (OR: 1.380, 95%IC 1,202-1.585; p<0.001) and negatively associated with HIV status vs general population (OR: 0.562, 95%IC 0.386-0.817; p=0.003). No correlation was observed for age (OR: 1.002; 95%IC 0.999-1.006; p=0.238) and gender (OR: 0.982; 95%IC 0.888-1086; p=0.728). In the subset of PLWH, in the logistic multivariable model, SARS-CoV-2 seroprevalence was positively associated with migrant status vs Italians (OR: 2.601; 95%IC 1.084-6.240; p=0.032); while sex (males vs female OR: 0.534; 95%IC 0.248-1.149; p=0.109) or age (OR=1.002; 95%IC 0.965-1.041; p=0.909) were not.

	HIV negative (N+36275; 97.4%)	HIV positive (N=984; 2.6%)	Total (N=37259, 100%)	p
Male sex, N (%)	14600 (40.2)	691 (70.2)	15291 (41.0)	<0.001
Age, years, median (IQR)	50 (37-60)	54 (46-59)	50 (37-60)	<0.001
Migrants, N (%)	3905 (10.8)	174 (17.7)	4079 (10.9)	<0.001
Positive COVID-19 serology, N (%)	1840 (5.1)	29 (2.9)	1869 (5.0)	<0.003

Table.

Conclusions: In PLWH, migrants had double probability for SARS-CoV-2 infection, while viro-immunological parameters as well as different antiretroviral regiment were not associated with occurrence of COVID-19. These data provide a public health warning to identify migrant population as the most vulnerable group. Properly designed prevention strategies are needed in these individuals independently from HIV status.

PEB229

Mortality COVID-19 in people living with HIV in a private insurance carrier in Colombia

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Background: On March 06,2020, the first case of COVID-19 infection was confirmed in Colombia. Since then, more than 2 million new cases and 57000 deaths have been reported due to COVID-19 up to the time of this article. There are more than 103000 people living with HIV in Colombia, from whom 129 have died due to COVID-19 so far as reported by the Colombian National Institute of Health. Here we describe a cohort of HIV patients cared under a private insurance carrier in Colombia who developed COVID-19 and evaluate predictors of death.
Methods: Prospective Cohort Study following patients affiliated with a health plan insurance carrier in Colombia, with presence in 16 cities and covering more than 11000 people living with HIV. Data was collected for 90 days or until death from new or existing HIV infected individuals diagnosed with COVID-19 confirmed by PCR between March 06,2020 and September 30,2020.
Results: Of 11088 people living with HIV covered by the insurance carrier, 429 were diagnosed with COVID-19 infection. Data was accrued up until December 31,2020, with a total of 334 person-years of follow-up. Among this cohort there were 12 deaths reported. The presence of chronic diseases was found to be significantly associated with death for Hypertension (p- value=0.004) and Diabetes (p-value= 0,003). As for HIV-related predictors, presence of Anti Retroviral Therapy (ART) at the time of the COVID-19 infection showed significant association (p- value<,0001): 1.7% of those on ART at the time of COVID-19 infection died, compared to 21.7% of those not receiving ART. ART was significantly associated with recovery (p- value<0,0001). There were no significative differences in outcomes according to ART type.
Conclusions: In this cohort of patients living with HIV affiliated with a private Health Care insurance carrier in Colombia, the relative risk of death due to confirmed COVID-19 was 10 times higher among those not received ART at the time of COVID-19 diagnosis, compared to those receiving ART, after adjusting for comorbidities such as Hypertension and Diabetes. There were no significant differences related to the type of ART received.

Track C

Epidemiology of HIV in the general population

PEC230

Trends in HIV mortality between 2001 and 2018: an observational study

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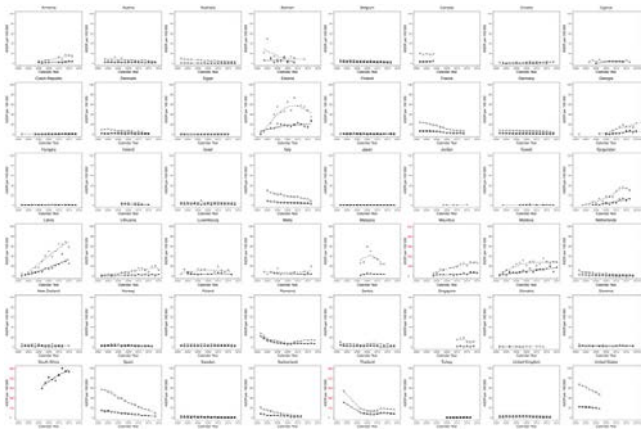
Background: Around 32.7 million people have died due to HIV since the start of the epidemic. HIV/AIDS has previously been the leading cause of death in many developed countries, subsequently gradually moving down the list. Currently it remains among the top 10 leading causes of death in low-income countries. The objective of this study was to describe current mortality rates for HIV in 48 countries.

Methods: We extracted HIV mortality data from the WHO Mortality Database, region-wise, based on the International Classification of Diseases 10 codes. Crude mortality rates were dichotomized by gender and reported by year. We computed Age Standardized Death Rates (ASDRs) per 100,000 population using the World Standard Population. We computed mortality rates and used locally weighted scatterplot smoothing (LOWESS) plots fit to the rates of male and female mortality using SAS v9.4 (SAS, Cary, NC).

Results: Out of 48 countries, 31 countries (64.6%) and 35 countries (72.9%) showed decreases in mortality in males and females, respectively. Amongst 48 countries, South Africa had the highest ASDRs for both males (467.7/100,000) and females (391.1/100,000), whereas the lowest mortalities were noted in Egypt for males (0.2/100,000) and in Japan for females (0.01/100,000). Kyrgyzstan had the greatest increase (+6998.6%) whereas Spain had greatest decease in male mortality (-81.89%). Estonia had the greatest increase (+5877.6%) whereas Australia had largest reduction in female mortality (-93.80%). Disparity in ASDR between Egypt and South-Africa was 2,338-folds for males whereas it was 39,110-folds for females between Japan and South Africa.



Squares and circles indicate ASDR/100000 for males and females respectively.

Conclusions: Although there has been a decrease in mortality attributed to HIV among most of the countries studied, a rising trend remains in a number of developing countries. A renewed and heightened commitment to address this ongoing epidemic by these countries, healthcare agencies and the global community is called for.

PEC231

Time-space cluster investigation using data from a recent infection surveillance system in 5 districts in Namibia, during July 2019 – February 2020

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Background: Assays that detect recent HIV infections (seroconverting in last 12 months) may efficiently guide prevention activities, including index partner testing (IPT) and pre-exposure prophylaxis (PrEP), in areas with active HIV transmission. We present data on the first time-space cluster investigations of recent HIV infection in 5 districts of northern Namibia.

Methods: Beginning in 07/2019, the Ministry of Health and Social Services and PEPFAR's Tracking with Recency Assays to Control the Epidemic initiative launched a surveillance system at 42 sites in 5 districts. Persons aged ≥16, newly diagnosed HIV-positive were offered a rapid test for recent infection (RTRI) with viral load testing done centrally. After data quality verification, sites meeting 3 criteria were prioritized for investigation: new diagnoses >2 Standard Deviations above the running quarterly mean for the site, recent infections >5% during the study period, and having populations at high risk. Data on IPT, anti-retroviral treatment (ART) retention, and PrEP uptake were abstracted from client records of those diagnosed from 07/2019-02/2020 at two prioritized sites.

Results: Two sites meeting the priority criteria and were investigated. Site 2 was located near the Angola border and Site 1 centrally located in the north.

Indicator	Site 1	Site 2
Number newly diagnosed	29	51
Number (%) initiated on ART	29 (100)	50 (98)
Number (%) defaulting within 6 months	9 (31)	17 (34)
Number of sex partners named (% elicitation)	24 (83)	36 (71)
Number (%) of sex partners tested	21 (88)	21 (58)
Number (%) of partners testing positive	1 (5)	11 (52)
Number (%) of positive partners linked to ART	1 (100)	10 (91)
Number (%) of negative partners linked to PrEP	5 (25)	0 (0)

Table: HIV services data outcomes by site, newly diagnosed clients

Conclusions: Recent HIV infection surveillance enabled rapid time-space cluster investigation in 2 sites. Initial results point to high potential for recent infection surveillance to optimize IPT based on the yield of partners testing, newly diagnosed, and linked to ART. Challenges in ART retention, PrEP uptake, and cross-border health-service seeking may contribute to ongoing HIV transmission.

PEC232

Progress and setbacks in HIV/AIDS mortality in Mexico from 1990 to 2019

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Background: Mortality is the key indicator for evaluating the impact of government programs to control the HIV/AIDS epidemic. Countries with universal and free access to HAART should achieve a constant reduction in HIV mortality. The aim is to analyze the recent trend of HIV mortality in Mexico.

Methods: Official mortality records (INEGI) and population estimates (CONAPO) were used to calculate HIV/AIDS mortality rates by sex and region. JoinPoint software was used to analyze trends in mortality.

Results: From 1990 to 2019, Mexico registered 129,615 deaths due to HIV/AIDS. The highest mortality rate was registered in 2008. From 2008 to 2017 the mortality decreased significantly in both men (-17.7%) and women (-22.6%).

However, from 2017 to 2019, mortality increased in both sex >10% in only two years. This increase means returning to the mortality rates of 2013, a six-year setback.

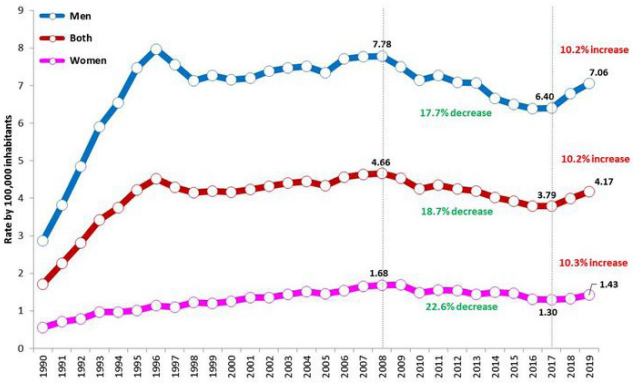

Figure 1. HIV/AIDS mortality in Mexico by sex from 1990 to 2019

From 2017 to 2019, Mexican States of Quintana Roo (10.5 per 00,000 inhabitants), Campeche (9.3) Veracruz (8.3), Colima (8.1), Baja California (7.9) and Tabasco (7.8) had the highest rates.

It is unacceptable that the highest mortality rate (Quintana Roo) was 7.5 times higher than the lowest rate (Zacatecas). In addition, 25 of 32 states increased their mortality rate in the last two years, some with increases >40%.

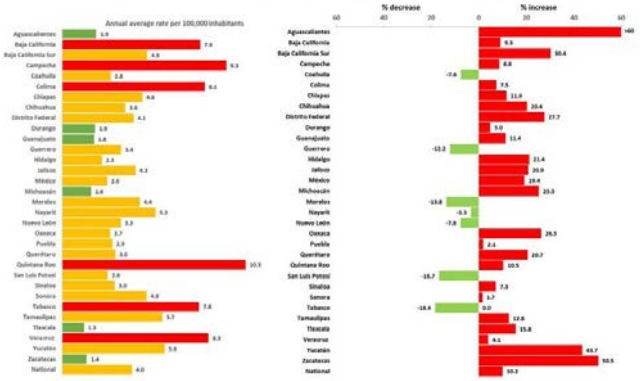

Figure 2. HIV/AIDS mortality in Mexico by state from 2017 to 2019

Conclusions: Declining trend in HIV/AIDS mortality has been reversed. The decrease in timely detection of HIV in key populations, coupled with a significant shortage of antiretroviral drugs, have led to an increase in mortality. It is urgent to change course and resume what had been working.

Epidemiology of HIV in paediatric and adolescent populations

PEC233

Estimating the population size of children of female sex workers: An analysis of ten countries across sub-Saharan Africa

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Background: Across sub-Saharan Africa, female sex workers (FSW) experience a high burden of HIV and a high incidence of pregnancies, with studies indicating the majority of FSW are mothers and primary caregivers. Disproportionate HIV prevalence among FSW and barriers to accessing HIV testing/treatment suggest that their infants may be at higher risk of vertical HIV acquisition.

Globally, 109,940 FSW were newly diagnosed through PEPFAR support in 2020, but their children remain largely invisible from programming. Estimating the number of children (0-14 years) of FSW (cFSW) is critical to inform programming needs for this vulnerable population.

Methods: Relevant indicators for ten countries were assessed from Integrated Biological and Behavioral Surveillance (IBBS) data and IBBS reports. With support from PEPFAR/USAID through the EpiC project, we collated national and subnational extrapolated size estimates for FSW and FSW living with HIV, which we previously derived for each country using imputation methods and regression modeling of existing direct size estimates. To calculate the number of cFSW for each country, extrapolated FSW size estimates were multiplied by the reported mean number of biological living children.

Results: The mean number of biological living children per FSW varied across ten countries (range 1.0-2.7). The overall proportion of FSW living with HIV was lowest in Ghana (0.016%); highest in Zambia (1.7%). The estimated size of cFSW ranged from 14,703 in Togo to 261,428 in South Africa, a high proportion of which were potentially exposed to HIV (Figure 1).

Country	FSW Size Estimate (number)	FSW Size Estimate (percent)	HIV Prevalence, ages 15-49 (percent)	HIV Prevalence among FSW (percent)	FSW Living with HIV (number)	FSW Living with HIV (percent)	Biological Living Children Mean (SD)	Children of FSW Size Estimate (number)	Children of FSW with Mothers Living with HIV Size Estimate (number)
Burkina Faso	59820	1.17	0.7	15.4	9212	0.18	1.5 (SD 1.5)	89730	13818
Côte d'Ivoire	125042	2.4	2.4	7.5	9378	0.18	1.8 (SD 1.2)	225075	16881
Ghana	20432	0.23	1.7	6.9	1410	0.016	1.0 - 1.5 (.)	30648	2115
Liberia[1]	19086	1.62	1.5	9.8	1870	0.16	1.9 (.)	38263	3354
Malawi	17763	0.53	8.9	62.7	11137	0.33	1.6 (SD 1.2)	27592	17820
Mali[1]	21618	1.5	1.2	8.7	1881	0.13	1.9 (.)	41074	3573
Senegal	15432	0.7	0.4	5.9	911	0.04	2.7 (SD 1.8)	41668	2458
South Africa	145238	1.01	19.0	37.4 - 74.7	68483	0.62	1.8 (SD 1.1)	261428	159270
Togo	10562	2.32	2.2	10.7	1066	0.21	1.4 (SD 1.4)	14703	1492
Zambia[2]	133566	3.34	11.5	50.7	67886	1.7	1.6 (SD 1.2)	200349	101830
Total	568499				193234			968530	322811

[1]Mean number of biological living children among FSW approximated using an average of four countries in West Africa for which data were available: Togo, Burkina Faso, Senegal, Côte d'Ivoire.
[2]Mean number of biological living children among FSW approximated using available data from Malawi.

Figure 1. Size estimates of FSW and children of FSW across ten countries in sub-Saharan Africa

Conclusions: Given substantial HIV vulnerabilities among cFSW, these results can directly inform the size of tailored HIV services among cFSW with a focus on eliminating vertical HIV transmission and supporting early HIV diagnosis among children. Given their substantial numbers and risk, incorporating cFSW into key populations programming and co-ordination with orphan and vulnerable children programs may play a central role in achieving the UNAIDS 95-95-95 goals.

PEC234

A cohort analysis of HIV and mortality incidence among orphaned, separated, and street-connected children and adolescents in western Kenya: association with care environment

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Background: We compared the HIV and mortality risk among orphaned and separated children and adolescents (OSCA) living in Charitable Children's Institutions (CCI) (i.e. orphanages and rescue centers), family-based settings (FBS), and street-connected children and youth (SCY).
Methods: This prospective cohort study followed OSCA from 300 randomly selected households (FBS), 19/21 CCI's registered in the county at the time of study initiation, and 100 conveniently sampled SCY in Uasin Gishu (UG), Kenya from 2010-2019. We fit survival regression models to investigate the association between care environment and incidence of HIV, death, and HIV-free survival. HIV counseling and testing was offered as part of annual assessments. Mortality ascertainment was conducted through study-dedicated community health workers.
Results: The analysis includes 2551 participants: 1230 in FBS, 1230 in CCI's, and 91 SCY. Overall, 52% were male, mean (standard deviation) age at baseline of 10.4 (4.8) years. The majority of participants in CCI's (85%) and SCY (78%) were double orphans. There were 59 participants who acquired HIV or died. After adjusting for gender and baseline HIV status, OSCA in CCI's were less likely to die (AHR: 0.23, 95%CI:0.06-0.89), and neither more nor less likely to acquire HIV (AHR:1.28, 95%CI:0.38-4.31). Compared to FBS, SCY were 7.11 (95%CI:3.00-16.81) times more likely to die, 21.25 (95%CI:8.73-51.67) times more likely to acquire HIV, and nearly ten times more likely (AHR:9.96, 95%CI:5.03-19.73) to die or acquire HIV.
Conclusions: OSCA living in CCI's in this setting have lower mortality compared to those in FBS, while SCY have higher mortality and HIV. In order for safe and effective deinstitutionalization to be implemented at scale, child protection systems need urgently to be strengthened alongside greater investments in evidence-based family supports that improve child and adolescent health and prevent their migration to the street.

Epidemiology of HIV in men who have sex with men

PEC235

Comparisons of associations between incarceration and sexual risk behavior and STI/HIV among Black sexual minority men in Six U.S. cities (HPTN 061)

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Background: Few studies have evaluated longitudinal associations between incarceration and post-release STI/HIV risk among Black sexual minority men (BSMM). We measured associations between recent incarceration and STI/HIV-related sexual risk behavior and incident STI/HIV in the six months post release among BSMM.
Methods: We used data from the HIV Prevention Trials Network (HPTN) 061 study conducted among BSMM in six US cities (Atlanta, Boston, Los Angeles, New York City, San Francisco, and Washington D.C.), restricting to those who returned for the six-month follow-up visit (N=1169). Recent incarceration was defined as having spent ≥one night in jail/prison in the past six months at six-months follow-up. Outcomes were measured at the 12-month follow-up and included multiple (≥two) partners; selling or buying sex; condomless anal intercourse with an HIV-positive or unknown status partner; and rectal and/or urethral infection with chlamydia and/or gonorrhea, syphilis infection, or HIV acquisition. We calculated adjusted risk ratios (ARRs) and 95% confidence intervals (CIs) to measure associations between recent incarceration and post-release STI/HIV risk using inverse probability of treatment weighting. We explored differences by city, and among BSMM who had sex with men only (BSMMO), BSMM who had sex with men and women (BSMMW), and Black transgender people (BT).
Results: Approximately 14% reported incarceration in the past six months. Incarceration was associated with selling sex (aRR=1.80, 95%CI: 1.12, 2.86) with strong associations in Washington DC (aRR=7.62, 95%CI: 1.58, 36.72) and Boston (aRR=3.09, 95%CI: 1.41, 6.79). Incarceration was associated with multiple partnerships among BSMMW (aRR=1.35, 95%CI: 1.12, 1.64) and BT (aRR=1.74, 95%CI: 1.21, 2.50). Incarceration was associated with incident gonorrhea (aRR=2.44, 95%CI: 0.99, 5.99), with particularly strong associations observed in Los Angeles (aRR=6.48, 95%CI: 1.48, 28.42).
Conclusions: There is evidence the inequitable burden of incarceration among BSMM plays a role in sexual risk-taking and STI/HIV risk in this population. Researchers, practitioners, and policy makers should establish and maintain collaborative relationships with criminal justice systems to expand provision of STI/HIV services (e.g., STI testing and treatment), and there is a need for social justice efforts and intentional criminal justice reform to focus on the needs of Black people to improve health equity.

PEC236

Geographical disparities in trends in national HIV diagnoses among gay, bisexual, and other men who have sex with men in Australia, 2014–2018

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Background: Australia aims to virtually eliminate HIV transmission, and has seen successes in scale-up of HIV pre-exposure prophylaxis (PrEP), testing, and treatment among gay, bisexual, and other men who have sex with men (GBMSM; Australia's primary at-risk population). However, evidence has suggested disparities in testing and PrEP uptake according to geography and engagement with gay community.
Methods: We examined national HIV diagnoses among GBMSM between 2014–2018. 'Newly-acquired infections' were defined as new diagnoses with evidence of a negative/indeterminate antibody test or reporting of symptoms consistent with seroconversion illness, in the last 12 months. Using a published method, we classified Australian postcodes as: gay capital city postcodes ('gay postcodes'; in which >5% of resident men were estimated to identify as gay); other capital city postcodes (OCC); or regional, rural, or remote postcodes (RRR).
Results: GBMSM HIV diagnoses declined by 29% overall (from 808 to 571), by 42% in gay postcodes (266–154), 28% in OCC (391–283), and 14% in RRR (135–116). Newly-acquired infections declined by 50% overall (380–190), with greater geographical disparities: they decreased by 70% in gay postcodes (162–48), 46% in OCC (166–90), and increased by 12% in RRR (43–48). There was a relationship between country of birth and postcode: newly-acquired diagnoses decreased by 66% among Australian-born GBMSM in gay postcodes (74–25), 33% among overseas-born GBMSM in gay postcodes (33–22), 26% among Australian-born GBMSM in non-gay postcodes (112–83), and increased by 72% among overseas-born GBMSM in non-gay postcodes (32–55).
Conclusions: Recent successes in HIV prevention have been influenced by geography. There were dramatic decreases in diagnoses, especially newly-acquired infections, among GBMSM living in areas with high concentrations of gay-identified men, and it may be possible to micro-eliminate new HIV transmissions in these areas. However, declines have been smaller in non-gay postcodes, and newly-acquired infections have actually increased in regional areas and among overseas-born GBMSM in non-gay postcodes. GBMSM living outside of capital city gay postcodes, especially those born overseas, need targeted HIV prevention efforts, including improvements to PrEP accessibility and HIV testing.

PEC237

Key correlates of lifetime HIV testing among young men who have sex with men in Seoul, South Korea

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Background: In the last 10 years, new HIV diagnoses in Korea have increased by 50%. Young Men who have Sex with Men (YMSM) are disproportionately impacted by HIV. While HIV testing can serve to link YMSM to prevention (e.g., PrEP) and care services, national estimates suggest that only 38% of MSM in Korea have ever tested for HIV. Given scant literature about Korean YMSM's HIV testing behaviors, we examined the prevalence of HIV testing and its association to sociodemographic and behavioral correlates in a sample of Korean YMSM.
Methods: Korean YMSM living in Seoul metropolitan area (N=180) were recruited from September to November 2020 through online advertisements and invited to participate in a brief online survey. The survey included questions related to their sociodemographic characteristics, HIV prevention behaviors, and sexual behaviors. Descriptive statistics and chi-squared tests were used to compare participants who have never tested for HIV with those who have.
Results: The mean age was 26.5 years (SD=4.2). A majority of YMSM completed military service (73.9%) and self-identified as gay (91.7%). More than half of YMSM were university graduates (52.8%), had low income (58.1%), and did not have a partner (57.8%). Two-thirds (67.2%) had tested for HIV. Key correlates associated with lifetime HIV testing were older age (p=0.0003), completion of military service (p=0.0198), higher income (p=0.0005), being gay (p=0.0435), and higher attachment to LGBT community (p=0.0078). Lifetime HIV testing was correlated with STI testing (p<0.0001), likelihood to test for HIV in the future (p<0.0001), and awareness of both home-based HIV testing (p<0.0001) and PrEP (p<0.0001). In addition, YMSM who had tested for HIV reported higher self-efficacy to test for HIV (p<0.0001), willingness to self-test at home (p=0.0008), and positive norms regarding HIV testing (p<0.0001).
Conclusions: Our findings underscore the need to strengthen HIV testing efforts for YMSM. Strategies to address sociodemographic disparities in HIV testing are needed. HIV prevention interventions that leverage HIV testing self-efficacy and norms may increase HIV testing rates, improve access to HIV testing, and ultimately reduce HIV disparities among YMSM in Korea.

PEC238

Geographical differences in uptake of HIV testing and PrEP among high risk gay and other men who have sex with men by gay population concentration in New South Wales, Australia

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Background: HIV surveillance data in NSW have shown that recent declines in HIV notifications have been greatest in areas with higher residential concentrations of gay men. We analysed self-reported data on HIV testing and PrEP uptake among gay, bisexual and other men who have sex with men (GBMSM) using estimates of the proportions of gay men resident in each NSW suburb.
Methods: We estimated the number and proportion of gay males among adult men by postcode by combining data from the 2016 Australian Census and self-reported population surveys. We grouped postcodes into three categories: >20%, 5-19.9%, and <5% adult male residents estimated to be gay. We report HIV testing in the previous 12 months and PrEP uptake from annual behavioural surveillance surveys of high-risk gay and bisexual men (i.e. reported condomless anal sex with casual partners in the previous six months), recruited at gay venues, events and online between 2015 and 2019. We used logistic regression to assess differences in trends over time and chi-square tests to assess differences between suburb categories within each year.
Results: Of the adult male population in NSW in 2016, 1.8% (52,893) were estimated to be gay-identified. 12,218 (23.1%) lived in postcodes where >20% of adult males were estimated to be gay, 12,434 (23.5%) in post-

	Proportion of adult males estimated to be gay per postcode	HIV testing among high risk GBMSM in previous 12 months – 2015 (%) N=503	HIV testing among high risk GBMSM in previous 12 months – 2019 (%) N=1066	Odds ratio (p-value)	PrEP use in previous six months among high risk GBMSM– 2015 (%) N=432	PrEP use in previous six months among high risk GBMSM – 2019 (%) N=986	Odds ratio (p-value)
Sydney Gay community Periodic Survey (self-reported population survey data)	<5%	79.2	89.4	1.21 (p<.001)	3.5	53.9	2.13 (p<.001)
	5-19.9%	81.2	94.0	1.36 (p<.001)	9.3	71.2	2.17 (p<.001)
	>20%	88.2	96.7	1.36 (p<.001)	2.5	73.9	2.20 (p<.001)
	Chi-square test result (*p-value*)	χ^2 =5.3, p=.069	χ^2 =17.3, p<.001		χ^2 =6.3, p=.043	χ^2 =38.4, p<.001	

PEC238 Table 1

codes where 5-19.9% were gay, and 28,241 (53.4%) in postcodes where <5% were gay. Between 2015 and 2019, HIV testing and PrEP uptake among high risk GBMSM increased in each suburb category. PrEP uptake was higher in suburbs with higher concentrations of gay men in 2015, and testing and PrEP uptake was higher in gay suburbs in 2019 (Table 1).

Conclusions: HIV prevention methods have been better adopted in suburbs with higher concentrations of gay men in NSW but need to be better targeted to GBMSM in suburbs with lower concentrations of gay men. New methods may need to be adopted by program implementers to reach higher proportions of GBMSM in suburbs with lower concentrations of gay men.

Epidemiology of HIV in people who use drugs

PEC239

Ongoing HIV transmission following a large HIV outbreak among people who inject drugs in Athens, Greece

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Background: In 2011-2013, an outbreak of HIV infection among People who Inject Drugs (PWID) occurred in Athens, Greece. This was the largest epidemic documented in this population in Europe and North America since 2010. Several interventions were implemented in Athens, and HIV incidence declined from 7.8 in 2012 to 1.7 cases/100 person-years in 2013. We aim to provide updated estimates of HIV incidence/prevalence up to 2020.

Methods: Two "seek-test-treat" community-based programs were implemented in 2012-2013 (ARISTOTLE, N=3,320) and 2018-2020 (ARISTOTLE HCV-HIV, N=1,635) aiming to reach rapidly PWID through Respondent-Driven Sampling and increase diagnosis/linkage to care for HIV/HCV. ARISTOTLE HCV-HIV was interrupted due to the national lockdown (March 2020). Participation included interviewing, anti-HIV testing and sequencing, and linkage to care. Multiple recruitment rounds were implemented (5 in 2012-2013, 2 in 2018-2020). PWID could participate in multiple rounds but only once in each round. Thus, multiple HIV tests/questionnaires were available over time for the majority of participants. To estimate HIV incidence after 2012-2013, we analysed initially seronegative participants with at least two available tests (N=701) using as seroconversion time the midpoint between the last negative/first positive test. Cox proportional hazards model was used to assess risk factors for seroconversion. We estimated the change in HIV prevalence from 2012-2013 to 2018-2020 in a sub-sample participating in both programs.

Results: At their first visit, participants' mean (SD) age was 35.8 (7.7) years, 79.9% were active injectors, 78.3% reported heroin as the main substance injected and 15.0% were on opioid substitution programs. HIV incidence (95% CI) for the periods 2012-February 2019 and August 2019-February 2020 was 1.98 (1.48–2.65) and 3.26 (1.81–5.89) new cases/100 person-years, respectively (N=59 seroconversions). Younger age, lower educational level, unemployment, larger injection network and daily injecting were associated with increased risk of HIV seroconversion. HIV prevalence (95%CI) increased from 14.2% (11.7%-17.1%) in 2012-2103 to 22.0% (19.0%-25.3%) in 2018-2020 (p<0.001).

Conclusions: There is ongoing HIV transmission among PWID in Athens, Greece. The increasing HIV prevalence in the era of the COVID-19 pandemic that has seriously compromised access to care and HIV-testing underlines the need for immediate action.

PEC240

Estimated HIV prevalence and incidence among people who inject drugs in Thessaloniki, Greece (ALEXANDROS program)

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Background: A community-based program is implemented in Thessaloniki (the second-largest city in Greece) since September 2019 with the aim to increase diagnosis and treatment for HCV/HIV among People Who Inject Drugs (PWID). HIV prevalence in people accessing drug treatment programs in Thessaloniki was 1.1% and 0.7% in 2017 and 2018, respectively. This analysis aims to estimate HIV prevalence and incidence in a sample of PWID participating in the program during September 2019-October 2020.

Methods: ALEXANDROS is a "seek-test-treat" community-based program where PWID are recruited through Respondent-Driven Sampling. Participation includes interviewing, rapid HIV/HCV test, other blood testing and counselling. The personnel and peer navigators support patients to linkage and retention to HIV/HCV treatment. During September 2019–October 2020, two consecutive recruitment rounds were conducted, with a short break in-between. Individuals could participate in both rounds but only once in each round. We analysed data from 843 unique

PWID participating in either or both rounds. To estimate HIV incidence, we analysed data from 164 initially seronegative PWID who participated in both rounds. The seroconversion time was estimated as the midpoint of the interval between the last negative and first positive test date.

Results: Participants had a mean (SD) age of 40.6 (8.6) years; 56.0% were current PWID (injection in the past 30 days), 16.4% were homeless and 2.9% reported having received syringes in the last 12 months. HIV prevalence (95% CI) was 4.9% (3.5%-6.5%) (41/843). Of those, 68.3% (28/41) were newly diagnosed cases and 46.4% of them (13/28) were identified within the first four months following the first national lockdown due to COVID-19 in Greece in March-May 2020. In 164 initially seronegative in the first round, there were 8 seroconversions (HIV incidence [95% CI]/100 person-years: 6.9 [3.4-13.8]).

Conclusions: ALEXANDROS was successful in reaching rapidly a large number of PWID most in need and in offering HIV/HCV testing and linkage to care. The high HIV incidence and the large proportion of newly diagnosed cases indicate the occurrence of an HIV outbreak in PWID in Thessaloniki that coincides with the COVID-19 pandemic and the implementation of social distancing measures.

PEC241

Low recency in HIV testing among injection opioid users seeking treatment: associated characteristics and implications for HIV prevention

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Background: Injection drug use continues to be a significant source of HIV transmission, with COVID-19-associated increases in opioid use potentially exacerbating the epidemic in the United States. While HIV prevention in high-risk groups includes reinforcing the need for adequate testing and reducing associated individual barriers such as fear and stigma, there is a need to better understand factors associated with HIV testing, or lack thereof, among injection opioid users seeking treatment.

Methods: Individuals newly entering one of 96 treatment centers across the United States for opioid use disorder (N=2,840) in 2018-2020 were surveyed on history of HIV/STI diagnosis/treatment, sociodemographic variables, opioid use behaviors and other risk behaviors such as injection opioid use and transactional sex.

Results: Of treatment-seeking injection opioid users (n=1,251), 12.4% had never been tested for HIV and 38.1% had not been tested in over three months. Demographically, injection opioid users with no history of being tested for HIV were significantly more likely to be sexual minorities, younger and less educated than those with a history of HIV testing. In addition, this group also had significant associations with their social network, with greater likelihoods of having healthcare coverage under another individual, using social networks as a primary source of opioids, and seeking treatment as a result of pressure from their social network. Finally, these individuals were significantly more likely to engage in transactional sex for drugs, have a lifetime diagnosis of syphilis or gonorrhea, and have a lack of any testing for Hepatitis C.

Conclusions: Low recency in HIV testing in over half of this sample of treatment-seeking injection opioid users highlights a need for opioid treatment programs to include HIV/STI testing services as part of managed care. Injection opioid users with no lifetime history of HIV testing represent a group with unique barriers, particularly among sexual minorities and those engaging in transactional sex. Greater engagement with social networks among young adults may have resulted in fears of disclosure and avoidance of HIV testing, underscoring the continued need for opioid treatment/harm reduction programs to promote anti-stigma campaigns and link injection opioid users to HIV prevention.

Epidemiology of HIV in other vulnerable populations

PEC243

Associations between individual and partner-level mobility, household food insecurity and women's transactional sex behavior: an analysis from six African countries

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Background: Women experiencing food insecurity demonstrate higher rates of migration and HIV infection in sub-Saharan Africa, as they may travel to seek economic opportunity and may have sex in exchange for material support. We assessed the relationship between mobility, food insecurity and transactional sex (TS) to understand mechanisms of HIV risk.

Methods: Data were pooled from 2016-2017 Population-based HIV Impact Assessments (PHIAs) in Eswatini, Lesotho, Namibia, Tanzania, Uganda and Zambia. Overall, 27,378 women were linked to their cohabitating or marital male partner using respondent ID and reported marital status. Survey-weighted logistic regressions evaluated the association between women's or their partner's mobility (away from home for one month or more in the past year) and TS (selling sex or exchanging sex for material support in the past year). Models were adjusted for individual (age, education, employment), partner-level (age) and household (food insecurity, wealth, economic support, household head gender, urban) variables. Results were stratified by food insecurity (hunger, lack of food or missing meals in the past month).

Results: Prevalence of TS was 8.0% (95% CI: 7.4 – 8.6%) among women linked to partners. Women were mobile in 8.8% (8.3 – 9.4%) of partnerships, while male partners were mobile in 12.6% (11.8 – 13.3%), and both partners were mobile in 2.3% (2.0 – 2.6%) of partnerships. Both mobile women with (aOR = 1.36 [0.94 – 1.97]) and without (aOR = 1.34 [1.07 – 1.67]) mobile partners were more likely to have TS compared to non-mobile women with non-mobile partners. Non-mobile women with mobile partners were not more likely to engage in TS (aOR = 0.91 [0.74 – 1.12] 1.12 [0.91 – 1.38]). Food insecurity, experienced by 18.2% (17.2 – 19.3%) of households, was associated with women's TS (aOR = 1.31 [1.11 – 1.53]). However, mobile women without mobile partners in food insecure households were not more likely to engage in TS compared to non-mobile counterparts (aOR = 0.90 [0.50 – 1.64]).

Conclusions: Women's mobility, but not their partner's, is associated with TS. Food insecurity is associated with TS irrespective of mobility. Multilevel interventions promoting gender-equitable food access and economic resilience are needed to address food insecurity and its consequences on mobility, TS and HIV risk.

PEC244

Prevalence of HIV, viral hepatitis and tuberculosis in prisons in the European Union: a multi-stage systematic review and meta-analysis

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Background: Behavioral and structural factors create situations in which people living in prisons are more likely to acquire major infectious diseases including HIV, viral hepatitis B and C, and tuberculosis (TB). The present study aimed to estimate the prevalence of these major infectious diseases in prisons in the European Union (EU) countries.
Methods: In line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria, we systematically searched 4 databases of peer-reviewed publications (MEDLINE (PubMed), ISI Web of Science, EBSCO, and ScienceDirect) and 53 databases containing gray literature to collect data published from January 2008 to August 2018. Estimates of biologically confirmed HIV, viral hepatitis B and C, and TB were extracted from identified reports.
Results: A total of 23,969 documents (17,297 papers and 6,672 gray documents) were identified and reviewed, of which 101 were included in qualitative synthesis and 48 were included in the meta-analysis. According to the meta-analysis, the overall HIV prevalence was 3.06% (95% Confidence Interval (CI): 2.82%-3.31%), 3.29% (2.17%-4.41%) among male prisoners, and 3.74% (0.81%-6.66%) female prisoners. The overall HBV prevalence was 2.59% (2.27%-2.92%), 4.44% (2.75%-6.13%) among male, and 2.52% (1.04%-3.99%) female prisoners. Overall prevalence of HCV was 12.36% (11.81%-12.91%), while the prevalence was 20.36% (16.86%-23.85%) among male, and 15.26% (7.66%-22.86%) female prisoners. The overall TB prevalence was 0.73% (0.58%-0.88%), while due to the lack of data we were unable to estimate the prevalence of TB by gender.
Conclusions: Compared with the latest estimates of the European Centre for Disease Prevention and Control (ECDC), our findings reveal that HIV, hepatitis B, hepatitis C, and tuberculosis in prisons are 546, 432, 1405, and 72-folds more prevalent than among the general population of the EU, respectively. The excessively high prevalence of HIV, hepatitis B and C, and TB is a serious cause for public health concern in the EU. Urgent and concrete actions are required to mitigate the burden of the major infectious diseases in prisons and ensure appropriate access to prevention and care for people exiting detention facilities in this region.

Risk factors for acquisition, infectivity and transmission of HIV

PEC245

Geosocial networking app use is correlated with increased high-risk sexual behaviors and prevalence of HIV among Chinese MSM university students: a mixed offline and online cross-sectional survey

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Background: Men who have sex with men (MSM) are a high-risk population for HIV infection and usually seek male sexual partners through mobile geosocial networking (GSN) apps. The HIV infection prevalence is increasing rapidly among Chinese MSM university students, and there is limited research on the association of GSN app use and HIV-related high-risk sexual behavior and HIV prevalence among MSM university students.
Methods: Chinese MSM university students were recruited using mixed online (through six WeChat public accounts) and offline (through attendance at the voluntary counseling and testing (VCT) clinic) methods from 2017 to 2019. Data on sociodemographic, sexual behavior, use of GSN apps, and eligibility for PrEP was collected. Participants after providing written informed consent were tested for HIV and syphilis, either through self-testing kits or rapid tests at the VCT clinic, and positive cases were confirmed at the study site laboratory.
Results: Of the 771 eligible MSM university students, 76.3% (n=588) and 23.7% (n=183) were recruited through online and offline methods, respectively. In total, 81.2% (n=626) of participants reported that they had mainly used GSN apps to find male sexual partners in the past six months. HIV prevalence among all participants was 3.5% (n=27), and 68.2% (n=526) were eligible for PrEP. After controlling for age, residence, education, and recruitment method, HIV prevalence was positively associated with GSN app use (4.2% (n=26) vs. 0.7% (n=1), adjusted odds ratios (aOR)=8.1 [95% confidence interval (CI): 1.05, 62.33]). Compared with GSN app nonusers, GSN app users were more likely to have used recreational drugs, have multiple male sexual partners, have casual sex, and been tested for HIV in the past six months.
Conclusions: Among MSM university students, those who mainly used GSN apps to seek male sexual partners more frequently engaged in high-risk sexual behaviors and had a higher prevalence of HIV infection compared to GSN app nonusers. GSN app platforms can reach Chinese MSM university students and should be used to promote HIV-testing and implement sexual behavior risk reduction interventions. Further research on implementation of PrEP among MSM university students is needed.

PEC246

Factors associated with recent HIV infection among pregnant women in Lilongwe, Malawi: a case control study

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Background: Malawi, like many countries in sub-Saharan Africa, has reduced HIV maternal to child transmission (MTCT) by providing antiretroviral therapy to all HIV-infected pregnant women through its Option B+ program. As a result, a growing proportion of MTCT stems from women who seroconvert during pregnancy. Understanding which pregnant women are at highest risk of HIV acquisition can help focus scarce prevention resources to those at highest risk of seroconversion.

Methods: This is a case-control study conducted at Bwaila District Hospital in Lilongwe, Malawi from 2017-2019. Five-hundred HIV-infected pregnant women were enrolled in a behavioral intervention trial. At baseline, participants were screened for recent HIV infection with a validated testing algorithm consisting of Limiting Antigen Avidity Enzyme Immunoassay and quantitative viral load (VL) testing. Those with final normalized optical density ≤1.5 and VL ≥1000 copies/mL were classified as having recent HIV infection (cases). To identify factors associated with recent HIV infection, cases were compared to 350 HIV-uninfected pregnant women presenting to the same setting (controls). Bivariate associations were estimated using logistic regression. A multivariate model was developed using a backward elimination approach. Variables with a p-value ≤0.05 in bivariable analysis were included in an initial full model and variables were removed sequentially until all variables in the final model had a p-value ≤0.05.

Results: At enrollment, 416/500 HIV-infected pregnant women (83.2%) provided a blood sample; of these, 44 had recent HIV infection (10.6%) and were classified as cases. In the final multivariate model, the odds of recent HIV infection were higher among women with a syphilis rapid test (odds ratio (OR)=5.6, 95% confidence interval (CI)=1.4-21.8), a primary partner known to be HIV-infected (OR=7.8, 95% CI=2.1-28.9) or a primary partner of unknown HIV status (OR=4.5, 95% CI=2.2-9.2). Additionally, the odds of recent HIV infection were higher if the woman reported not being married to her primary partner (OR=4.0, 95% CI=1.2-13.1), or if either she or her partner had traveled overnight within the past six months (OR=3.1, 95% CI=1.4-6.7).

Conclusions: A set of biomedical and behavioral characteristics may put HIV-uninfected women at elevated risk of HIV acquisition with a need for combination HIV prevention approaches.

Epidemiology of non-AIDS infections and communicable diseases (e.g., viral hepatitis, STIs)

PEC247

Hepatitis C virus reinfection incidence among gay, bisexual, and other men who have sex with men living with HIV before and after the availability of direct acting antivirals in Australia

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Background: Hepatitis C virus (HCV) reinfection has been reported among gay, bisexual and other men who have sex with men (GBM) living with HIV globally. There is concern that reinfection may offset HCV elimination efforts. However, most studies of reinfection precede HCV DAA availability, and there is limited understanding of HCV reinfection among GBM in the DAA era.

Methods: Data were drawn from the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance in seven of eight Australian jurisdictions. GBM with evidence of spontaneous clearance or treatment induced cure (HCV RNA negative twice, >30 days apart, following RNA detection) with at least one subsequent HCV RNA test were included. Reinfection incidence was examined from 2010-2019. Piecewise Poisson regression was used to examine trends from 2010-2015 and from 2016 onwards when DAA treatments were government funded. Reinfection date was defined as the mid-point between first positive and last negative RNA test.

Results: A total of 506 GBM with HIV had evidence of ≥1 HCV clearance or cure event of whom 387 (77%) had ≥1 subsequent HCV RNA test. There were 41 cases of reinfection over 858 person-years, resulting in an incidence of 4.9 cases/100 person-years (PY) (95%CI 3.6-6.6). Prior to 2016, over 204 PY, reinfection incidence was 8.8/100PY (95%CI 5.6-14.0). From 2016 to 2019 over 660 PY, reinfection incidence was 3.6/100PY (95%CI 2.4-5.4). Incidence declined prior to 2016 (IRR 0.71, 95%CI 0.53-0.95) and was stable from 2016 onwards (IRR 1.1, 95%CI 0.72-1.6).

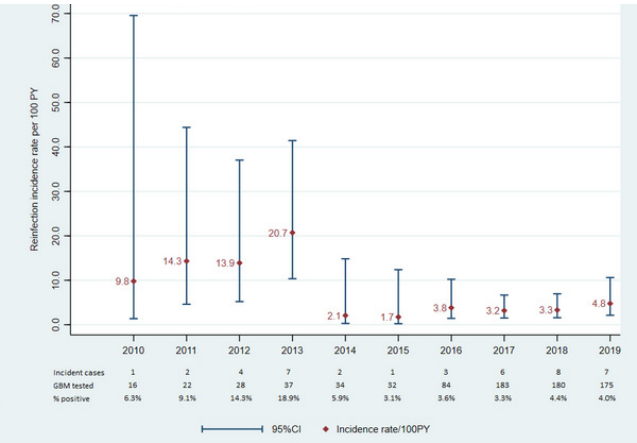

Figure. Hepatitis C reinfection among GMD living with HIV attending primary care and sexual health clinics in Australia

Conclusions: HCV reinfection incidence was lower from 2016 to 2019 compared to prior to 2016. Reinfection incidence declined prior to DAA availability and has remained stable since. Prompt treatment of primary infection and reinfection is essential to sustain HCV elimination among GBM living with HIV. Further research is needed to understand testing following cure and the drivers of reinfection events to further reduce their occurrence.

PEC248

Trends in syphilis testing and incidence among gay and bisexual men attending sexual health and primary care services in Australia between 2012-2019, by HIV status and PrEP use

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Background: Syphilis notifications have increased among gay and bisexual men (GBM) in Australia over the past decade. Changes in testing, condom use and serodiscordant mixing following PrEP implementation may influence transmission. We analysed trends in syphilis testing and incidence among GBM attending sexual health and primary care services in Australia.

Methods: Data were extracted from 31 services participating in the ACCESS sentinel surveillance network. We calculated the annual syphilis testing rate (GBM tested/GBM attending) and mean number of tests/person (among those tested) from 2012-2019. Using repeat testing methods we estimated annual incidence rates of infectious syphilis among GBM with ≥2 tests between 2012-2019.

Data were disaggregated by HIV-status (time-varying), and HIV-negative GBM were split into ever-PrEP-users (any evidence of PrEP during 2012-2019, retrospectively categorised before PrEP-initiation) and never-PrEP-users.

Results: From 2012-2019, annual testing rate increased among HIV-positive GBM (77% [3,977/5,139] to 79% [5,867/7,409], *P*=0.023), HIV-negative never-PrEP-users (65% [10,058/15,549] to 70% [17,438/24,839], *P*<0.001) and ever-PrEP-users (67% [3,695/5,535] to 85% [15,287/17,973], *P*<0.001).

Mean number of tests/person/year increased among ever-PrEP-users (1.7 to 2.7) and increased slightly among never-PrEP-users (1.4 to 1.5), however decreased among HIV-positive GBM (2.5 to 2.2)(all *P*<0.001). Among 8,543 HIV-positive GBM (43,056 person-years), incidence fluctuated from 2012-2019, however increased overall from 6.0/100py-9.1/100py (*P*-trend=0.002).

Among 21,114 HIV-negative ever-PrEP-users (80,858 person-years), incidence increased from 1.6/100py in 2012 to 6.8/100py in 2019 (*P*-trend<0.001). Among 36,924 HIV-negative never-PrEP-users (107,602 person-years), incidence remained stable from 2012-2017, then increased to 2.3/100py in 2019 (*P*-trend<0.001).

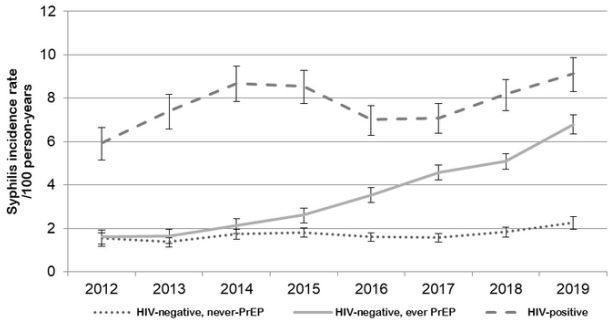

Figure. Annual incidence rate of infectious syphilis among gay and bisexual men attending primary care and sexual health services in Australia, by HIV status and PrEP use, 2012 to 2019

Conclusions: Syphilis incidence is increasing among all groups of GBM. Although incidence was increasing among PrEP users prior to PrEP rollout in 2016, recent increases are most prominent in this group and appear to be approaching levels historically seen among HIV-positive GBM. Despite increases in testing driven largely by PrEP uptake, testing has likely not reached the threshold required to curtail increasing syphilis transmission in Australia.

Describing the spread of HIV through molecular epidemiology

PEC249

Frequently transmission and close relationship among immigrants in the China–Myanmar border region indicated by molecular transmission network analysis

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Background: Accurate identification of molecular transmission clusters (MTCs) and understanding the dynamics of human immunodeficiency virus (HIV) transmission are conducive to precise interventions to prevent HIV transmission. We evaluated the characteristics of HIV-1 MTCs of antiretroviral therapy-naïve individuals in the China–Myanmar border region.

Methods: Phylogenetic analyses were undertaken on *pol* sequences to characterize subtypes/circulating recombinant forms and identify MTCs. MTCs were defined as those with ≥2 sequences having bootstrap support >95%. Factors associated with MTCs were evaluated using logistic regression analysis. The chi-square test was used to compare differences of all participants and individuals in MTCs between Chinese and Burmese.

Results: 900 people have successfully sequenced the *pol* gene, among whom the median age was 28 years, 506 (56.2%) were non-Han ethnicity, 539 (59.9%) were male, and 386 (42.9%) were junior middle school or above educated. Twenty-three MTCs were identified and involved 116

individuals (12.9%). Of 116 individuals who belonged in MTCs, 73 (62.9%) were Chinese and 43 (37.1%) were Burmese. Age, nationality, cluster of differentiation (CD)4 cell count, and subtype were associated significantly with MTCs in the multivariate analysis.

Individuals in MTCs were more likely to come from Myanmar (OR = 2.66, 95%CI = 1.58–4.46, P<0.001), be younger (0.35, 0.20–0.59, <0.001 for age 26–50 *vs.* <26 years), have a lower CD4 cell count (3.51, 1.68–7.33, 0.001), and have a higher proportion of subtypes CRF07_BC and C (9.75, 4.39–21.66, <0.001; 2.45, 1.26–4.77, 0.008) than their Chinese counterparts. In MTCs, Burmese were younger (88.4% *vs.* 56.2% for age <26 years), had a lower education level (41.9% *vs.* 9.6% for illiteracy), were more likely to be injecting-drug users (37.5% *vs.* 12.3%), and had a higher proportion of subtype BC (34.9% *vs.* 16.4%) and CRF01_AE (18.6% *vs.* 8.2%) than their Chinese counterparts (P<0.05 for all).

Conclusions: More Burmese belong in MTCs and had a close relationship with Chinese in terms of HIV-1 transmission. These data highlight the pivotal role of Myanmar in the bidirectional transmission of HIV-1 in the China–Myanmar border region.

PEC250

HIV-1 CRF19_cpx strains identified in Spain derive from multiple introductions and from the local expansion of three major clusters, and frequently exhibit CXCR4 tropism

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Background: CRF19_cpx, an HIV-1 A1/D/G recombinant form of African ancestry, is one of the major HIV-1 genetic forms circulating in Cuba and is associated with rapid disease progression and frequent CXCR4 tropism. Previous reports indicated its circulation in Spain and United Kingdom (UK). Here we analyze phylogenetic relations and epidemiological associations of CRF19_cpx viruses identified in Spain.

Methods: HIV-1 protease-reverse transcriptase (PR-RT) sequences obtained by us from samples collected in Spain from 11 regions or downloaded from the HIV Sequence Database were phylogenetically analyzed via maximum likelihood with FastTree, IQ-Tree, and PhyML. Recombination was analyzed with COMET and bootscanning. Coreceptor usage was predicted using V3 sequences with Geno2pheno. Times of most recent common ancestors (tMRCAs) of clusters were estimated with a coalescent Bayesian method.

Results: 404 PR-RT sequences grouped with CRF19_cpx references, most of them from Cuba, but also from Spain (n=102, 31 of them obtained by us), UK (n=48) and 7 other countries (n=10). In subsequent analyses, 26 were found to be recombinant between CRF19_cpx and other genetic forms, most of them CRF19/B recombinants. CRF19_cpx infections from Spain analyzed by us were mainly found in Spaniards (n=16, all but one men and 56% diagnosed in 2017-2020) and Cubans (n=9), and 23 of 24 with available data were transmitted sexually, with at least 54% being from men who have sex with men (MSM). 68 sequences from Spain grouped in 3 major clusters, comprising 51 (CRF19_ES-1), 11 (CRF19_ES-2), and 7 (CRF19_ES-3, including 1 from Germany) sequences, respectively, with the rest branching interspersed among Cuban sequences. CRF19_ES-1 and CRF19_ES-2 correspond to clusters from Andalucía and Valencia, associated with MSM, described previously. CRF19_ES-3 is a newly identified cluster, comprising infections from 3 Spanish regions, at least 4 from Spaniards, and also associated with MSM. Their tMRCAs were estimated around 2009, 2000, and 2015, respectively. V3 sequences were obtained for 12 newly diagnosed infections, 6 of which were CXCR4-tropic, all with false positive rates <5%.

Conclusions: CRF19_cpx has been introduced multiple times in Spain, where it is circulating in three major clusters associated with MSM. In newly diagnosed infections, CRF19_cpx viruses frequently exhibit CXCR4 tropism.

PEC251

Inflammation and microbial dysbiosis in young gay and bisexual men living with HIV

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Background: Compared to heterosexual men, gay and bisexual men have elevated systemic inflammation and unique intestinal microbial profiles, which are influenced by HIV infection and drive risk of comorbidities. Young men who have sex with men (YMSM) have a particularly high burden of risk factors associated with inflammation-related comorbidities. However, links between inflammation, microbial dysbiosis and HIV in YMSM have not been well described. Here, we aimed to characterize these complicated interrelationships in YMSM.

Methods: Data and samples come from a subset of participants (n=40) in the RADAR cohort of YMSM (aged 16-29) in Chicago. HIV-positive (HIV+) participants were demographically matched to HIV-negative (HIV-) participants. Systemic inflammation was assessed via C-reactive protein (CRP). Rectal microbial communities were assessed via 16s rRNA sequencing and data was processed using DADA2. Taxonomy was assigned with the Silva 132 classifier. Alpha diversity was calculated using the microbiome package in R. Beta diversity was calculated using pairwise sample dissimilarity and unweighted unifrac ordination analysis using principal coordinates analysis (PCoA). Multivariable regression models were used to assess the relationship between HIV and inflammation, adjusting for measures of microbial diversity and other risk characteristics.

Results: No significant difference in alpha diversity (richness, p=0.26; evenness, p=0.38; Wilcoxon test) or beta diversity (p=0.76; Pairwise Adonis test) was observed between HIV+ and HIV- participants.

Across all participants, *Prevotella* was the most abundant genus followed by *Peptoniphilus*, *Fenollaria*, *Streptococcus*and *Megasphaera*. In adjusted analyses, HIV+ individuals had significantly lower abundance of *Verrucomicrobiota* compared to HIV- individuals (b=-111.52; 95% CI: -214.32, -8.71). Mean CRP was 5.33 mg/L (range=0.10-39.41). No significant relationship was observed between HIV and inflammation when excluding microbiome health variables.

However, after adjusting for species richness and evenness, HIV+ participants exhibited significantly higher systemic inflammation (aOR=4.58; 95% CI: 1.08,19.34).

Conclusions: We demonstrated a strong relationship between HIV infection and systemic inflammation after adjusting for within population differences in microbial communities. This suggests that the microbiome-related factors evaluated here contribute in a complex way to systemic inflammation in HIV, and that more integrated analyses are warranted.

PEC252

HIV-1 molecular epidemiology among Latin American patients recently diagnosed in Spain reveals frequent infections with locally circulating strains

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Background: HIV-1 infection diagnoses have increased among Latin American immigrants in Spain over the last years. Currently, this group represents the second most affected population in the country (22.3%). We conducted a cross-sectional study to characterize the molecular epidemiology of HIV-1 in Latin Americans (LA), comparing with immigrants from other regions and Spaniards diagnosed in 2017-2019.

Methods: Phylogenetic analyses of 1,481 *pol* sequences (protease-reverse transcriptase) from HIV-1-infected patients residing in Spain diagnosed in 2017-2019 were performed with FastTree, including all sequences available in our laboratory (n=12,202) and public databases (n=209,726), in order to establish the probable geographical origin of the infections. Clusters were defined as clades with ≥4 patients supported by SH-like values ≥0.95. We also compared the epidemiological characteristics of cluster members with nonclustering individuals and investigated factors associated with clustering, using statistical tests and logistic regression models.

Results: LA represented 28% of HIV-infected individuals in our cohort. 84.9% were men, mainly MSM (73.1%), younger at diagnosis, and with the highest prevalence of subtype B infections (79.3%) among the study groups (p<0.05). 73% of the 1,481 sequences grouped in 452 clusters, with differences by region of origin: 65% for LA, 79% for Spaniards and Europeans, and 57% for Africans (p<0.05). Among individuals in clusters, 29% LA, 74% Spaniards, 32% Europeans, and 7% Africans belonged to predominantly Spanish clusters. On the other hand, 46% LA and 10% Spaniards belonged to clusters comprising viruses circulating mainly in Latin America, while 85% Africans belonged to clusters of variants circulating in Africa (p<0.05). Clustering frequency was lower for LA (OR=0.39; 95%CI:0.28-0.54) and Africans (OR=0.27; 95%CI:0.14-0.52), as well as for non-MSM patients (OR=0.65; 95%CI:0.42-0.99). Genetic form (subtype B vs. non-B) or drug resistance mutations were not associated with clustering (p<0.05).

Conclusions: The results reflect the characteristics of HIV-1 molecular epidemiology in the countries of origin of the studied populations. However, a significant proportion of LA probably acquired HIV-1 in Spain, indicating transmission between Spaniards and LA, probably related to linguistic and cultural affinities, in contrast to what was observed in African patients. These findings suggest the need to intensify public health measures in this vulnerable population.

Participatory practice and community involvement in prevention research

PEC254

Contribution of CABs in the health research process - a case study of th e National Cross-CAB Network in Uganda

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Background: Community Advisory Board (CABs) are a common mechanism for community input into the research process. The cross-CAB network is a virtual body that brings together CABs in Uganda. Ethical guidelines for health research encourage platforms that promote community input in the research agenda to promote an inclusive, responsive and accountable research process. This study aimed to document the contribution and effectiveness of CABs in the research process in Uganda.

Methods: The study team conducted qualitative and quantitative research, including seven focus group discussions (FGDs) with CABs, as well as seven key informant interviews with community liaison officers (CLOs) and six with researchers. An online survey was conducted to collect quantitative data from key stakeholders. A total of 68 (80%) male and female CABs members, CAB liaisons and researchers from seven research institutions in Uganda were reached.

Data collected was analyzed using the Nvivo 12 software. Tools were translated to Luganda, the most commonly used language in the region where the research was conducted. Ethical approval was obtained from Mildmay Uganda Institutional Review Board and the Uganda National Council of Science and Technology (UNCST).

Results: The majority of CAB members had given feedback to researchers and had knowledge about and participated in the Cross-CAB network. However, due to limited funding, CAB members were not able to organize a detailed training on the Good Participatory Practice (GPP) guidelines to fully comprehend the principles outlined. FGD discussions also revealed that CAB members find health research language complex, and require more time to critically understand research documents.

Conclusions:

1. Managers of research institutions should allocate resources to train and retrain community leaders, research study participants, and CABs in understanding and implementation of GPP to enhance meaningful stakeholder engagement in research.
2. CABs and researchers should design a comprehensive plan for monitoring and evaluating all CAB activities.

The Cross-CAB network and CABs are effective avenues to engage all stakeholders in the design and conduct of biomedical HIV prevention trials. GPP capacity of CABs should be enhanced and adequately be funded for effective engagement of communities and researchers.

Modelling the HIV epidemic

PEC255

Modeling the impact of HIV-1 RNA testing among symptomatic adult outpatients in Kenya

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Background: Up to 69% of adults who acquire HIV in Kenya seek care before seroconversion, providing an important opportunity for early diagnosis and care engagement. The *Tambua Mapema Plus* (TMP) trial tested a combined HIV-1 RNA testing, linkage, treatment, and partner notification intervention for adults aged 18-39 presenting to health facilities with symptoms of acute HIV infection (AHI). We estimated the potential impact of this intervention on the Kenyan HIV epidemic using data on standard care outcomes from the observation period and intervention outcomes from the intervention period.

Methods: We developed a stochastic, agent-based network model parameterized with TMP data and current statistics to simulate the HIV epidemic in Kenya. The model included formation and dissolution of main, casual and one-time partnerships; sexual behavior within partnerships; HIV testing; initiation, adherence and discontinuation of ART; transmission; intra-host viral dynamics; and demographic change. The model was calibrated to demographic-group-specific HIV prevalence and annual testing rates. The simulation included 10,000 persons with the same age, sex and marriage distribution as Kenya. Three main scenarios were modelled: standard care (low use of provider-initiated counseling and testing [PITC]); the TMP intervention; and scaled HIV rapid testing (scaled-up PITC).

Results: PITC at current rates (25.6% of symptomatic individuals tested) diagnosed 90.7% of persons living with HIV (PLWH) on average, with 67.5% of those diagnosed on treatment. The TMP intervention (reaching 94.9% of those targeted) diagnosed 97.5% of PLWH on average, with 80.6% of those diagnosed on treatment. Scaled-up PITC with rapid tests only diagnosed 94.4% of PLWH on average, with 70.4% of those diagnosed on treatment. The proportion of all PLWH achieving viral suppression was 59.0% for TMP, 50.0% for scaled-up PITC and 46.0% for standard care. The percentage of infections averted during the 10-year simulation was 9.4% (95% simulation interval [SI]: -8.1%, 24.5%) for TMP and 1.0% (95% SI: -19.2%, 19.9%) for scaled-up PITC.

Conclusions: Our simulation study suggests that leveraging new technologies to identify AHI among symptomatic adult outpatients is superior to both standard care and scaled-up PITC, reaching the UNAIDS 95% target for knowledge of HIV status, and reducing new infections in Kenya.

PEC256

Evaluating the impact and cost-effectiveness of existing HIV prevention interventions among people who inject drugs in Ukraine

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Background: In Ukraine, people who inject drugs (PWID) have high prevalences of HIV and hepatitis C virus (HCV). Non-governmental organizations (NGOs) provide PWID with needles and syringes, condoms, HIV and HCV testing, and linkage to opioid agonist therapy (OAT) and HIV antiretroviral therapy (ART). We estimated the impact and cost-effectiveness of NGO activities for PWID in Ukraine.

Methods: We developed a dynamic HIV and HCV transmission model among PWID which was parameterised and calibrated to detailed data from multiple rounds of national PWID surveys. Based on these surveys, the model incorporated effects of NGOs (coverage 33% in community) on reducing injecting risk, and increasing condom use and recruitment onto OAT and ART.

We estimated the historic (1997-2020) and ongoing impact (2020-2040) of NGOs in terms of proportion of HIV or HCV infections averted. We also estimated the potential impact of scaling-up NGOs to 60% coverage with and without a concurrent scale-up in OAT from 5% to 20% and ART from 64% to 81%.

We estimated the incremental cost-effectiveness ratio (ICER) of NGOs by comparing incremental costs and DALYs averted over 2020-2045 between the status quo scenario and a counterfactual scenario in which NGO activities are stopped over 2020-2025.

Results: The model projects that NGOs averted 10.7% (95% credibility interval: 8.7-12.9) and 6.7% (5.4-8.0) of HIV and HCV infections over 1997-2020, respectively, and will avert 15.8% (13.0-18.8) and 8.4% (7.1-9.8) of infections over 2020-2040. Without NGOs, HIV and HCV incidence would have been 31.3% (25.3-38.3) and 17.8% (15.1-20.8) higher in 2020 and would be 28.0% (21.7-34.8) and 17.7% (15.0-20.5) higher in 2040.

Only scaling-up NGOs could reduce HIV and HCV incidence by 29.9% (23.4-35.8) and 23.1% (19.6-26.2) by 2040, respectively, or 52.8% (44.5-64.6) and 30.6% (27.2-33.1) with concurrent scale-up of OAT and ART. The mean ICER was estimated to be US$ 1,606/DALY averted.

Conclusions: NGOs have had important impacts on HIV and HCV transmission among PWID and are cost-effective compared with a willingness-to-pay threshold of Ukraine's GDP ($3,096).

It is important that these activities continue and preferably scale-up in the face of upcoming changes to the HIV funding landscape.

PEC257

Elucidating drivers for variations in the explosive HIV epidemics among people who inject drugs in Pakistan

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Background: Pakistan's explosive HIV epidemic among people who inject drugs (PWID) varies widely across cities and has increased dramatically over time. To help guide future HIV programming, we used statistical and mathematical modelling to evaluate possible drivers for these variations.

Methods: Five rounds of national biological and behavioural surveillance survey data (n=18,467) describing high-risk factors and HIV status among PWID were collected by the Canada-Pakistan HIV/AIDS Surveillance Project (HASP) from 2005-2017. We undertook mixed-effects multivariable regression analyses to identify associations between city-level HIV prevalence and population prevalences of different risk factors. We then developed a dynamic HIV transmission model to reflect these associations, calibrating to 25 cities included in the surveys to estimate the increased HIV transmission risk associated with identified risk factors, and their respective population-attributable fractions (PAFs) to new HIV infections over 10-years. Lastly, we investigated the relative decrease in HIV incidence resulting from reducing each risk factor to the lowest observed prevalence.

Results: Regression analyses identified the use of professional injectors at last injection ('ProfInjUse'), heroin use within the past month ('HeroinUse'), and injecting 4+ times per day ('Inj4xpd') as three key high-risk factors associated with city-level HIV infection, with HIV prevalence increasing by 2.5 (95% Confidence Interval [CI] 1.0-4.0), 1.9 (95%CI 1.1-2.6), and 4.7 (95%CI 2.3-7.1) percentage points for every 10-percentage point increase in the prevalence of each respective factor. Model projections estimated that ProfInjUse, HeroinUse, and Inj4xpd increase the relative risk of HIV transmission by 2.3 (95% Uncertainty Interval [UI] 1.1-5.4), 1.9 (95%UI 1.1-3.8), and 2.9 (95%UI 1.2-6.7) times, respectively, with the 10-year PAFs across all cities being 45.3% (95%UI 4.3-79.7%), 45.9% (95%UI 8.1-78.4%), and 22.2% (95%UI 2.0-58.4%), separately, and 88.7% (95%UI 74.9-95.4%) combined. Lowering the city-level prevalence of each risk factor to the lowest observed prevalence in 2020 (2.8% ProfInjUse, 0.9% HeroinUse, 0.1% Inj4xpd) reduced overall HIV incidence by 52.7% (95%UI 6.1-82.0%), 53.0% (95%UI 11.3-80.2%), and 28.1% (95%UI 2.7-66.6%) over 10-years, respectively.

Conclusions: Using professional injectors, heroin use, and frequent injecting are important risk factors contributing substantially to Pakistan's heterogeneous HIV epidemic, and so should be a focus for interventions.

PEC258

Impact and cost-effectiveness of non-governmental organizations on the HIV epidemic in Ukraine among men who have sex with men

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Background: Men who have sex with men (MSM) in Ukraine have a high prevalence of HIV (2018: 5.2%). MSM-targeted non-governmental organisations (NGOs) are associated with improved HIV testing, treatment coverage and increased condom use. We use mathematical modelling to estimate the impact and cost-effectiveness of these interventions.

Methods: A mathematical model of HIV transmission, parameterised and calibrated to bio-behavioural survey data for MSM in Ukraine (2011-2018), was used to evaluate the historical (up to 2020) and future impact (2020-2040) of status quo coverage levels of NGOs compared to scenarios where there were no NGOs over 2003-2019 or 2020-2040. Impact was measured in terms of HIV incidence, infections and HIV-related deaths averted.

We then compared the costs (ART and NGO costs, in 2018 USD) and disability adjusted life years [DALY] for the status quo scenario and a counterfactual scenario (no NGOs over 2020-2025, but with NGOs thereafter to 2040) until 2040 to estimate the mean incremental cost-effectiveness ratio (ICER, cost per DALY averted). We assumed a 3% annual discount rate for costs and outcomes.

Results: Over 2003-2019, the model projects there were 29,088 (26,241-31,908) HIV infections and 23,927 (20,918-27,463) HIV-related deaths with existing levels of NGO interventions, with these increasing by 18% and 11%, respectively, with no NGOs over that period. Going forward with existing NGO coverage levels, the model projects HIV prevalence will decrease from 6.4% (95% credibility interval: 5.5%-7.1%) to 3.0% (2.0%-3.9%) over 2020-2040 and HIV incidence will decrease from 0.76 (0.63-0.89) to 0.27 (0.16-0.40) per 100 person years. However, with no NGOs over this period,

HIV prevalence would increase by 80% (63%-121%) by 2040 and HIV incidence by 189% (137%-334%), with there being 77% (60%-115%) more HIV infections and 38% (31%-54%) more HIV deaths over the period.

Compared to a scenario where NGO activities cease over 2020-2025, the status quo scenario averts 38,993 DALYs by 2040, with the mean ICER being $302.88 per DALY averted.

Conclusions: MSM-targeted NGOs in Ukraine have prevented considerable HIV infections and deaths and are highly cost-effective compared with a willingness-to-pay threshold of 50% of Ukraine's GDP ($3,096 in 2018).

PEC259

Impact and cost-effectiveness of scaling up pre-exposure prophylaxis among female sex workers in South Africa: a modelling analysis

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Background: In 2016, a national program was initiated in South Africa (SA) to scale-up HIV pre-exposure prophylaxis (PrEP) among female sex workers (FSWs), with >12,000 initiating PrEP by 2020. We evaluated the impact and cost-effectiveness of this national program, including future scale-up scenarios.

Methods: An existing HIV transmission model calibrated to SA, was adapted to include PrEP with low/high adherence. PrEP drug level data from the SA TAPs demonstration study among FSW was used to determine the proportion of FSWs with high adherence (detectable drug levels), transition probabilities between low and high adherence, and factors associated with retention. Calibrating to the national PrEP scale-up among FSWs, we estimated the HIV infections prevented over 2016-2020. Using adapted cost data from the TAPs study, we estimated the cost-effectiveness of PrEP (2016-2020), accounting for disability-adjusted life years (DALYs) and ART costs averted over 2016-2040. We estimated the future impact of PrEP over 2021-2040, at current coverage levels or if adherence and coverage improved.

Results: TAPs study data suggests 62.5% of FSWs were highly adherent when initiating PrEP. Loss-to-follow-up was lower among those highly adherent (aHR:0.56; 95%CI:0.38-0.82) and connected with FSW services (aHR:0.47; 95%CI:0.23-0.95). Each 3-months, on average 15.1% (10.2-21.0%) of highly adherent FSW transition to low adherence and 38.2% (28.1-49.1%) vice-versa. Model projections suggest 3.2% of HIV-negative FSW are on PrEP in 2020. This has prevented 0.91% (0.76-1.1%) of new HIV infections among FSWs over 2016-2020 or 1,003 (747-1,379) infections in the overall population. PrEP is cost-saving with $1.79 (1.34-2.37) in ART costs saved per dollar spent on PrEP. Going forward, if PrEP initiation is doubled, loss-to-follow-up halved, and only highly adherent FSWs use PrEP, then PrEP coverage increases to 12.3% (10.5-14.6%) and impact increases 4.6-times with 64,878 (45,713-93,675) infections averted by 2040. Doubling recruitment or halving loss-to-follow-up increases impact by 93.2% and 77.7%, respectively, while ensuring all FSWs are highly adherent increases impact by 24.1%.

Conclusions: Although overall impact is small, the current rollout of PrEP is likely to be cost-saving and could have greater impact if coverage and adherence are improved. This may be achieved through targeting those in contact with FSW services.

Surveillance in key population groups

PEC260

Evidence of disparities in achieving viral load suppression among young Black MSM

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Background: Critical to ending the HIV epidemic are efforts to suppress viral load (VL), particularly among disproportionately affected populations like Black MSM. We describe the epidemiology of HIV VL suppression in Chicago and hypothesize that young non-Hispanic (NH) Black MSM are less virally suppressed than other groups.

Methods: HIV surveillance data from the Chicago Department of Public Health reported during 2009-2018 were analyzed to determine population characteristics and percent of the population virally non-suppressed (defined as VL >200 copies/mL). Trends in viral non-suppression were examined by age and race/ethnicity groups among MSM.

Results: In 2018, 20,703 persons ≥18 years were living with HIV/AIDS in Chicago (80.6% male, 17.8% female, 1.6% transgender, 49.9% NH Black, 20.8% young [18-34 years], and 63.8% MSM). Nearly 40% did not have a VL test. Among those who had a VL test (n=12,479), 21.2% of MSM and 30.8% of NH Black persons were not suppressed. Younger persons were much more frequently non-suppressed than persons ≥35 years (39.2% vs 19.2%; RR 2.0, 95% CI: 1.9, 2.2). Almost half of all young non-suppressed persons were NH Black MSM (46.9%).

During 2009-2018, the trend in the proportion of persons non-suppressed improved substantially by race/ethnicity and age (p<.0001 for all groups), though not consistently among all groups. While the percentage of non-suppression steadily decreased among young NH Black MSM from 83.3% in 2009 to 42.7% in 2018, this was at a slower rate than that observed for young NH white MSM, of which 66.7% were not suppressed in 2009 and 20.4% in 2018.

Older MSM began the observation time at a lower level of non-suppression than younger MSM (32.3% vs 80.3%) and experienced a similar rate of decline but maintained a disparity at the end of the period (16.1% vs 36.0%).

Conclusions: Young adults living with HIV were twice as likely to be non-suppressed compared to older persons. Young Black MSM continue to experience higher rates of non-suppression compared to other races/ethnicities. These data indicate that viral suppression in young Black MSM must be a priority in order to reach the goal of eliminating HIV.

PEC261

Factors associated with unsuppressed viral loads among HIV positive sexually transmitted infected patients (STI) attending STI services in South Africa (2019)

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Background: South Africa has a high burden of HIV and sexually transmitted infections (STIs). Among HIV-positive persons with unsuppressed viral loads (VLs), STIs may facilitate the onward transmission of HIV to uninfected partners. We determined factors associated with unsuppressed viral load (VL>50 copies/ml) among HIV-positive individuals attending STI services in South Africa.

Methods: We analyzed data from HIV-positive STI service attendees enrolled at two primary care services in Western Cape and Gauteng provinces in 2019. We described demographic, sexual behavioral, clinical characteristics and VL results from a sample of attendees at enrolment.

A Poisson regression model with robust error variance was used to identify factors associated with having unsuppressed VL (>50 copies/ml).

Results: Among 93 HIV-positive STI service attendees with viral load data, the median age was 32 years (IQR 27-37 years)with the majority of attendees aged >25 years (90.63%). Most attendees were male-65% (n=61) and 34 % (n=32) reported being on ART. The median HIV viral load for attendees was 8011 RNA copies/ml (IQR= 78 -99171).

More than half (56.25 %) of patients on ART had an unsuppressedVL, while 86.89 % of those not on ART had an unsuppressed VL. After adjusting for age, gender, STI syndrome and ART use, self-reported ART use in the preceding three days was associated with a 33% lower prevalence of unsuppressed VL — adjusted prevalence rate ratio (aPRR) = 0.67 (95% confidence interval [CI] 0.49–0.92). The prevalence of unsuppressed VL was higher among those aged <25 years (aPRR = 1.25; 95% CI 0.99-1.60) and among females aPRR = 1.12 (95% CI 0.64-1.97).

In a subgroup analysis including only those on ART, those <25 years had a higher likelihood of unsuppressed viral load (aPRR = 1.94; 95% CI 1.27–2.97) in a model adjusting for sex partner number and age.

Conclusions: There was a low proportion of HIV-positive STI service attendees reporting ART use and a high prevalence of unsuppressed VLs regardless of ART status. There should be intensified ART support to young and female STI-HIV positive adults to improve viral suppression outcomes.

Results: Individual movement data revealed that in April 2020 (following lockdown announced March 21, 2020), time spent at home increased markedly. Also in April, there were statistically significant reciprocal reductions in access to services, including ART initiation (p=0.03), pre-exposure prophylaxis (PrEP) prescriptions (p=0.0003), plasma viral load tests (p=0.004), HIV testing episodes (p=0.006), and new HIV diagnoses (p=0.049); all rebounded within the subsequent 3 months, to below pre-lockdown levels (Fig.1A).

Overall, new HIV diagnoses in the province remained on a stable declining course. However, phylogenetic analyses showed rapid growth (e.g.Fig.1B) in a limited number of clusters involving key populations, accounting for >13% of total BC 2020 new diagnoses.

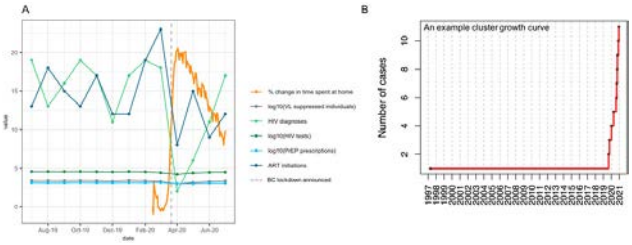

Figure 1.

Conclusions: Our results reveal increased HIV transmission in a limited number of clusters in association with reduced access to health services during the SARS-CoV-2-related lockdown. Increased vigilance and innovative targeted solutions are critical to offset potential negative impacts of SARS-CoV-2 related restrictions on HIV treatment and prevention efforts.

PEC262

SARS-CoV-2 lockdown associated with expansion of HIV transmission clusters among key populations

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Background: Public health measures designed to reduce SARS-CoV-2 transmission have led to reduced access to care and prevention services for people living with, or at risk of acquiring HIV which could lead to increases in HIV transmission. We synthesize available data from HIV treatment programs in British Columbia, Canada together with publicly available data to investigate SARS-CoV-2 impacts on HIV transmission.

Methods: Data describing engagement with HIV prevention and management services were collected by the BC Centre for Excellence in HIV/AIDS Drug Treatment Program. Mann-Whitney tests quantified changes in service engagement in August-2019-March-2020 versus April-July, 2020. Sequence data were collected during routine clinical HIV drug resistance genotyping. Movement trends were assessed using the Google COVID-19 Mobility Reports data. Alignments of 39,597 HIV-1 partial pol sequences were used to infer phylogenetic trees. Transmission clusters were determined using a phylogenetic distance threshold of 0.02 substitutions/site.

Novel methods/algorithms for detecting acute and recent HIV infections

PEC263

Determinants of long-term HIV infections at point of HIV diagnosis in the Kingdom of Eswatini: results from the HIV-1 recent infection surveillance program

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Background: Delayed HIV diagnosis continues to be a major obstacle for epidemic control. We examined determinants of long-term (LT) infection among newly diagnosed people living with HIV that participated in the Eswatini HIV-1 recent infection surveillance program.

Methods: We used data collected during July 2019–September 2020 for individuals ≥15 years newly diagnosed with HIV in routine HIV testing services who additionally received a rapid test for recent infection (RTRI). LT infection was defined as a RTRI LT result, which likely indicates infection of ≥12 months.

Bivariate and stepwise backward multivariate logistic regressions were run to determine adjusted odds ratios (aORs) between a range of sociodemographic, geographic, and health risk factors and LT infection. Python 3.7 was used for the analyses.

Results: Of 6,171 newly diagnosed clients from 113 testing facilities, 5,502 (89.2%) had LT infection and 669 (10.8%) had a recent infection. In adjusted analyses, male sex ($aOR_{vs.non\text{-}pregnant\ female}$: 2.00; 95% CI: 1.59 – 2.51), clients who were >25 years of age (see age-group-specific aORs in Figure 1), residence in the Hhohho region ($aOR_{vs.Lobombo}$: 1.32; 95%CI: 1.03 – 1.70), clients who do not report testing history ($aOR_{vs.tested\ before}$: 1.86; 95%CI: 1.55 – 2.23) and clients who reported no use of a HIV self-test kit in the past 12 months ($aOR_{vs.use\ of\ HIV\ self\text{-}test\ kit}$): 1.44; 95%CI: 1.06 – 1.94) were more likely to have LT infection. Distance traveled for HIV diagnosis, marital status, education, injection drug use, number of partners in the past 12 months and experiencing forced sex in the past 12 months were not associated with LT infection.

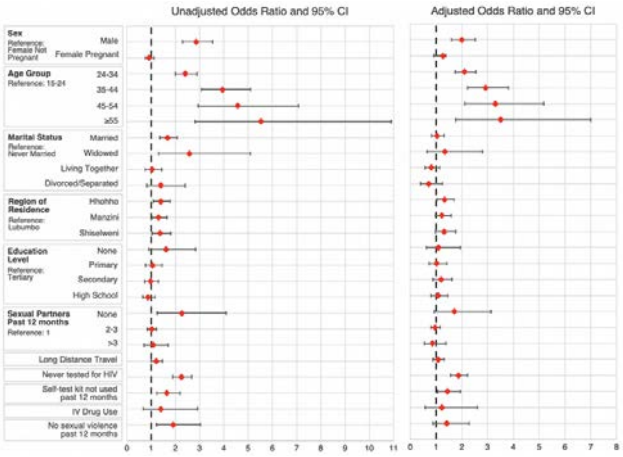

Figure. Predictors of long-term infection

Conclusions: Recent infection surveillance can sharpen program response to accelerate epidemic control. Further promotion of frequent HV testing, including through expanded access to self-test kits, particularly among men and older individuals, is critical to reduce delayed HIV diagnosis—a major impediment to achieve epidemic control.

PEC264

Ensuring quality in HIV point of care testing for recent infections in a surveillance program

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Background: The Eswatini HIV-1 Recent Infection Surveillance (EHRIS) program is a national surveillance program to track new HIV infections. From July 2019, testers already deployed at health facilities and community points with HIV testing services (HTS) were trained on EHRIS. These testers offered a rapid test for recent infections (RTRI) to all newly diagnosed individuals 15+ years, and RTRI quality was assessed through proficiency testing (PT) every 6 months.

Methods: PT was conducted using prepared Dried Tube Specimen with 5 panels containing three types of specimens (HIV-negative, HIV-positive long term, and HIV-positive recent). Testers were eligible to participate in PT if they had implemented EHRIS for approximately 6 months. PT was conducted in March and September 2020. Each eligible tester was provided 5 panels and given a two-week period to test the 5 PT panels and report their results electronically using tablets loaded with an Open Data Kit form. To pass the PT, testers were required to get the correct result for all 5 PT panels. Testers who failed underwent a corrective action and preventive action (CAPA) intervention and were given 5 new PT panels to repeat PT. We analysed PT outcomes using descriptive analyses.

Results: In March 2020, 183 testers at 52 sites conducted PT, and in September 2020, 387 testers at 123 sites participated. Most testers correctly reported all 5 PT panels: 85% (n=156) in March and 96% (n=370), in September. The percentage of testers correctly reporting all 5 PT panels was similar among those conducting EHRIS at health facilities (85% (146/172) in March and 95% (341/358) in September) vs community testing points (91% (10/11) in March and 29/29 (100%) in September). Following a CAPA intervention 20% (n=36) and 9% (n=17) of testers from March and September respectively passed the PT at second attempt; and the rest at third attempt.

Conclusions: Testers in health facilities and community testing points exhibited high PT performance, with improvement over time. These results provide assurance in the quality of point of care testing for HIV recent infections in this national surveillance program.

PEC265

Finding the missing: characterization of HIV recent infection clusters in Rwanda

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Background: Real-time recent HIV infection surveillance can enhance case-finding and inform targeted prevention. To identify and respond to signals of recent HIV acquisition, Rwanda adopted an HIV recent infection response strategy in January 2020.

Methods: HIV recent infection surveillance data from newly diagnosed adults (≥15 years) were collected at 479 health facilities during February–September 2020. Blood samples from these adults were submitted to 9 laboratories to complete a Recent Infection Testing Algorithm (RITA). Investigation teams were sent to health facilities with ≥2 RITA recent HIV infections within a month—time-space cluster—to collate information from existing registers on index cases and their contacts. Data were abstracted and recorded on a recent HIV infection response form. Descriptive statistics were used to summarize the data.

Results: Of 4,336 new HIV diagnoses that underwent recent infection testing, 191 (4%) were classified as RITA recent. Teams investigated 15 clusters comprised of 30 index cases who were RITA recent from 14 health facilities. Ninety-three percent (28/30) of these cases were initiated on ART and 73% (22/30) were offered partner notification services (PNS). Of those offered PNS, 100% agreed and listed 39 contacts (Contact Ratio: 1.7). Fifty-nine percent (23/39) of contacts were tested for HIV and 30% (7/23) were newly diagnosed with HIV, of whom 100% were initiated on ART. Of the 7 newly diagnosed with HIV, 43% (3/7) were RITA recent and 57% (4/7) were long-term (Table).

Characteristic	Total	Female	Male
Offered (n/N, %)	22/30, 73.3%	13/17, 76.5%	9/13, 69.2%
Accepted (n/N, %)	22/22, 100.0%	13/13, 100.0%	9/9, 100.0%
Contacts Elicited (N)	39	20	19
Contacts tested for HIV (n,%)	23, 59.0%	13, 65.0%	10, 52.6%
Contacts known positive (n,%)	3, 7.7%	2, 10.0%	1, 5.3%
Contacts not tested for HIV[1] (n,%)	13, 33.3%	5, 25.0%	8, 42.1%
New HIV-positive contacts (Testing yield) (n/N, %)	7/23, 30.4%	3/13, 23.0%	4/10, 40.0%
Contacts linked to ART (n/N, %)	7/7, 100.0%	3/3, 100.0%	4/4, 100.0%
HIV-negative contacts, % eligible for PrEP (n/N, %)	0/16, 0.0%	0/10, 0.0%	0/6, 0.0%
[1]Reasons for not testing for HIV (n=16) were already knowing their HIV-positive status (3), untraceable (11), and refusing (2).			

Table. Summary of outcomes from HIV recent infection cluster investigations overall and by sex, February–September 2020

Conclusions: Index cases with recent infections were linked to high-risk HIV-negative partners, as well as partners with known and unknown HIV-positive status. Recency surveillance, combined with index testing/PNS, can maximize the impact of HIV prevention interventions, including PrEP, and treatment support efforts to curb continued transmission and accelerate epidemic control.

PEC266

Risk factors for recent HIV infection in Zambia, 2020

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Background: As Zambia approaches HIV epidemic control, identifying recently infected (<1 year) persons is important to interrupt HIV transmission chains. Persons with recent infection are often undiagnosed with high viral load (VL), and likely to transmit the virus to others while still engaging in high-risk behaviors. As such, the Zambia Ministry of Health instituted HIV recent infection surveillance in late 2019.
This analysis describes risk factors for recent infection among newly diagnosed HIV-positive clients enrolled in the surveillance program.
Methods: We conducted a cross-sectional analysis of persons tested for recent HIV infection in 173 health facilities across 16 districts in Lusaka and Copperbelt provinces from January to November 2020. Rapid tests for Recent Infection (RTRI) were performed on whole blood samples from newly diagnosed HIV-positive clients aged ≥15 years using the Asante™ HIV-1 Rapid Recency Assay. Clients with recent RTRI results and unsuppressed VL results (>1000 copies/ml) were classified as recent infections per the recent infection testing algorithm (RITA). Proportions of RITA recent infections were calculated by sex, age, and testing modality (VCT, PITC, Index, PMTCT, and VMMC) and multivariate logistic regression was used to identify associations between these factors and recent infection status.
Results: Overall, 2,748 persons were tested for recent infection, and 1,940 (71%) with complete demographic information and VL testing were included in this analysis.
The overall prevalence of recent infection was 8.6%. The prevalence was 10.7% among females versus 5.6% among males (p<0.001).
The prevalence was highest in ages 15-24, followed by ages 25-34, 35-44, and >45 years (15.5%, 8.6%, 6.0% and 4.3%, respectively). Youth ages 15-24 (Odds Ratio=1.5, 95% Confidence Interval: 1.2-1.9) and females (OR=1.6, 95% CI: 1.1-2.4) were significantly more likely to present with recent infection.
Conclusions: One in 12 newly diagnosed persons with HIV in Zambia were infected within the last year. Women and youth have higher prevalence of recent HIV infection. Targeted scale-up of evidence-based interventions, such as PrEP, contact tracing and counseling, is needed to decrease transmission rates among these high-risk groups. HIV recent infection surveillance should continue to track population-specific recent infection trends over time as a measure of progress toward HIV epidemic control.

Novel studies to measure HIV incidence

PEC267

Using multiplex assay to detect HIV-1, HIV-2 and recent HIV-1 infection in Nigeria

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Background: We developed a multiplex assay that combines several testing steps into one, reducing the cost and labor. We evaluated the performance and accuracy of a newly developed multiplex assay to diagnose HIV-1 and HIV-2 and distinguish HIV recent (<6months) and long-term (LT) (≥6months) infections using stored plasma samples from the Nigeria AIDS Indicator & Impact Survey (NAIIS).
Methods: Plasma samples from consenting HIV-positive (n=2,773) and HIV-indeterminate (n=174) persons (as determined by the Bio-Rad Geenius™ HIV-1/2 Supplemental Assay) age 18 months-64 years and a subset of HIV-negative persons (n=6,848) age 18 months-64 years from the NAIIS survey were tested using the multiplex assay. The assay was used to classify specimens as HIV-1 positive, HIV-2 positive, dual (HIV-1/2) infections, or HIV-seronegative. All HIV-1 and dual infections were further classified as either HIV-1 recent or HIV-1 LT based on the mean fluorescent intensities. Multiplex results were analyzed and compared with final confirmatory NAIIS test results.
Results: Multiplex results were compared to NAIIS results for HIV prevalence and incidence. Unweighted estimated HIV prevalence from both multiplex assay and NAIIS test results were similar (1.6%) and only differed in confidence intervals [95% CI: 1.6-1.7] and [95% CI: 1.5-1.6] respectively. Incidence calculated (age 15-64 years only) based on multiplex assay and adjusted for VL and ARV was 0.8 per 1,000 [95% CI: 0.6-1.0]; the same estimate calculated using the final NAIIS test results. The diagnostic sensitivity of the multiplex assay was 99.7% and specificity was 99.4% with *kappa* of 0.987 when compared to the confirmatory test results conducted in NAIIS.
Percent agreement between the multiplex assay and the LAg-Avidity for recent or LT detection was 98.9% with a kappa of 0.799 and a Spearman ranked correlation (ρ) of 0.689. Indeterminate specimens were analyzed separately and 8 (4.6%) of 174 were found to be HIV-1 positive, 5 (2.9%) additional samples were found to be HIV-2 positive, and the rest were all HIV-negative by multiplex assay.

Conclusions: The multiplex assay combines multiple assays in one, providing highly accurate results for the estimation of HIV-1 prevalence and incidence and HIV-2 prevalence. This assay can simplify surveys making them affordable, easier, and quicker.

PEC268

A novel tool to estimate HIV-incidence in mothers living in resource-limited settings

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Background: HIV incidence is a key indicator for monitoring the progress towards the UNAIDS 95-95-95 targets. However, measurement is a challenge because of the need for long-term follow-up and large number of persons at risk for HIV infection. Novel approaches to obtain rapid and accurate HIV-incidence estimations in low-and middle-income countries are required.

Methods: From October 2017 to April 2018, a cross-sectional household HIV-testing survey was conducted to estimate the incidence of HIV among mothers of children born in the last four years, residing in the Manhiça Health Demographic Surveillance System, Mozambique. Randomly selected mothers were asked to present documentation of their last HIV-tests, such as the pregnancy card, child health card, HIV-care card, or HIV-counseling-and-testing card. Mothers were offered HIV-testing if they had never been tested or if they had an HIV-negative result obtained more than three months before the visit. We estimated the HIV-incidence as the number of mothers newly infected per total person-years among mothers who had prior documentation of an HIV-negative test. For those without a date of the last HIV-test registered, the date of delivery was used. Person-years were calculated as the difference in time between the new HIV-test and the last documented HIV-negative test. For those women testing HIV-positive at the survey, the date of seroconversion was a random-point date between the last negative and the first positive sample. The 95% confidence intervals (CI) were based on the Poisson distribution.

Results: Among the 5000 mother-child pairs selected, 3069 were found and interviewed, and 2221 reported a previous HIV-negative test. We included 1714 HIV-negative women receiving a new HIV-test during the survey. Median age of mothers was 24.8 years (IQR:20.7-31.5). Most mothers (83.3%, 1428/1714) had a documented HIV-test result and date. Median time from last test to survey was 15.5 months (IQR:8.0 – 25.9). A total of 57 new HIV-infections were diagnosed over 2530 person-years of follow-up. The estimated overall HIV-incidence was 2.25 (95%CI:1.74-2.92) per 100person-years.

Conclusions: It is feasible to estimate HIV-incidence among women who delivered in the last 4 years using a combination of community HIV-focused survey data coupled with previous HIV-testing history based on patients' clinical documents.

PEC269

HIV incidence in postpartum period: findings from Uganda's national PMTCT Impact Evaluation (PMTCT-IE) 2017-2019

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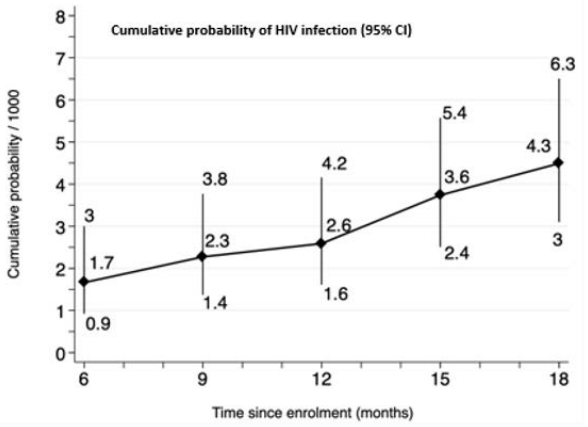
Background: There is a paucity of data on postpartum HIV incidence. We determined HIV incidence in recently delivered HIV-negative mothers followed for 18 months (m) postpartum in Uganda's PMTCT-IE (2017-19).

Methods: Recently delivered caregiver-infant pairs were prospectively enrolled at 4-12 weeks post-partum during immunization visits at 206 randomly selected, nationally representative health facilities (HF). A cohort of 6593 HIV-negative mothers were followed quarterly through 18m postpartum to ascertain HIV serostatus using Uganda's national HIV rapid testing algorithm. Social-demographic, behavioural, and health-related data were ascertained from interviews and medical records. Cumulative probability of incident HIV-infection using life tables and the inter-follow-up visit hazard of incident HIV were determined. Cox proportional hazard regression was used to determine independent factors associated with time to incident HIV infection.

Results: During the 18m postpartum follow-up, 27 (4.1/1000) new HIV infections were detected. The cumulative probability of incident HIV per 1000 was 4.3(3.0-6.3) at 18m (Figure 1). The risk of incident infection at each follow-up interval did not significantly vary. Adjusting for maternal age, education, and HF level, only HF level reached significance, with attendance at lower level HF correlated with fewer incident HIV infections as compared with attendance at hospitals [HC-III 0.37(0.15-0.94), p=0.037; HCII 0.19(0.05-0.69), p=0.012)]. Women aged 25-29 were at 4.69(0.98, 22.40) times higher risk as compared to women aged 15-19, although only reached borderline significance (p=0.053).



Risk of HIV infection during each follow-up interval [Hazard, (95% CI)]				
0-6m	6-9m	9-12m	12-15m	15-18m
1.7 (0.8-2.8)	0.6 (0.2-1.3)	0.3 (0.0-0.9)	0.1 (0.4-1.9)	0.8 (0.2-1.7)

Figure 1. Cumulative probability of HIV infection and risk of infection during each follow-up interval per 1000 postpartum women

Conclusions: The cumulative incidence of HIV infection during the 18m postpartum periods is 4.3/1000, with no significant variation in risk between early and late postpartum periods. Interventions targeting post-

partum mothers of all ages are necessary to reduce incident infections throughout this period. Further investigation is recommended to determine risk factors associated with postpartum incident infection, including confounding factors that may explain why attendance at lower level HF appears to be protective.

Measuring the epidemic through population-based surveys, including the undiagnosed fraction

PEC270

Managing HIV infection in the COVID-19 era. The cascade of care as tool to evaluate the effectiveness of city-wide programs against HIV/AIDS

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Background: Measuring HIV care cascade allows to identify processes useful to achieve UNAIDS 90-90-90 goal, we used the same elements to assesses the effect of COVID-19 pandemic on the HIV care cascade in a Province of Northern Italy.
Methods: We calculated the number of PLWHIV using the eCDC HIV modeling tool (version 1.3.0) that estimates the size of the undiagnosed population. Inputted data covered the period from 1984 to 2020. Data (year of diagnosis, AIDS diagnosis, CD4 at diagnosis, death, HIV-RNA blood level) on the diagnosed and treated populations were derived from a clinical provincial database and cross-checked with the Regional administrative data-base. Virological response to cART was defined according to last available HIV-RNA. Data from 2019 and 2020 were compared to identify possible negative effects of COVID-19 pandemic.
Results: The total estimated number of PLWHIV was 3314 in 2019 and 3371 in 2020. Taking into account subjects undiagnosed and lost to follow up 83.5% of subjects were actively followed in 2019 and 83.8 in 2020; 99.6% in 2019 and 100% in 2020 of them were taking cART. Finally 97.7% (2019) and 98.5% (2020) of patients taking cART had the last HIV-RNA <200 copies/ml (cut-off to define U=U) (figure). The use of an independent check-point referring to a city-wide program named "friendly test" to favor voluntarily testing, the switch to alternative methods of clinical management (tele-medicine), the implementation of a home-delivery system of ARV drugs, allowed us to limit the detrimental effects of COVID-19 and lock-down.

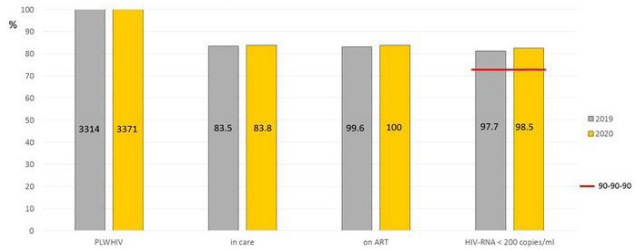

Figure 2. Cascade of care, Bergamo

Conclusions: The Achille's heel of our cascade of care is still the proportion of PLWHIV who are unaware of their status mostly because they do not perceive they are at risk and do not seek for the test. The programs implemented during the COVID-19 pandemic, however, allowed to counteract negative effects of the pandemic and lock-down periods.

PEC271

Estimates of undiagnosed children living with HIV in Eswatini, Malawi, Tanzania and Zambia using the Population HIV Incidence Assessments (PHIA)

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Background: While there are an estimated 1.8 million children living with HIV (CLHIV), there are few data on the proportion of CLHIV who are undiagnosed. Data from the Population HIV Incidence Assessments (PHIA) from 2015-2017 were used to estimate the number and proportion of undiagnosed CLHIV 1-14 years in Eswatini, Malawi, Tanzania and Zambia.
Methods: PHIAs are nationally representative surveys measuring HIV outcomes. HIV rapid test data (PCR confirmatory testing for children <18 months) were used to calculate the number of CLHIV 1-14 years in each country and to estimate the proportion not previously known to have HIV. Mothers or guardians reported previous HIV testing of children and results. Detection of ARVs was conducted using dried blood spots (DBS). Children with prior negative or unknown HIV test results and without detectable ARVs were considered previously undiagnosed. Survey weights with jackknife variance were used to generate national estimates of undiagnosed CLHIV (population estimates derived from national statistical projections).
Results: Estimates of CLHIV 1-14 years by country were: 10,000 (95% probability bounds (PB) 8,000-13,000) in Eswatini; 119,000 (95%PB 90,000-148,000) in Malawi, 101,000 (95%PB 61,000-141,000) in Tanzania and 80,000 (95%PB 62,000-98,000) in Zambia (figure 1).

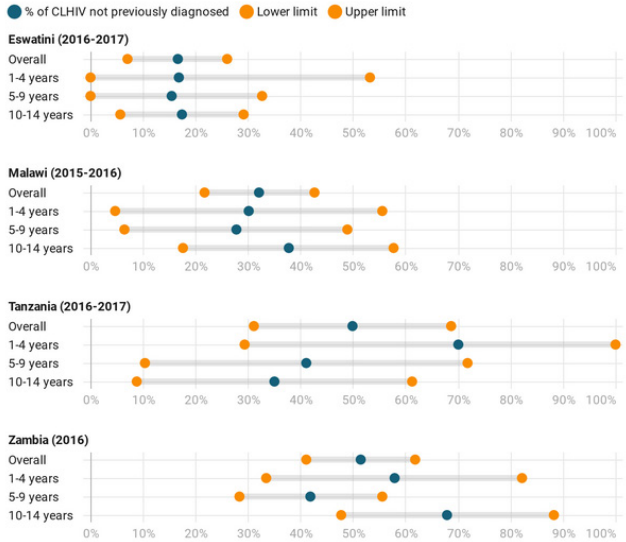

Figure 1. Estimates of proportions of undiagnosed CLHIV* in Eswatini, Malawi, Tanzania and Zambia using the population HIV incidence assessments (PHIA)
*CLHIV=children living with HIV, ages 1-14
Source: PHIA - created with Datawrapper

Among all CLHIV, 2,000 (16.6%) in Eswatini, 38,000 (32.2%) in Malawi, 50,000 (50.0%) in Tanzania and 41,000 (51.5%) in Zambia were undiagnosed. Missed diagnosis varied by age group in Malawi, Tanzania and Zambia. In Tanzania, the youngest children had the highest proportion undiag-

nosed (70.1% of CLHIV 1-4 years). In Malawi and Zambia, 10-14 year olds were the age group with the highest proportion of undiagnosed CLHIV (37.8% and 68.0%, respectively).

Conclusions: Across four countries we estimate that 132,000 CLIHIV were undiagnosed and thus not on treatment. These findings show the uneven coverage of pediatric HIV testing and underscore the urgent need to address gaps in diagnosis and treatment for all CLHIV.

PEC272

Older persons living with HIV (OPLWH) aged 50+ make more progress toward the UNAIDS 90-90-90 targets in four African countries

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Background: Achieving optimal HIV outcomes, as measured by UNAIDS 90-90-90 targets, is critical. Yet realizing 90-90-90 targets across all demographic groups is a challenge. Therefore, it is crucial to understand where further programmatic efforts are required to reach these goals.

Methods: We examined 90-90-90 progress by sex and age (15-24, 25-49, 50+) in Eswatini, Malawi, Tanzania and Zambia via Population-based HIV Impact Assessment (PHIA) nationally-representative surveys conducted between 2015-2017. Demographic interview and clinical data and blood for HIV testing and viral load measurement were collected from consenting individuals (minors provided informed assent) from randomly-selected households. The 90-90-90 estimates included: HIV status awareness (first 90); antiretroviral therapy (ART) use among aware (second 90); and viral load suppression (<1,000 copies/milliliter) among ART users (third 90). Data were weighted using jackknife variance estimation. P-values were calculated using Wald test statistic on the log of the ratio of proportions with Bonferroni adjustment for multiple comparisons.

Results: Overall, 78,815 individuals were interviewed: 51.3% female, 48.7% male, 36.8% 15-24 years, 49.1% 25-49 years, and 14.1% aged 50+.

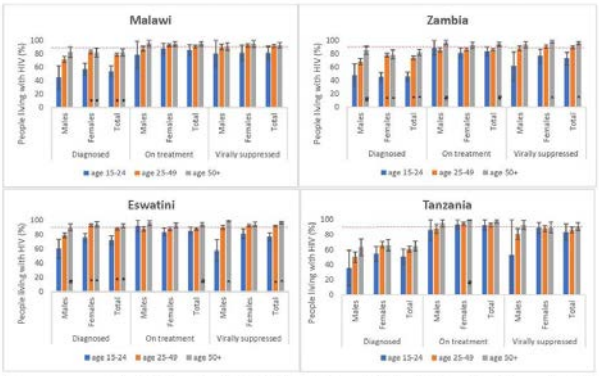
Achievement of 90-90-90 targets was more common among those 25 and older compared with 15-24 years and among women compared with men (Figure).

The first 90 was achieved in Eswatini by all aged 50+ and women 25-49 years.

The second 90 was achieved across countries among those aged 50+ and among women 25-49 years in Malawi, all ages in Tanzania, and Eswatini men 15-24 years.

The third 90 was achieved across countries among those aged 50+ except Tanzanian women, and by all 25-49 years in Malawi, Zambia, and Eswatini except among Zambian men.

Conclusions: OPLWH were more likely to reach 90-90-90 targets than younger individuals. However, the shortfall in first 90 achievement spans all age groups, except in Eswatini, indicating expanded HIV testing across countries and ages is needed.



Notes: ——— represents the 90-90-90 target; P-value ≤ 0.00046 indicates significance with Bonferroni adjustment for multiple comparisons: *statistically significant difference with 15-24 only, # statistically significant difference with 25-49 only, ^ statistically significant difference with both 15-24 and 25-49

Figure. ARV-adjusted 90-90-90 estimates among 15-24, 25-49 and 50+ years in four PHIA countries, conditional percentage

PEC273

Risk factors of recent HIV infection among sexually active women in 13 sub-Saharan African countries: results from the Population-based HIV Impact Assessment, 2015-2019

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Background: Sub-Saharan Africa has the highest HIV incidence in the world, with higher rates in women than men. Demographic shifts towards younger people have resulted in larger numbers of HIV infections in recent years, even as incidence rates decline. Population-based risk factors for recent HIV infections across countries are not well described. Identifying risk factors can help characterize HIV acquisition dynamics and identify sub-populations for ongoing prevention efforts.

Methods: The Population-based HIV Impact Assessments (PHIA) are nationally representative household surveys with one primary objective being to estimate HIV incidence. Demographic and behavioral data were collected by interview, and recent HIV infection defined as an HIV-positive result with (1) a Limiting Antigen (LAg)-Avidity EIA with median

normalized optical density ≤ 1.5 (plasma) or ≤ 1.0 (DBS), (2) viral load >1000 copies/mL, and (3) no antiretrovirals detected. Using data from PHIA in 13 countries, we described women with recent infection and assessed risk factors for recent infection using weighted log-binomial regression accounting for the survey design. Women aged 15-49 years who had sex in the past year, had valid biomarker and interview data, and were HIV-negative or recently infected were included in this analysis.

Results: Of the 84,670 included participants, 84,505 were HIV-negative and 165 were recently infected (0.2%). A plurality of recently infected women were between the ages of 15-24 (unweighted proportion: 43.0%), and most were unaware of their positive status (91.5%). Compared to HIV-negative women, those with recent infection were more likely to have first had sex before turning 18 (adjusted weighted Prevalence Ratio (aPR): 1.9 [95% Confidence Interval:1.4-2.7]), had sex with at least one non-marital or live-in partner in the last year (aPR: 2.6 [1.8-3.7]), and had sex with at least one partner of unknown (aPR: 2.4 [1.7-3.4]) or positive (aPR: 4.1 [2.0-8.4]) HIV status in the last year.

Conclusions: HIV prevention efforts aimed at delayed sexual debut and safer sex practices can reduce HIV transmission for women. Strategies targeting both testing and disclosure of positive status for young men, as well as routine testing for young women may facilitate more rapid awareness of HIV-positive status and antiretroviral initiation.

PEC274

COVID-19 pandemic on intimate partner violence; victimization and perpetration in the context of a generalized HIV epidemic in Uganda

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Background: Large scale disasters can lead to increase in intimate partner Violence (IPV). The COVID-19 pandemic control measures which included a national lockdown, restricted movement outside the household and reduced income generation opportunities, thereby increasing the risk of economic and food insecurity. Uganda experiences high rates of unemployment and under-employment; these circumstances were exacerbated by the lockdown. IPV is both a risk factor for HIV and more common among people living with HIV/AIDS (PLWHA), making it particularly important to understand in Uganda, which experiences a generalized HIV epidemic. The present abstract explores changes in IPV before and after the national lockdown in urban, peri-urban and rural settings in Wakiso district, Uganda.

Methods: Data was collected through population health surveillance (PHS), an ongoing longitudinal open population-based cohort. Consenting participants aged 13-80 years are followed annually. Participants from round two of the survey (Nov 2019-Mar 2020) were invited to participate in phone interviews during the COVID-19 lockdown (June-Aug 2020). Data on social demographics and effects of COVID-19 on IPV, and other associated factors like food security, were collected. Bivariate and multivariable analyses were done using Stata® 15 to determine proportions of different covariates and associations to IPV.

Results: A total of 1014 respondents participated in both the before and after surveys. During the lockdown, women reported to be more victimized (113 vs 52/555, 11%, p=0.046) compared to prior participant visit (visit 2). Majority of IPV victims (67.2%) occurred in the semi-urban. Women were also more likely to report perpetrating violence at follow up (72 vs 43, 5.2%, p=0.010) associated with increased alcohol use (p=0.031) and food insecurity (p=0.007). A greater proportion of men experienced IPV victimization during the lockdown than before (8% vs 6%).

Conclusions: Prevalence of IPV victimization increased among both men and women during the COVID-19 lockdown. IPV during the lockdown was associated with food insecurity and alcohol use and these may have been drivers of the IPV observed. Given that IPV, alcohol use and food insecurity are all risk factors for HIV and more common among PLWHA they represent an important cluster of health risks to address in this setting.

Measuring the population impact of prevention and treatment interventions

PEC275

Accelerating progress towards the United Nations' 90-90-90 target: the impact of a province-wide HIV Treatment-as-Prevention-based initiative in British Columbia, Canada

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Background: In British Columbia (BC), Canada, "HIV treatment as prevention" (TasP), encompassing widespread HIV testing and immediate initiation of free ART, was piloted and subsequently expanded to the rest of the province under the Seek and Treat for Optimal Prevention of HIV/AIDS initiative (STOP HIV/AIDS) starting in 2010. We compared the time from HIV diagnosis to antiretroviral therapy (ART) initiation, and from ART initiation to first virologic suppression before and after the full implementation of STOP HIV/AIDS.

Methods: This population-based cohort study used longitudinal data from STOP HIV/AIDS population-based cohort of all diagnosed people living with HIV (PLWH) in BC. Eligible PLWH were ≥18 years old, ART naïve, and newly diagnosed in BC between 2005 and 2016. Validated case-finding algorithms ascertained the HIV diagnosis date from clinical and administrative datasets, while the Drug Treatment Program identified the ART initiation date. The virologic suppression date was the first of ≥2 consecutive viral load measures <200 copies/mL within four months. Negative binomial regressions modelled the effect of STOP HIV/AIDS on the time from diagnosis to ART initiation, and from ART initiation to suppression, adjusting for confounders.

Results: PLWH diagnosed before (N=1601) and after STOP HIV/AIDS (N=1700) were significantly different as follows, respectively: 81% vs. 84% were men, 30% vs. 15% ever injected drugs, and the median CD4 level at diagnosis 280 vs. 380 cells/μL (p-values<0.005).

After controlling for different confounders, STOP HIV/AIDS was associated with a 65% shorter time from diagnosis to treatment (adjusted mean ratio: 0.35 [95%CI: 0.32-0.38]) and a 22% shorter time from treatment to suppression (adjusted mean ratio: 0.78 [95%CI: 0.72-0.85]).

Of note, median time from diagnosis to treatment initiation following the implementation of STOP HIV/AIDS decreased by as much as 23 months among PLWH aged <30 years.

Conclusions: In a large population-based cohort with universal health coverage, a TasP-based intervention was significantly associated with early ART initiation and faster time to virologic suppression, thus accelerating progress towards the United Nations' 90-90-90 target. Our results support the global expansion of TasP to accelerate the control of HIV/AIDS, as currently recommended by the United Nations.

PEC276

Zimbabwe's progress toward the UNAIDS 90-90-90 targets: comparing 2016 and 2020 population-based surveys

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Background: Joint United Nations Programme on HIV/AIDS (UNAIDS) set the ambitious goal of ending the AIDS epidemic by 2030. To achieve this goal, UNAIDS set a three-part target, 90% of HIV-positive individuals know their status; of these, 90% are receiving antiretroviral therapy [ART], and of these, 90% have viral load suppress (VLS; HIV RNA<1000 copies/mL). The Zimbabwe Population-based HIV Impact Assessment (ZIMPHIA) assessed progress toward the 90-90-90 UNAIDS targets in 2016 and 2020. We compared the two surveys' results among adults aged 15–64 years living with HIV (ALWH).

Methods: Consenting participants (20,577 in the 2016 and 17,728 in 2020 surveys) from randomly selected households provided demographic and clinical information and blood samples for household HIV testing per national guidelines, with HIV+ results confirmed via a supplemental assay. The analysis included 3,385 ALWH in 2016 and 2,820 in 2020 who tested positive in the survey. Estimates of HIV awareness and ART status were based on self-report or antiretroviral detection in blood. We applied multilevel logistic regression models to examine the correlation of time with each of these targets, using survey weights and estimated variances via jackknife series.

Results: Among ALWH who tested HIV-positive in the survey, awareness of HIV-positive status increased from 76.8% (95% CI: 74.9%–78.7%) to 86.6% (95% CI: 84.8%–88.3%); those receiving ART increased from 88.4% (95% CI: 87.0%–89.7%) to 96.9% (95% CI: 95.9%–97.6%). VLS prevalence among those receiving ART increased from 85.3% (95% CI: 83.4%–87.0%) to 90.1% (95% CI: 88.6%–91.4%).

On multilevel analysis, controlling for demographic covariates, ALWH were significantly more likely to know their HIV-positive status in 2020 than in 2016 (adjusted odds ratio [aOR], 1.12 [95% CI: 1.08–1.16]; p<0.001), those aware of their status were more likely to be receiving ART (aOR, 1.31 [95% CI: 1.24–1.39]; p<0.001), and those receiving ART were more likely to have VLS (aOR, 1.07 [95% CI: 1.03–1.11]; p=0.001).

Conclusions: We found significant progress toward linking HIV-positive individuals with treatment and increased VLS rates in Zimbabwe. Expanding targeted HIV testing could help increase awareness of the HIV-positive status and end the AIDS epidemic in Zimbabwe by 2030.

PEC277

Differential reductions in HIV clusters' effective reproductive number following population level interventions in British Columbia, Canada

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Background: Evaluating the impact of population-level interventions on epidemic dynamics within subpopulations is critical to understanding their effectiveness. Phylodynamic analyses of viral genetic sequences offer unparalleled insight into the factors influencing the timing of pathogens' population dynamics. We applied Bayesian phylogenetic modelling to investigate temporal changes in the effective reproduction number (R_e) within HIV phylogenetic clusters in British Columbia (BC), Canada. We hypothesized that declines in cluster-specific R_e among all clusters would follow the wide-scale availability of both highly active antiretroviral therapy (HAART) starting in the summer of 1996 and pre-exposure prophylaxis (PrEP) since January 2018.

Methods: Using 37,304 HIV partial pol sequences representing 9,848 people living with HIV in BC between 1996 and 2019, we inferred 100 approximate maximum likelihood phylogenies using FastTree2. Clusters comprised of at least 5 individuals with pairwise patristic distance <0.02 subs/site supported by >90% of phylogenies were identified. The four largest clusters were selected for subsequent analysis; two predominantly included people who inject drugs (PWID), while two were primarily composed of men who have sex with men (MSM). Using the oldest sequences available for patients within clusters, we analyzed clusters in birth-death skyline models in BEAST2 with a relaxed uncorrelated log normal clock and an informed prior for the become uninfectious rate to evaluate temporal changes in R_e in relation to the expanded availability of HAART and PrEP.

Results: Consistent with other data, the predominantly PWID clusters attained their respective maximum R_e=2.1 (95%HPD 1.1-3.6) in 1995 and R_e=1.4 (1.2-2.0) in 1989, then declined continually with the advent of HAART, with R_e<1.0 since ~2010. In contrast, predominantly MSM clusters displayed more variation; the R_e of the first MSM cluster peaked in early 2019 with R_e=2.5 (1.8-3.5), following the availability of publicly-funded PrEP while the R_e of the second MSM cluster has been declining since its peak in 2012 at 2.3 (1.4-3.3), with a marked decline in 2015 to R_e<1.0.

Conclusions: Contrary to our hypothesis, transmission dynamics within major phylogenetic HIV clusters have varied despite widespread availability of HAART and PrEP in BC. These analyses illuminate sub-populations who might benefit from enhanced connection with HIV treatment and prevention services.

PEC278

A comparison of self-reported antiretroviral therapy use and detection of antiretrovirals in the blood: the Zimbabwe Population-based HIV Impact Assessments (ZIMPHIA 2016 and 2020)

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Background: Identifying people receiving antiretrovirals (ARVs) is essential to accurate estimation of UNAIDS 90-90-90 targets. We compared self-reported antiretroviral therapy (ART) use with detection of ARVs in blood among adults (15-64 years) living with HIV (ALWH) in two population-based surveys in Zimbabwe (2016 and 2020).

Methods: We used participants' data from randomly selected households. Viral load (VL) suppression defined as <1000 copies/ml, and non-adherence as missed ARV doses for ≥ one day in the past month. Most prescribed first- and second-line ARVs, efavirenz, nevirapine, and lopinavir in 2016, and additionally dolutegravir in the 2020 survey, were assayed.

Results: Of all participants (20,577 in 2016 and 17,728 in 2020), 3,385 ALWH were identified in 2016 and 2,820 in 2020. In 2016, 63.4% (95% CI: 61.3-65.4%) and in 2020, 79.2% (95% CI: 77.1-81.1%) of ALWH self-reported ART use, however no ARVs were detected in 6.7% (95% CI: 5.4%-8.3%) in 2016 and in 2.9% (95% CI: 2.2%-3.8%) in 2020. Of those who reported ART use but no detectable ARVs, 6.0% (95% 3.2%-10.1%) in 2016 and 15.1% (95% CI: 8.3%-25.9%) in 2020 reported non-adherence. In 2016, 3.9% (95% CI: 3.2%-4.8%) and in 2020, 4.2% (95% CI: 3.4%-5.1%) of ALWH reported no prior HIV diagnosis, but ARVs were detected in their blood. Controlling for demographic covariates, ALWH were significantly less likely to have VL suppression if reported ART use but had no detectable ARVs (adjusted odds ratio [aOR]: 0.07, 95% CI: 0.05-0.10, P<0.001) and if they reported non-adherence (aOR: 0.66, 95% CI: 0.52-086, p=0.003). Including ARV detection improved the 90-90-90 estimations (Figure 1).

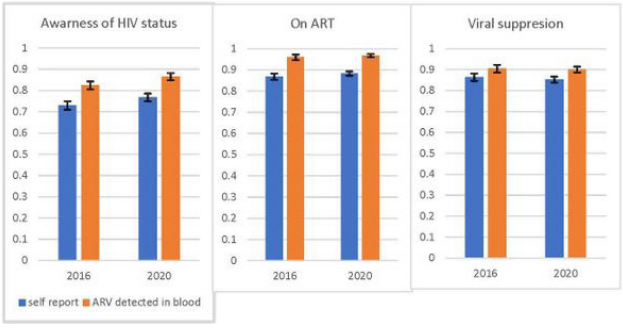

Figure 1. Progress in the achievement of the 90-90-90 targets (conditional) among HIV-positive adults, based on self-reported ART or ARV detectable in blood: the Zimbabwe Population-based HIV Impact Assessments (ZIMPHIA 2016 and 2020)

Conclusions: The findings indicate consistency between self-reported ART use and ARV detection, evidence of high ART adherence, but some level of unwillingness to disclose HIV+ status and ART use. Inclusion of ARV detection enhanced estimates of ART coverage and VL suppression for 90-90-90 target calculations.

PEC279

Long-term survival among people living with HIV in rural South Africa: results from 6 years of observation in the ANRS 12249 treatment as prevention trial

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Background: Universal test-and-treat trials increased population-level virological suppression across trial sites in sub-Saharan Africa. We followed the ANRS 12249 TasP trial population for 6 years to determine whether the intervention had longer-term survival benefits.

Methods: The TasP trial was a cluster-randomised trial implemented in 22 communities in rural South Africa, from 2012–2016. Households were offered six-monthly home-based HIV testing. Immediate antiretroviral therapy (ART) was offered in trial clinics to all people living with HIV (PLHIV) in the intervention clusters and according to national guidelines in the control clusters. At trial end, individuals attending the intervention clinics were transferred to the public ART programme, with a 'treat-all' strategy adopted in September 2016. Deaths during and two years after trial end were ascertained through annual demographic surveillance. Random effects Poisson regression was used to estimate rate ratios (RR) and 95%CI for the effect of trial arm on mortality among i) all PLHIV regardless of serostatus awareness, ii) PLHIV aware of their status, iii) those not on ART at entry to trial clinics. An interaction term between period and treatment arm was included, to allow the effect of trial arm to differ between periods.

Results: Amongst all PLHIV and those aware of their serostatus, there was no effect of immediate ART on mortality (Table).

	All people living with HIV		Diagnosed (aware of status)		Started ART during trial	
	Control (N = 4619)	Intervention (N = 3936)	Control (N = 4058)	Intervention (N = 3416)	Control (N = 912)	Intervention (N = 953)
Median age at entry (IQR), years	33 (26-43)	32 (25-43)	34 (26-44)	33 (26-43.5)	36 (28-45)	33 (26-44)
Sex, Female (n, %)	3452 (74.7)	2948 (74.9)	3060 (75.4)	2557 (74.9)	651 (71.4)	680 (71.4)
Death/person-years	158/17,201	151/14,767	144/14,708	129/12,453	52/3044	39/3341
Overall mortality rate/1000 person-years	9.30	10.38	9.95	10.54	17.09	11.67
Crude rate ratio (RR) [95% CI]	1	1.11 (0.86 - 1.43); p = 0.44	1	1.06 (0.78 - 1.43); p = 0.72	1	0.69 (0.45 - 1.04); p = 0.07
Adjusted RR (95% CI)	1	1.10 (0.85 - 1.43); p = 0.46	1	1.06 (0.79 - 1.42); p = 0.71	1	0.69 (0.45 - 1.04); p = 0.08
Mortality rate during trial/1000 person-years	11,34	11.96	12.04	12.09	22.43	10.99
Mortality rate after trial/1000 person-years	6.79	8.36	7.56	8.72	11.46	12.49

Table

Among individuals who started ART during the trial, there was evidence that the intervention decreased mortality (aRR=0.69, 95%CI=0.45-1.04, p=0.08), although the effect was primarily during the trial (aRR=0.49, 95%CI=0.28-0.85, p=0.01), but not after the trial ended (aRR=1.15, 95%CI=0.59-2.21, p=0.69).

Conclusions: The "treat-all" strategy resulted in a mortality benefit amongst individuals who started ART within the trial but not in all PLHIV over 6 years of follow-up. To achieve maximum benefit of immediate ART in South Africa, barriers to ART uptake and retention in care need to be addressed.

Describing the spread of HIV through geographical information systems

PEC280

Geospatial clusters of recent HIV-1 infection, Malawi, October 2019 - March 2020

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Background: In Malawi, recent HIV-1 infection surveillance was implemented within HIV testing services (HTS). The surveillance system utilizes a point of care (POC) test to detect persons recently infected with HIV, to guide public health response in targeting areas with ongoing transmission.

Methods: Newly diagnosed clients at 103 facilities, from October 2019 through March 2020, were included. We conducted an analysis of recent infections per facility using a spatial scan statistic in a discrete Poisson model with SaTScan™ to identify clusters of facilities with significantly elevated rates of recent HIV infections.

Rates were calculated as the number of recent HIV infections per 100,000 HIV testers at-risk and relative risk (RR) measures were calculated based on observed and expected counts of recent infections inside and outside of each cluster.

Using a denominator of recent infections plus total negative HIV tests per facility to simulate an at-risk population, clusters were ranked by probability of occurrence based on log-likelihood, adjusting for sex and age, not allowing cluster overlap, at ≤20-kilometers.

Results: Of 9,168 new HIV diagnoses, 304 (3.3%) were recent. Spatial analysis detected (Figure 1) three clusters where the observed rate of recent infections was higher than the expected rate: one in District A among four facilities, with a recent infection rate of 589 (RR: 3.1, p<0.001); the second, in B and C Districts, among four facilities with a rate of 374 (RR: 2.0, p<.02); and the third, in District A, one facility, with a rate of 825 (RR: 4.2, p=0.03).

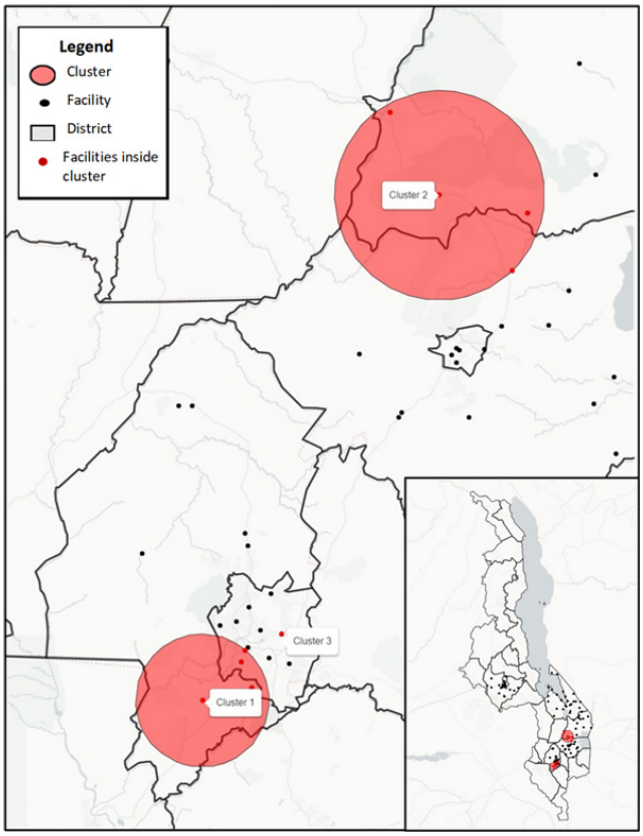

Figure 1. Geospatial clusters of recent HIV-1 infection among health facilities implementing recent HIV infection surveillance in five districts – Malawi, October 2019 - March 2020

Conclusions: These findings describe significantly high rates of recent HIV infection among three geospatial clusters of health facilities in Malawi. Public health responders should investigate facilities within geospatial clusters to identify risk factors for infection, inform interventions to improve HIV program services and interrupt transmission to achieve epidemic control.

Male circumcision

PEC281

Characterizing the effect of the COVID-19 pandemic on PEPFAR-supported voluntary medical male circumcision services, 2020

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Background: The 2020 COVID-19 pandemic led to a significant disruption in the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) voluntary medical male circumcision (VMMC) program for HIV prevention in sub-Saharan Africa. VMMC programs are vulnerable to COVID-19 mitigation measures given that interventions aimed at curbing COVID-19 transmission such as suspension of elective medical interventions, and closure of healthcare facilities, directly impact VMMC services and health seeking behavior.

Methods: PEPFAR Monitoring, Evaluation, and Reporting (MER) Data were analyzed to characterize VMMC service disruptions during the COVID-19 mitigation measures among the 15 sub-Saharan African countries prioritized for VMMC. VMMC annual and quarterly performance in U.S. Government fiscal year (FY) 2020 were compared to FYs 2017 to 2019 including the number of males circumcised and achievement of national targets.

Results: Globally, 65% of the VMMC annual target was met in 2020 compared to 102% in 2019 and the majority, 12 of 15 countries, did not meet their annual national target. 2020 had the lowest achievement of annual target for the period of 2016 – 2020 (Figure 1).

Among all 15 countries combined, annual VMMC performance decreased 33% from 3,899,572 VMMCs performed in 2019 to 2,631,202 performed in 2020. Quarter 3 2020 was the most significantly impacted quarter (Figure 2), with 13 countries experiencing a reduction in services ranging from 18% to 100% compared to the same quarter in 2019.

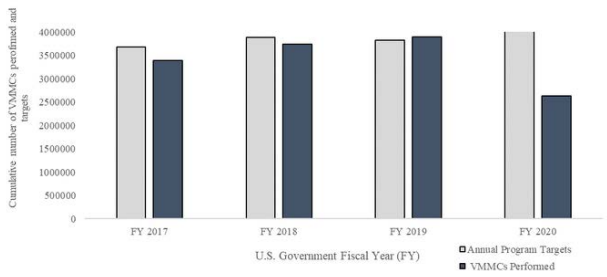

Figure 1. Annual U.S. President's Emergency Plan for AIDS Relief-supported voluntary medical male circumisions and program targets among 15 sub-Saharan African countries, 2017 - 2020

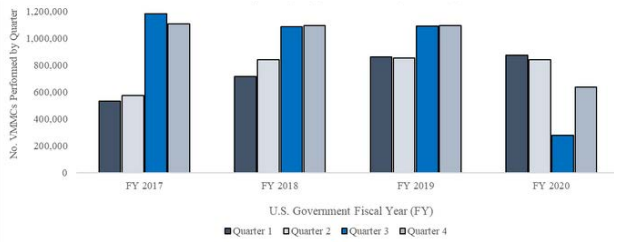

Figure 2. U.S. President's Emergency Plan for AIDS Relief (PEPFAR) supported voluntary medical male circumisions (VMMCs) performed by quarter and year, among 15 sub-Saharan African countries, fiscal years (FYs) (October 1 - September 30) 2017 - 2020

Conclusions: Country-specific targets are established to maximize the benefits of VMMC; however, during the COVID-19 pandemic in 2020, most countries did not reach these targets.

PEC282

Changes in the quality of voluntary medical male circumcision services in selected districts of the Mpumalanga, Eastern Cape, Free State and North West Provinces of South Africa

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Background: Recent studies in the Sub-Saharan countries in Africa have indicated gaps and challenges for voluntary medical male circumcision (VMMC) quality of service. Less has been focused on the changes in quality of service after implementation of continuous quality improvement (CQI) action plans.

This study aimed to determine changes in the quality of services between baseline and follow-up re-assessments after CQI support intervention at VMMC sites in the North West, Mpumalanga, Eastern Cape and the Free State provinces in South Africa.

Methods: This was a pre-post design intervention study based on data collected from the National Department of Health sites supported by Right to Care (RTC) on VMMC services in South Africa, from July 2018 to October 2019. Data for baseline CQI assessment and re-assessments was collected using a standardized National Department of Health (NDoH) CQI assessment tool for VMMC services. Quality improvement support was provided through provision of standard operating procedures and guidelines, mentoring and on-site in-service trainings on quality improvement planning and implementation. A paired sample t-test was used to compare the quality of service mean scores before and after CQI implementation by quality standard.

Results: A total of 40 health facilities were assessed at both baseline and after CQI support visits. Results showed significant increases for the overall changes in quality of service after CQI support intervention of 11.89% for infection prevention (95%CI: 6.60-17.15; p<0.001) and 8.28% for male circumcision surgical procedure, (95%CI: 3.25-13.30; p<0.01). Similarly, individual counselling, and HIV testing increased by 13.56%, (95%CI: 6.94-20.19; p<0.001), group counselling, registration and communication by 8.5%, (z=3.529; p<0.001), and 35.08% for monitoring and evaluation, (95%CI: 28.03-42.12; p<0.001).

In addition, there were significant increases for management systems of 28.65%, (95%CI: 22.30-35.00; p<0.001), leadership and planning 23%, (95%CI: 12.85-33.88; p<0.001%) and supplies, equipment, environment and emergency 5.10%, (95%CI: 1.09-9.11; p<0.01). The overall quality of service performance across provinces increased by 17.79% (95%CI: 14.24-21.34; p<0.001).

Conclusions: The overall quality of service performance across provinces was significantly improved after implementation of CQI support intervention program. However, more support was required for male circumcision surgical procedure and infection prevention in Mpumalanga and the Free State respectively.

PEC283

HIV Prevention in COVID-19 lockdown: The impact of suspending VMMC in SA and the subsequent effects on HIV transmission dynamics

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Background: The VMMC program in South Africa commenced in 2010 with just over 4,3 million men circumcised by 2019. Due to traditional beliefs and cultural practices of male circumcision in the country, SA has a seasonal trend of VMMC uptake. High demand periods coincide with the winter season in SA (April to July), and low demand for VMMC is between August and March. SA achieves approximately 60-70% of its annual VMMC coverage within the winter months. The National Department of Health suspended all VMMC across the country from mid-March 2020, coinciding with the National COVID-19 lockdown. The suspension was lifted in September 2020, with strict limitations on number of patients that may be circumcised per day. The suspension coincided with the high demand season for VMMC across SA, resulting in a decade low number of VMMCs performed for 2020. We aimed to assess the impact of the nationwide VMMC suspension on number of HIV infections averted.
Methods: Data was collected from the National VMMC program database. Using SPSS 22.0 we determined the loss of VMMC coverage due to the COVID-19 related suspension, and the consequent loss of prevention impact by province. Using time-series design and modelling of HIV transmission dynamics, we determined the potential loss of number of HIV infections averted through the loss of VMMC for the suspension period.
Results: SA observed a mean reduction of 514% of VMMCs done for 2020 compared to prior years (2016-2019). The loss of HIV infections averted is estimated to be approximately 114481. Based on the postulated R0 of HIV in Africa (4,5%), this loss in VMMC coverage could result in thousands of additional HIV infections considering the high risk of exposure due to high background prevalence.
Conclusions: The interruption of services related to COVID-19 mitigation erodes the momentum and gains achieved through decades of program implementation. It is imperative that the syndemics of COVID-19 and HIV be addressed in a manner that does not detract from the collective objectives of curbing transmission and elimination of infections.

PEC284

Demand creation and voluntary medical male circumcision during COVID-19 pandemic

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Background: Voluntary Medical Male Circumcision (VMMC) programs were negatively impacted by COVID-19 restrictions since they predominantly rely on community-level demand creation, the activities of which were indefinitely halted in March 2020 due to such restrictions.
Description: From April 2020, EGPAF established a VMMC referral initiative to recruit men through HIV testing services (HTS) within health facilities with the use of HTS Counsellors. Men who agreed to VMMC and those who contemplated undergoing the procedure were referred to demand-creation assistants (DCAs), who followed up with clients by phone. If the client decided to get circumcised, the DCAs linked the client to a VMMC nurse in a VMMC site who ensured the facility was ready to provide VMMC services, and booked the client for VMMC. After the circumcision, the client received routine follow-up from the DCA and VMMC nurse. Men completing the referral had transport costs reimbursed, starting in August 2020.
Lessons learned: Health facilities recruited 169 clients; 68% (n=115) were successfully followed up by phone, 12% (n=21) could not be reached (their phones were not available on the network, did not answer calls, or had purposefully provided incorrect numbers), and 20% (n=33) did not receive follow-up. Of the 169 clients recruited, 88% (n=148) reached a VMMC site and 82% (n=122) were successfully circumcised. Non-circumcision was mainly due to medical conditions, which clients needed to treat before they could get circumcised. The referrals improved over time, with the highest numbers in September 2020 when transport reimbursements for clients was provided (Figure 1).

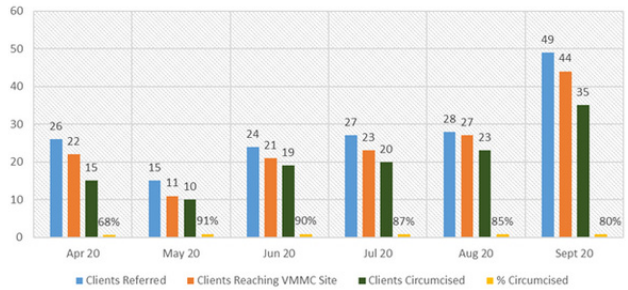

Figure 1. Clients referred for VMMC and circumcised during countrywide lockdown due to COVID-19 pandemic from April to September 2020 (N=169)

Conclusions/Next steps: The COVID-19 restrictions created an opportunity to increase demand generation for VMMC at the facility level. This intervention improved demand and referrals for VMMC, and calls for further engagement of health facilities to recruit clients and support them through the VMMC process. Transport reimbursement can be provided to facilitate access to VMMC services.

PEC285

Association between medical male circumcision and HIV risk compensation among heterosexual men: a systematic review and meta-analysis

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Background: Medical male circumcision (MMC) reduces HIV infection among heterosexual men. There are concerns MMC may prompt higher risk sexual behaviors because of lower self-perceived of HIV infection. We reviewed the published literature to examine associations between MMC and both condom use and number of sex partners among heterosexual men.
Methods: We searched PubMed, Embase, and the Cochrane Library for studies published before May 5, 2020. Interventional and observational studies were included if they contained original quantitative data de-

scribing the association between MMC and condom use and/or number of sex partners among heterosexual men. We excluded data from men whose circumcisions were ritual/religious and data from men who have sex with men. We used the Mantel-Haenszel random effects model to calculate pooled odds ratios (OR) and 95% confidence intervals (CI). In subgroup analysis, the standardized mean differences' difference (SMDD) of condomless sex or multiple partners was calculated for cohort studies and randomized controlled trials (RCTs) and then pooled with a random effects model. We assessed bias with the Cochrane Handbook of Systematic Reviews of Interventions and the Newcastle-Ottawa Scale.

Results: From 27 eligible studies, we identified 99,292 men from 31 independent population samples. 24 (88.9%) studies were from Africa. We did not find statistically significant association between MMC and condomless sex (OR 0.91, 95% CI 0.80-1.05; k=30; I^2=88.7%) or multiple sex partners (OR 1.02, 95% CI 0.88-1.18; k=27; I^2=90.1%). Subgroup analysis of cohort and RCT studies showed that circumcised men were less likely to have multiple sex partners at 6 months (SMDD -0.12, 95% CI -0.19-–0.04; k=5) and 12 months (SMDD -0.09, 95% CI -0.17-–0.01; k=5;) post-MMC, but there was no statistically significant difference in number of sexual partners after 12 months post-MMC (18 months: SMDD 0.10, 95% CI -0.01-0.20; k=3; ≥24 months: SMDD 0.07, 95% CI -0.10-0.24; k=4).

Conclusions: The promotion of circumcision as an HIV preventive measure does not appear to increase higher risk sexual behavior in heterosexual men. Ongoing sexual health education should be maintained as a vital component of effective MMC programs.

PEC286

Experience with ShangRing circumcision in Malawi voluntary medical male circumcision program

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Background: Malawi has implemented voluntary medical male circumcision (VMMC) for HIV prevention since 2008. Between 2015 and 2019, the country evaluated ShangRing (collar clamp) device through pilot, active (AAES), and passive (PAES) adverse event surveillance to inform its use within the program. We present lessons learned for the period May 2015 to December 2020.

Description: The ShangRing device was first introduced in Malawi in 2015, through implementation pilot(n=498) in one fixed site to assess safety and acceptability among males 18 to 49 years. The device safety and acceptability were further evaluated in 10 sites under AAES from April to September 2019 (n=1862). Following favorable results, the device was endorsed in October 2019 for routine services under PAES. Since endorsement, 5,104 ShangRing circumcisions have been conducted in 15 sites (Blantyre) by December 2020, with an overall low moderate(MAEs) and severe(SAEs) adverse event (AE) rate of 0.001%(5/5104) reported. The MAEs(2) were post removal wound disruptions while SAEs(3) were ring displacements requiring surgical intervention.

Lessons learned: During the pilot phase, the AE rate was 1.4% (7/498, MAEs), and 98% (488/498) of males circumcised were happy with cosmetic outcome. During AAES, the AE rate was low (0.0005%: 1/1862,SAE) compared to the national acceptable rate (1%), and 31(82%) out of 38 ShangRing clients separately interviewed were satisfied with placement and removal procedures because of less pain experienced. ShangRing circumcision has short placement procedure time (7 minutes, AAES; 5 minutes, PAES) compared to the time taken on conventional surgical techniques (15 minutes). Key challenge associated with ShangRing circumcision is the requirement for multiple device sizes (15) leading to frequent sites stock outs.

Conclusions/Next steps: ShangRing circumcision is safe, fast, and acceptable in Malawi context. It prevents potential penile glans injuries and urethral fistulas associated with deep stitches of conventional surgical techniques, especially among younger clients (10-14 years).
The national program should promote ShangRing circumcision as an equivalent alternative to conventional surgical circumcision, and should scale it up to accelerate achievement of national and global prevention targets.

PrEP

PEC287

HIV pre-exposure prophylaxis amongst most-at-risk populations in Cameroon: lessons learnt from the CHAMP project

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Background: In addition to condom use, WHO recommends the use of Pre-exposure prophylaxis (PrEP) among most-at-risk populations to prevent new HIV infections, but its scale-up in low- and middle-income countries remain sub-optimal. This concept analysis seeks to understand PrEP use in the context of Cameroon.

Description: The Continuum of prevention, care and treatment of HIV/AIDS with most-at-risk populations (CHAMP) project implemented in Cameroon since 2014 targets most-at-risk populations for promoting HIV prevention and management. Through the CHAMP project and for the very first time, female sex workers (FSW) and men who have sex with men (MSM) who tested negative for HIV and who were assessed to be at a high risk of contracting HIV, got enrolled in the cities of Yaoundé and Douala and were offered PrEP using the daily model. Routine program data used for this analysis were collected from June 2019; when the intervention began through April 2020 with which frequencies were calculated and contingency tables generated. PrEP uptake was compared between age groups and population types using a Chi-square test.

Lessons learned: Overall, 11,007 beneficiaries were sensitized for PrEP and of those, 1,539 (13.9%) underwent a PrEP eligibility assessment (FSW: 565/5,323; 11%; MSM: 974/5,684; 17%). Over 80% (1,287) of those who took assessment were eligible to start PrEP and of those, 512 (40%); aged atleast 21years, effectively started PrEP.
Despite showing less onset interest on PrEP, its uptake among eligible beneficiaries was higher among FSWs (198/429; 46%) than MSM (314/858, 37%) with p-value 0.0011. Of those who started PrEP, 86% continued at one month; 42% at three months; and 36% at six months with some of the reasons for discontinuation being feeling less incentive, high mobility and drug side effects.

Conclusions/Next steps: We observed low successful referral likewise suboptimal PrEP acceptance from those eligible and continuation. PrEP discontinuation was highest within the first three months of PrEP. More sensitization to improve risk perception and on the benefits of PrEP may help improve the interest and subsequent uptake of PrEP. There is also the need to better understand factors influencing PrEP continuation, especially within the first three months to inform on PrEP continuation strategies.

PEC288

Substantial increase in HIV risk behaviors and poor PrEP adherence among men who have sex with men during the COVID-19 pandemic: an observational longitudinal study in four cities of China

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Background: The novel coronavirus disease (COVID-19) pandemic has a massive impact on the oral Pre-exposure prophylaxis (PrEP) project, with dramatically reduced PrEP use. However, the changes in HIV risk behaviors, HIV testing behaviors, and PrEP adherence has remained unclear since the COVID-19 pandemic. We investigated these changes among men who have sex with men (MSM) taking PrEP in China and analyzed the associated factors of poor PrEP adherence before and during the COVID-19 pandemic.

Methods: An observational longitudinal analysis of HIV-negative MSM using PrEP with two oral strategies based on an ongoing PrEP trial in four cities of China from February 12 to March 8, 2020, assessing the change in sexual behavior characteristics and PrEP adherence before and during the COVID-19 pandemic. We used logistic models to analyze the correlated factors of poor PrEP adherence.

Results: We enrolled 791 eligible participants from CROPrEP (418 in daily PrEP, 373 in on-demand PrEP). Compared with the follow-up data (the 4th-week visit) before the COVID-19, both condomless anal intercourse (CAI) with regular partners (25.7% vs. 11.8%) and with casual partners (9.0% vs. 3.6%) were significantly increased (all P < 0.05). Meanwhile, the proportion of HIV testing in the past month decreased from 50.1% to 25.9%, the proportion of PrEP use decreased from 97.9% to 64.3%, while the prevalence of poor PrEP adherence increased from 23.6% to 50.1% (Odds ratio [OR] 3.3, 95% CI 2.6-4.0). Poor PrEP adherence in the past month correlated with the absence of HIV test (Adjusted odds ratio [AOR] 1.4, 95% CI 1.0-1.9), using condoms with regular sexual partners all time (vs. never aOR 2.2, 95% CI 1.2-4.1) and marring or cohabitating with females (vs. not married aOR 3.1, 95% CI 1.6-5.9).

Conclusions: CAI and poor PrEP adherence increased substantially, coinciding with a dramatic reduction in HIV testing among MSM PrEP users may undermine PrEP's protection effect and increase the risk of HIV drug resistance. Our research highlight that it's necessary to provide HIV self-testing (HIVST) reagents or online interventions to improve protective sexual behaviors and PrEP adherence, especially for those MSM who marry or cohabitate with females.

PEC289

Acceptability of and preferences for long-acting injectable PrEP (LAI-PrEP) and other PrEP modalities among sexual minority men in Nigeria, Africa

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Background: Sexual minority men (SMM) in Nigeria have been disproportionately affected by the HIV epidemic. Pre-exposure prophylaxis (PrEP) has been shown to reduce HIV acquisition among SMM. Recently, substantial scientific progress has been made in the development and testing of new modalities for PrEP including long-acting injectable (LAI-) PrEP. The goal of the current study was to investigate willingness to use long-acting injectable (LAI-) PrEP and preferences for other PrEP modalities among HIV-negative SMM in Nigeria.

Methods: Between March and June 2019, 413 SMM residing in four regions of Nigeria (Abuja, Delta, Lagos, and Plateau) were recruited and completed a quantitative assessment. We assessed the distribution (percentages and means) of all variables by willingness to use LAI-PrEP and PrEP modality preferences. Chi-square global tests of independence were used to assess independent associations between variables. To examine willingness to use LAI-PrEP and PrEP modality preferences, multivariable binomial and multinomial logistic regression models were fit. Variables that were significant at $p < .05$ in the bivariate logistic regression models were retained in the multivariable models.

Results: We found that a majority of the SMM (88%) were willing to use LAI-PrEP. Furthermore, almost half (44%) preferred LAI-PrEP, 24% preferring other PrEP products (subdermal implant and rectal microbicides), 21% preferred daily oral PrEP, and 11% liked them all equally. We found that participants who reported interest in LAI-PrEP were more likely to be [adjusted odds ratio (aOR) 2.14; 95% CI: 1.04-4.39], report inconsistent condom use for insertive sex acts in the previous 3 months (aOR 3.94; 95% CI: 1.47-10.59), and report having a primary care provider (aOR 2.68; 95% CI: 1.20-6.00). Compared to participants who preferred daily oral PrEP, participants who preferred other PrEP modalities had higher odds of having some university/university degree or higher (aOR 2.70; 95% CI: 1.28-5.70). and reporting low financial hardship (aOR 4.12; 95% CI: 1.63-10.42).

Conclusions: As more data are released on the efficacy and effectiveness of LAI-PrEP and other PrEP modalities, it is imperative that SMM in Nigeria are prioritized for access to these prevention interventions, as they bear a disproportionate burden of HIV and are especially vulnerable to HIV infection.

PEC290

Risk of HIV infection, knowledge and use of pre-exposure prophylaxis (PrEP) among transgender and gender non-binary adults

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Background: PrEP is recommended as a critical element of a combined approach to HIV prevention for those at high risk of infection. However, there is a dearth of data to inform strategies for PrEP scale-up specifically among transgender individuals.

Methods: We conducted an online survey to estimate the prevalence of self-reported HIV risk factors, knowledge, and uptake of PrEP among transgender and gender non-binary adults in Kaiser Permanente Southern California, a large integrated health system in the United States.

Results: Among the 396 survey respondents (164 transmen, 151 transwomen, and 81 gender non-binary), the majority were young (age, mean [SD]: 33.7 years [13.18]) and of white race (table), and 87.3% had some college or higher education. Approximately 60% were not in a committed relationship. Almost all participants had a drug benefit through the health plan (98%). Among the 170 participants (42.9%) who reported behaviors associated with HIV risk and/or having an sexually transmitted infection (STI) within the prior 6 months, only 15 (8.8%) reported using PrEP in the prior 6 months and only 11 (6.5%) reported taking PrEP at the time of survey. Most participants (74.8%) had knowledge of PrEP; 77.5% endorsed the statement that PrEP users should use condoms during sex, but only 52% agreed that PrEP use does not prevent other STIs and 39% did not know whether PrEP helps prevent other STIs. The most common barriers to PrEP use were cost (61.6%), possible side effects (43.7%), not sure who to talk with to get PrEP (40.7%), unsure if PrEP is needed (37.9), not enough information if PrEP works (37.6%), and having to take PrEP everyday (36.9%).

Characteristics of survey respondents		Total (N=396)
Age, years, n (%)	18 - 32	231 (58.3)
	33 - 45	88 (22.2)
	46 - 58	47 (11.9)
	≥ 59	30 (7.6)
Race/ethnicity, n (%)	Non-Hispanic White	212 (53.5)
	Hispanic	55 (13.9)
	Non-Hispanic Asian	25 (6.3)
	Non-Hispanic Black	10 (2.5)
	Other/multiple	94 (23.7)

Table

Conclusions: PrEP use was very low among those with self-reported HIV risk factors. Tailored PrEP education and patient-centered programs targeting barriers to PrEP use among high risk transgender and gender non-binary adults are urgently needed.

PEC291

Pre-exposure prophylaxis (PrEP) use among MSM in Brazil is associated with greater HIV knowledge and lower internalized homonegativity

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Background: Although Brazil is one of the few Latin American countries where pre-exposure prophylaxis (PrEP) is freely available under national policy, PrEP use remains low. We explored the impact of HIV knowledge and internalized homonegativity on PrEP use among PrEP-eligible men who have sex with men (MSM) in Brazil.

Methods: We administered an online, cross-sectional survey to Brazilian *Hornet* application users in February-March 2020. This analysis includes cis-males ≥18 years-old who reported sex with men in the previous six months and were eligible for PrEP per at least one of the following: condomless anal intercourse, HIV-infected partner(s), transactional sex, and sexually transmitted infection.

Our primary outcome was current PrEP use. Key predictors included the HIV/AIDS Knowledge Scale, with higher scores indicating more knowledge, and Reactions to Homosexuality Scale (RHS), with higher scores indicating higher internalized homonegativity. Both scales were standardized. Associations with PrEP use were estimated using adjusted odds ratios (aOR) in logistic regression with 95% confidence intervals (95%CI).

Results: A total of 2,222 PrEP-eligible MSM were included. Mean age was 34.6 years, 52.3% lived in the state of São Paulo, and 87.6% identified as gay. A minority (n=370, 16.7%) reported currently taking PrEP. Increasing HIV knowledge scores were associated with increased odds of PrEP use (aOR:1.65 per standardized unit [95% CI:1.35-2.03], p<0.001), while increasing RHS scores were associated with lower odds of PrEP use (aOR:0.84 [95% CI:0.73-0.97], p=0.015).

Among other variables, PrEP use was lower in the 18-24 age group compared to 40+ (9.4% vs. 20.4%, aOR:0.43 [95% CI:0.27-0.69], p<0.001), and in respondents who identified as Black compared to White or Asian (10.6% vs. 17.9%, aOR:0.50 [95% CI:0.31-0.82], p=0.006)). Rates of PrEP use were highest among those reporting an HIV-infected partner (31.8%, aOR:3.01 [95% CI:2.28-3.97], p<0.001) or 30+ sexual partners (32.5%, aOR:2.92 [95% CI:1.95-4.36], p<0.001) in the previous six months.

Conclusions: PrEP use remains low in Brazil, even among eligible MSM. We found that greater HIV knowledge was associated with increased PrEP use, while internalized homonegativity was associated with decreased use. Wider dissemination of HIV prevention knowledge and addressing stigma experienced by MSM when engaging with healthcare services could promote increased PrEP use.

PEC292

How MSM PrEP users accommodate PrEP with other effective HIV prevention tools: analysis of prevention effective adherence

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Background: The concept of prevention-effective adherence (PEA) provides a perspective that PrEP adherence for effective protection against HIV acquisition should be considered with other preventive measures such as using condoms and undetectable viral load.

This study presents the analysis of PEA using pilot data from UPrEPU app, which aims to improve daily and event-driven PrEP use by self-monitoring on the app.

Methods: PEA requires measurement of

1) Risk of HIV,

2) Use of PrEP and

3) Use of other effective HIV prevention tools (i.e. condoms, undetectable viral load).

The risk for HIV acquisition in each sex act was classified by condom use and sexual partners' HIV status, including viral load (minimal risk, low risk and moderate to high risk). A correct intake of PrEP for each sex act was defined as:

1. Taking two pills on the day X (i.e. a sex day), day X-1 (i.e. the day before) or at least one pill on X or X-1 if a pill was taken between day X-6 and X-1, and followed by two single doses on the following two days after the day first drug intake for event-driven PrEP use;

2. At least one pill a day from day X-3 to day X+3 for daily PrEP use. Correct intake of PrEP in each risk category was compared by chi-squared tests.

Results: From May 2020 to October 2020, thirty-two participants had 1872 pill taken records and 572 sex-act records in the app over four-month observation period. Participants' overall median correct intake of PrEP was 81% (IQR: 50%-91%) with a mean of 69% (SD: 29%). Risk for HIV acquisition was considered moderate to high, low, and minimal at 141 (25%), 207 (36%) and 224 (39%), respectively. More than half of sex acts were correct use of PrEP (57%). Intake of PrEP was not significantly different among three risk groups (p=0.835).

Conclusions: Overall high-level of PrEP adherence was observed in this study. Future efforts should develop interventions to improve MSM PrEP users' correct intake of PrEP during high risk for HIV acquisition period.

PEC293

High interest in long-acting injectable HIV pre-exposure prophylaxis among nationwide online sample of United States men who have sex with men, 2019

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Background: Long-acting injectable HIV pre-exposure prophylaxis (LAI-PrEP) is efficacious. Understanding the degree and variation in willingness to use LAI-PrEP among high-risk populations, such as men who have sex with men (MSM), will help inform equitable uptake of this intervention. We assessed willingness to use LAI-PrEP among a 2019 US nationwide online sample of MSM age 15+, the American Men's Internet Survey.

Methods: Participants who did not report a prior HIV diagnosis were provided with a brief descripition of LAI-PrEP and were asked "How likely would you be to use an injectable form of PrEP to reduce the risk of getting HIV?" with 5-point Likert scale from very likely to very unlikely. Interest in LAI-PrEP was examined by participant demographics, risk behaviors, and history of daily oral PrEP use using bivariate and multivariable ordinal logistic regression and was reported as odds ratios and 95% confidence intervals.

Results: Among 2489 MSM, 72.9% were willing to use LAI-PrEP (44.9% very likely, 28.0% somewhat likely), while 17% were unlikely to use LAI-PrEP. Two-thirds of PrEP-naïve MSM and 89% of current daily oral PrEP users were very or somewhat likely to use LAI-PrEP (Table I). Likelihood of using LAI-PrEP was higher among black MSM (compared to white MSM), MSM who had condomless anal sex with a male partner, and current users of daily oral PrEP (compared to PrEP-naïve MSM).

	N	(%)	Very likely n	(%)	Somewhat likely n	(%)	Neither likely or unlikely n	(%)	Somewhat unlikely n	(%)	Very unlikely n	(%)	Odds ratio[a] (95% CI)	Adjusted odds ratio[a] (95% CI)
Age														
15-24	1081	(43.4)	458	(42.4)	324	(30.0)	110	(10.2)	89	(8.2)	100	(9.3)	0.96 (0.80, 1.17)	
25-29	517	(20.8)	242	(46.8)	142	(27.5)	41	(7.9)	36	(7.0)	56	(10.8)	1.20 (0.96, 1.50)	
30-39	365	(14.7)	187	(51.2)	81	(22.2)	40	(11.0)	19	(5.2)	38	(10.4)	1.27 (0.99, 1.62)	
40 and older	526	(21.1)	231	(43.9)	149	(28.3)	63	(12.0)	29	(5.5)	54	(10.3)	REF	
Race/Ethnicity														
Black, non-Hispanic	278	(11.2)	149	(53.6)	65	(23.4)	24	(8.6)	13	(4.7)	27	(9.7)	**1.30 (1.03, 1.65)**	**1.27 (1.00, 1.62)**
Hispanic	400	(16.1)	194	(48.5)	106	(26.5)	38	(9.5)	32	(8.0)	30	(7.5)	1.04 (0.85, 1.27)	1.03 (0.84, 1.27)
Other or multiple races	206	(8.3)	88	(42.7)	60	(29.1)	28	(13.6)	13	(6.3)	17	(8.3)	0.84 (0.64, 1.10)	0.85 (0.65, 1.11)
White, non-Hispanic	1567	(63.0)	667	(42.6)	458	(29.2)	159	(10.1)	114	(7.3)	169	(10.8)	REF	REF
Urbanicity														
Urban	966	(38.8)	451	(46.7)	262	(27.1)	97	(10.0)	72	(7.5)	84	(8.7)	REF	
Suburban	530	(21.3)	234	(44.2)	151	(28.5)	57	(10.8)	36	(6.8)	52	(9.8)	0.96 (0.79, 1.17)	
Small/medium metro	764	(30.7)	335	(43.8)	211	(27.6)	84	(11.0)	48	(6.3)	86	(11.3)	1.01 (0.85, 1.21)	
Rural	223	(9.0)	94	(42.2)	71	(31.8)	16	(7.2)	16	(7.2)	26	(11.7)	1.04 (0.80, 1.36)	
Condomless anal sex in past 12 months														
Yes	1813	(72.8)	871	(48.0)	490	(27.0)	156	(8.6)	114	(6.3)	182	(10.0)	**1.50 (1.27, 1.76)**	**1.43 (1.21, 1.69)**
No	676	(27.2)	247	(36.5)	206	(30.5)	98	(14.5)	59	(8.7)	66	(9.8)	REF	REF
Male sex partners in past 12 months														
Two or more	1741	(69.9)	848	(48.7)	502	(28.8)	137	(7.9)	106	(6.1)	148	(8.5)	1.21 (0.99, 1.49)	
One	374	(15.0)	124	(33.2)	87	(23.3)	69	(18.4)	32	(8.6)	62	(16.6)	REF	
Male partner type in past 12 months														
Casual only	900	(36.2)	408	(45.3)	253	(28.1)	90	(10.0)	67	(7.4)	82	(9.1)	1.09 (0.89, 1.34)	
Main and casual	1009	(40.5)	486	(48.2)	304	(30.1)	79	(7.8)	59	(5.8)	81	(8.0)	1.14 (0.93, 1.39)	
Main only	479	(19.2)	165	(34.4)	122	(25.5)	78	(16.3)	39	(8.1)	75	(15.7)	REF	
STI diagnosis in past 12 months														
Yes	336	(13.5)	195	(58.0)	80	(23.8)	16	(4.8)	22	(6.5)	23	(6.8)	**1.39 (1.13, 1.73)**	1.14 (0.91, 1.43)
No	2153	(86.5)	923	(42.9)	616	(28.6)	238	(11.1)	151	(7.0)	225	(10.5)	REF	REF
Illicit drugs in past 12 months														
Yes	977	(39.3)	463	(47.4)	257	(26.3)	90	(9.2)	69	(7.1)	98	(10.0)	**1.16 (1.00, 1.35)**	1.12 (0.96, 1.30)
No	1512	(60.7)	655	(43.3)	439	(29.0)	164	(10.8)	104	(6.9)	150	(9.9)	REF	REF
Daily oral PrEP use														
None	2031	(81.6)	774	(38.1)	570	(28.1)	229	(11.3)	149	(7.3)	220	(10.8)	REF	REF
Current	383	(15.4)	244	(63.7)	80	(20.9)	16	(4.2)	21	(5.5)	17	(4.4)	**1.56 (1.27, 1.92)**	**1.39 (1.11, 1.72)**
Past	161	(6.5)	95	(59.0)	43	(26.7)	8	(5.0)	2	(1.2)	10	(6.2)	**1.44 (1.06, 1.94)**	1.32 (0.97, 1.79)
Willing to take daily oral PrEP[b]														
Yes	1457	(69.4)	723	(49.6)	428	(29.4)	115	(7.9)	81	(5.6)	87	(6.0)	REF	
No	643	(30.6)	92	(14.3)	158	(24.6)	118	(18.4)	69	(10.7)	138	(21.5)	**0.76 (0.64, 0.90)**	

Table 1. Likelihood of using long-acting injectable HIV pre-exposure prophylaxis among 2,489 US men who have sex with men, 2019

Conclusions: Interest in LAI-PrEP is consistently high among US MSM, particularly among some groups potentially at higher risk of HIV infection. Though interest in LAI-PrEP varied by experiences with daily oral PrEP, interest was also high among those who were PrEP naïve, indicating the potential for this new PrEP modality to increase MSM engagement in biomedical HIV prevention. Monitoring of LAI-PrEP interest and exploring factors that could increase interest will be important to LAI-PrEP uptake.

PEC294

Predictors of no PrEP or condom use among MSM in West Africa (CohMSM-PrEP ANRS12369 – Expertise France)

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Background: Pre-exposure prophylaxis (PrEP) data for men who have sex with men (MSM) are essential for scale-up in West Africa, where access to HIV prevention and care remains difficult for this key population. We investigated the factors associated with neither PrEP nor condom use in a cohort of MSM on PrEP in West Africa.

Methods: CohMSM-PrEP recruits MSM in four community-based clinics in Mali, Côte d'Ivoire, Burkina Faso and Togo. During quarterly follow-up, which includes daily or event-driven PrEP, socio-behavioral data are collected. This analysis used data collected from November 2017 to November 2020. The study population included participants who declared a male partner in the previous three months (primary/casual). PrEP or condom use during most recent anal intercourse (insertive/receptive with male partners) was classified into four possibilities ('No PrEP or condom use,' 'PrEP use only,' 'Condom use only,' and 'PrEP and condom use') and covered M3-M33. Generalized estimating equations were used to identify factors associated with no prevention use.

Results: 632 participants were included in this analysis (1801 observations). Declaring PrEP use only increased from 47% at M3 to 55% at M33 and no PrEP or condom use from 10%-14%. Using condoms only decreased from 12%-9% and combined PrEP and condom use from 30%-23%. Overall, 12% of most recent anal intercourses were not protected by condoms or PrEP. Associated factors with no PrEP or condom use included declaring PrEP use to be difficult or very difficult (1.80[1.19-2.72], 0.005) and having high sexual risk perception with casual male partners (3.26[1.92-5.54], <0.001). Most recent anal intercourse being insertive (0.54[0.38-0.76], 0.001) and having intercourse with a primary male partner in the last month (1-4 intercourses, 0.53[0.37-0.75], <0.001; ≥5, 0.45[0.24-0.84],0.012) were protective factors.

Conclusions: Globally, most participants used at least one form of prevention during their most recent anal intercourse. However, despite PrEP and condoms being offered free of charge and as a part of a comprehensive sexual health prevention package, rates of no prevention use were non-negligible and persisted throughout follow-up. High sexual risk perception did not necessarily leverage prevention uptake. Further research is necessary to understand these participants' choice to forgo prevention.

PEC295

Incremental costs of integrated PrEP provision and effective use support in community-based platforms for adolescent girls and young women in South Africa

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Background: Adolescent girls and young women (AGYW) are a priority population for HIV prevention in South Africa. PrEP is a highly effective prevention method when used with high adherence (effective use), yet effective use among AGYW has been sub-optimal. Interventions aimed at supporting effective use of PrEP may improve pill-taking, and the affordability and sustainability of these programs depend on their cost. We therefore evaluated the cost of community-based PrEP provision and effective use support for AGYW.

Methods: We conducted a micro-costing analysis using data collected from a randomised controlled trial to evaluate the cost of PrEP provision and effective use support offered to AGYW through community-based HIV counselling and testing (CBCT) platforms between November 2018 and November 2019. AGYW initiating PrEP were randomised to receive:
1) group-based community health club effective use support,
2) individualised effective use support, or
3) community-based PrEP dispensary (standard-of-care).
Task shifting of effective use counselling services from nurses to trained counsellors was implemented in arms 1 and 2 above. Personnel costs were estimated from time-and-motion observations and staff interviews. Expenditure and ingredients-based approaches were used to estimate costs for medical and non-medical supplies and equipment. The average cost per person-month of PrEP was calculated as the total annual cost divided by the total number of months of PrEP coverage.

Results: In total, 603 AGYW initiated PrEP and accrued a total of 1,280 total months on PrEP. The average cost per person-month on PrEP with community-based PrEP dispensary, group-based community health club and individualised effective use support were estimated to be USD$13.99, $15.48, and $26.40 respectively.
Despite the addition of effective use support, the cost per person-month for group-based community health club PrEP provision model was similar to the standard-of-care model due to task shifting of effective use counselling services.

Conclusions: As designed, individualised effective use support increased the cost of standard-of-care PrEP delivery by 89%, while group-based community health effective use clubs increased the cost of standard-of-care PrEP delivery by 11%. These estimates are useful to policy makers in planning PrEP implementation and can inform cost-effectiveness and budget impact analysis for PrEP provision with effective use support services in CBCT platforms.

PEC296

Rapid scale-up of oral pre-exposure prophylaxis (PrEP) for key populations: experience from the PEPFAR/USAID-funded EpiC project

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Background: Improved access to oral pre-exposure prophylaxis (PrEP) as part of a comprehensive prevention strategy is urgently needed to respond to the unmet prevention needs of high-risk key populations (KPs), including sex workers, men who have sex with men (MSM), transgender (trans) people, and people who inject drugs (PWID), and to interrupt HIV transmission among them. The PEPFAR/USAID-funded Meeting Targets and Maintaining Epidemic Control (EpiC) project expanded differentiated service delivery (DSD) models to support PrEP scale-up in 16 countries.
Description: From October 2018 to September 2020, EpiC implemented PrEP programs tailored to high-risk KP individuals in 16 countries across Africa, Asia, and the Caribbean. The program trained providers to offer PrEP services through DSD models, including at KP-run community sites such as drop-in centers, mobile units, and facilities. Routine program data were collected, aggregated, and analyzed to understand trends in PrEP uptake and the major factors relevant to scale-up.
Lessons learned: Over the two-year period, EpiC expanded PrEP services from nine to 16 countries. In FY19, we initiated 4.5% of the 252,671 KP individuals who tested HIV negative onto PrEP. In FY20, we identified an additional 25,727 HIV-negative KP individuals and initiated 8.0% of those who tested negative onto PrEP. The relative increase in PrEP initiation was greatest among trans people (3.6 times in FY20 as in FY19). While no countries were offering PrEP to PWID in FY19, 1,322 (17.2%) were initiated on PrEP in FY20 (Table 1). The scale-up of DSD models, including the introduction of community-based initiation in FY20, contributed to the rapid expansion of PrEP to KPs, although overall PrEP uptake remains low.

KP Type	FY19			FY20		
	Tested HIV Negative	Started PrEP	% Who Started PrEP	Tested HIV Negative	Started PrEP	% Who Started PrEP
FSWs	132,062	3,400	2.6	150,797	6,330	4.2
MSM	112,454	7,759	6.8	108,855	12,988	12.0
Trans	7,659	296	3.9	11,052	1,514	14.0
PWID	496	0	0.0	7,694	1,322	17.2
Total	252,671	11,455	4.5	278,398	22,154	8.0

Table 1. PrEP uptake among HIV-negative KP individuals in FY19 and FY20

Conclusions/Next steps: As we strive toward achieving epidemic control, sustained collaboration with the KP community, governments, donors, and other stakeholders is essential for addressing barriers to PrEP uptake among KPs. Furthermore, expansion of DSD models for PrEP services is needed for PrEP scale-up.

PEC297

Acceptability of and willingness to pay for long-acting injectable pre-exposure prophylaxis among men who have sex with men, transgender women, female sex workers and people who inject drugs in Vietnam

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Background: Oral pre-exposure prophylaxis (PrEP) was first introduced in 2017 and has since been made available in nearly half of the provinces in Vietnam. The Ministry of Health was fast to adopt national PrEP guidelines (2017) and event-driven (ED) PrEP (2020), and has approved a five-year plan to reach 70,000 people by 2025 with a range of models and formulary including long-acting injectable PrEP.
Methods: To assess acceptability of and willingness to pay (WTP) for long-acting injectable PrEP (cabotegravir (CAB-LA), specifically), we implemented a cross-sectional study in four high-burden HIV provinces among 246 men who have sex with men (MSM), 124 transgender women (TGW), 121 female sex workers (FSW) and 125 people who inject drugs (PWID) as part of a larger study on use, preferences and WTP of health services.
Snowball sampling was applied among KP seeking services from KP-led clinics and community-based organizations. Interviews were conducted in person or online based on participant preference.
Results: In all, 23.2% of KP interviewed had heard of CAB-LA: 32.9% of MSM, 26.6% of TGW, 16% of PWID and 7.4 of FSW. Among the 65.3% (n=402) KP taking or interested in taking PrEP, 62.2% said they preferred long-acting injectable PrEP over oral PrEP (daily or ED) including 63.8% of MSM, 63.6% of FSW, 61.6% of PWID and 58.1% of TGW. The top two reasons for selecting long-acting injectable PrEP were not having to remember to take pills regularly (61.4%), and greater convenience (48.6%). While for those choosing oral PrEP, not liking injections (37.8%) and greater convenience (34.8%) were the primary factors.
Overall 80.1% of KP were WTP $30, 66.7% $40 and 48.8% $60 per CAB-LA injection; 54.% stated CAB-LA should cost = or < than oral PrEP while 29.9% said it needed to be free.
Conclusions: Awareness of CAB-LA was modest overall though higher among MSM and TGW. Of those using/interested in using PrEP, nearly two-thirds indicated a desire to use long-acting injectable PrEP over oral PrEP while both groups highlighted convenience as an important factor in their decision making. Ensuring CAB-LA is offered at low-cost or free of cost will be crucial for uptake.

PEC298

The reverse PrEP cascade in a multicentric cohort of recently HIV-infected patients (ANRS OMaPrEP 95041 study)

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Background: The HIV epidemic remains active in France despite PrEP implementation since 2016. We aimed to evaluate missed PrEP opportunities for patients with a recent HIV infection by analyzing the reverse PrEP cascade and identifying factors associated with PrEP knowledge.

Methods: Self-reported questionnaires (SRQ) were proposed to patients diagnosed with a recently acquired HIV infection (incomplete Western blot or negative HIV test in the previous 6 months) in 28 French HIV clinics. Socio-demographic, psychosocial and biologic data at HIV diagnosis were collected, as well as individual behaviors and health system use preceding the diagnosis. Logistic regression models were used to identify factors associated with PrEP knowledge.

Results: Between March 2019 and October 2020, 224 patients were diagnosed with a recent HIV infection. Among them, 185 responded to the SRQ (response rate=83%), 80.5% were men who had sex with men (MSM), 4.3% were women infected through sex with men and 15.1% were men infected through sex with women or in a non-sexual way.

According to 2018-French guidelines, 166 patients (89%) presented an indication for prescribing PrEP: 156 MSM, 2 transgender women, 11 sex workers, 2 patients with an untreated HIV-infected partner.

Among them, 89% declared seeing at least one physician in the previous 12 months, mostly general practitioners (85%). The reverse PrEP cascade is shown in Figure 1.

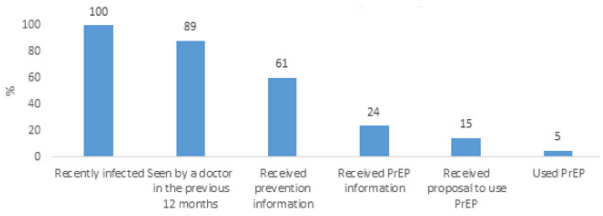

Figure 1. Reverse PrEP cascade (N=185)

Fear of side effects and low risk perception were the two most common reasons for not using PrEP.

In the multivariate logistic model, being MSM, younger than 35 years, practicing chemsex and doing HIV/STI screening at least once a semester (vs. less often) were associated with a higher probability of knowing about PrEP.

Conclusions: Two steps were deficient in the reverse cascade leading to PrEP: insufficient information about PrEP from caregivers and low levels of PrEP acceptance from informed and eligible patients.

PEC299

PrEP initiation in community safe spaces increases PrEP access among key and priority populations in Zambia

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Background: HIV pre-exposure prophylaxis (PrEP) is a highly effective biomedical prevention, yet uptake remains limited particularly among key and priority populations (KPs/PPs). In Zambia, PrEP has been available at government health facilities since 2017; however, KPs and PPs remain unreached through traditional health services. Novel ways are needed to provide PrEP access to KPs and PPs.

Description: Under the Z-CHECK and CIRKUITS projects, the University of Maryland Baltimore (UMB) implemented community PrEP initiation in October 2020. UMB conducted hotspot mapping to identify at-risk populations, and then set up community prevention posts (CPPs). CPPs provide a safe space within the community for KPs/PPs to access health services, including health education, HIV testing services (HTS), and PrEP. UMB recruited and trained community health workers to conduct HTS and PrEP education, and then facilitated health facility nurses to initiate PrEP on site at the CPP. KP gatekeepers helped to educate and mobilize KPs to access PrEP.

Lessons learned: From October 2020 to December 2020, UMB set up 8 CPPs for community PrEP initiation, initiating 4,533 clients in the community. Of these, 2527 (56%) were female, of whom 811 (32%) were aged 20-24 years and 615 (24%) were aged 25-29 years; 2006 (44%) were male of whom 477 (24%) were aged 25-29 years and 399 (20%) were aged 30-34 years (see Figure 1). Among 2,543 (56%) key populations initiating PrEP in the community, 1849 (73%) were female sex workers, 525 (21%) were men who have sex with men, 116 (5%) were transgendered persons, and 53 (2%) were people who inject drugs.

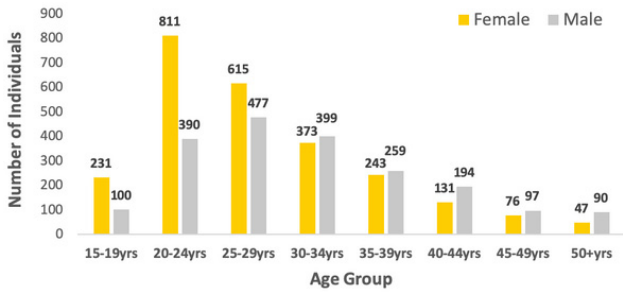

Figure 1. Age and Sex Distribution of Community PrEP Initiation, Oct-Dec. 2020

Conclusions/Next steps: Community PrEP initiation via CPPs is an effective way to reach underserved KPs and PPs in Zambia with biomedical HIV prevention. Further assessment on PrEP continuation amongst community initiates is needed.

PEC300

Delivering PrEP to young women in a low-income setting in South Africa: lessons for providing both convenience and support

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Background: Daily oral pre-exposure prophylaxis (PrEP) is a key tool in addressing high HIV incidence among young women.

Description: From 2017-2020, Médecins Sans Frontières provided PrEP, in conjunction with contraception and risk-reduction counselling, to 164 women aged 18-25, in a government-run clinic in Khayelitsha, a low-income, high HIV prevalence area in South Africa. Drawing on quantitative and qualitative interview data, we describe participants' engagement with the program and the indirect benefits of the program.

Lessons learned: Overall, 47 (29%) completed 18 months follow-up, with 15 (9.1%) attending all visits, and 28.7% of exits happening in the first month.

Proximity and convenience mattered: the main reported barrier to adherence was forgetting to take or travel with the pills. Despite attempts to recruit participants from other areas, most of those enrolled were those whose local clinic was the study clinic, and 15 (9%) exited because they left the area. More widespread availability of PrEP would help address these issues. PrEP provision also needs to adapt to changing contraception schedules, minimizing unnecessary facility visits.

Encouragement from family, friends, partners and other PrEP users (primarily through a Whatsapp group), was reported as a facilitator to PrEP use increasingly over the first six months, but with declining frequency from 6 to 18 months. Our experience and participant feedback highlighted the importance of peer support, primarily through Whatsapp and group gatherings, when they needed it, often in the first six months of PrEP use. Counselling prepared participants to be open about PrEP use with friends, family, and partners, as they were knowledgeable enough to answer questions about PrEP, and combat any misconceptions, highlighting the importance of strong initial counselling and education.

Participants' self-reported risk behavior decreased over time, (sex with more than one partner, p<0.001, and sex without a condom,p=0.063). In interviews, participants credited the program counselling with changing their behavior.

Conclusions/Next steps: Integrating PrEP into sexual and reproductive health services provides an additional entry point for engagement and has positive effects beyond PrEP use, including peer education, and reduced risky behaviours. Services need to be flexible enough to provide convenience and support, as needed, within resource constraints.

PEC301

Awareness of ED-PrEP and interest in switching from daily oral PrEP to ED-PrEP in Brazil, Peru and Mexico – the ImPrEP study

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Background: The WHO recommend Event Driven (ED)-PrEP for cisgender men who have sex with men (MSM) at risk for HIV and reporting infrequent sex. ImPrEP is a PrEP demonstration study conducted in Brazil, Peru and Mexico. We report results of a cross-sectional study to evaluate awareness of and interest in ED-PrEP among participants.

Methods: Participants responded questions about sex frequency, current PrEP use and ED-PrEP (awareness/interest). Reasons for interest in switching from daily PrEP to ED-PrEP were assessed using a four-point Likert scale and responses were grouped as "strongly agree/agree" vs. "strongly disagree/disagree". We used chi-square test to compare across countries.

Results: From February/2020 to January/2021, 3,764 completed the questionnaire in Brazil (58.5%), Mexico (27.1%) and Peru (14.4%). The majority were MSM (97.6%) and median age was 31 years (IQR:26-37). Daily PrEP use as prescribed was reported by 96.9%. Sex < 2 days/week was reported by 23.4%. ED-PrEP awareness was higher in Mexico (36.3%) than in Brazil (30.2%) and Peru (27.8%) (p<.001). After a brief explanation, 22.1% reported interest in switching from daily PrEP to ED-PrEP, with higher rates in Mexico (26.9%) and Peru (26.0%) than in Brazil (18.8%) (p<.001). The main reasons for interest were: ED-PrEP is more convenient (85.4%), ability to postpone unplanned sex (80.8%) and capacity to predict sex (73.6%). For the 77.9% not interested, the main reasons were: comfort with daily PrEP (98.1%), ED-PrEP is a difficult regimen (92.7%) and feeling anxious about own HIV risk (90.8%). Inability to anticipate sex was higher in Mexico (93.1%) than Peru (89.6%) and Brazil (85.3%) (p<.001), while having concerns with ED-PrEP efficacy was less reported in Brazil (53.0%) than Peru (73.9%) and Mexico (75.7%) (p<.001). MSM reporting sex < 2 days/week were more interested in switching to ED-PrEP than those having sex ≥ 2 days/week (38.1% vs. 17.2%; p<.001).

Conclusions: Awareness and interest in switching to ED-PrEP was low among Latin-American MSM who use daily PrEP. However, those who reported infrequent sex showed interest and considered it a convenient regimen. Beliefs about low efficacy and anxiety about HIV infection risk suggest that knowledge dissemination is necessary to increase interest in ED-PrEP.

PEC302

Initial implementation of PrEP in Zambian correctional facilities demonstrates high uptake among incarcerated people

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Background: As of 2021, Zambia has an estimated 21,078 incarcerated persons across 87 correctional facilities with occupancy of over 300%. Incarcerated persons represent a critical key population who are often at risk of HIV infection during incarceration but have limited access to HIV prevention options. The prevalence of HIV infection among incarcerated people in Zambia is estimated at 17.4%, over 50% higher than the national HIV prevalence. The University of Maryland Baltimore (UMB) has recently begun providing HIV pre-exposure prophylaxis (PrEP) to incarcerated people under the CIRKUITS and Z-CHECK projects.
Description: UMB started implementing PrEP service in the Zambia Correctional Services (ZCS) facilities in October 2020. Prior to scaling up PrEP services, orientation meetings were held with the ZCS leadership, where the benefits of PrEP for incarcerated people were explained. UMB trained 28 ZCS health care workers in PrEP management using the national PrEP training package. Inmates that screened positive for substantial HIV risk were offered HIV testing; those who tested negative were further counselled and offered PrEP services.
Lessons learned: From October 2020 to January 2021, across 18 correctional facilities from Eastern, Lusaka, Western, and Southern Provinces, a total of 8,065 inmates, 7,659 (95%) males and 406 (5%) females aged ≥15, were assessed via the PrEP and HIV Prevention Screening tool. Of these, 777 (9.6%) were initiated on PrEP, including 738 (95%) males and 39 (5%) females, respectively. The distribution of inmates reached with PrEP screening by age group and PrEP initiation by age group was similar. The highest proportion of inmates reached and initiated on PrEP was in the 25-29 years age group, 1,574 (20%) and 193 (25%), respectively.
Conclusions/Next steps: We describe one of the first demonstrations of PrEP service delivery in correctional settings in sub-Saharan Africa. Initial service delivery efforts have provided PrEP to a substantial number of incarcerated people in Zambia. Further assessment is needed of uptake, persistence, and adherence, as well as justice-involved persons' perceptions of risk and preferences for combination HIV prevention services. Offering PrEP in correctional settings is a key strategy to offer HIV prevention services for this underserved key population.

PEC303

Factors associated with PrEP uptake among adolescent´s men who have sex with men and transgender women in Brazil

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Background: HIV prevalence among adolescents' key-population (AKP) of men who have sex with men (MSM) and transgender women (TGW) is disproportionally high. PrEP is an important prevention technology but there are still few studies about PrEP uptake among AKP. We aimed to analyze factors associated with PrEP uptake among AKP in Brazil.
Methods: Baseline data from the first demonstration PrEP cohort study among AKP 15-19 years old ongoing in three large Brazilian cities (PrEP1519). Participants were enrolled in the cohort between March/2019-December 2020. A socio-behavioral questionnaire was applied and multivariate analyses were performed using logistic regression with adjusted odds ratio (aOR) and 95% confidence intervals (95%CI) estimation.
Results: The majority of the 756 AKP participants were MSM (92.6%), black or mixed-race (68.5%), aged 18-19 years old (80.3%), with 12 or more years of schooling (51.2%). A third of the adolescents reported an experience of violence and/or discrimination due to their sexual orientation or gender identity (32.4%). Self-perception of risk for HIV was classified as low (34.0%), medium (46.4%), and high (19.6%). The prevalence of PrEP uptake was 87.2%, and it was significantly higher among TGW, compared with MSM (98.2% and 86.3%, respectively, p-value=0.01). Factors associated with PrEP uptake were self-perception of high risk for HIV (OR 2.24; 95%CI: 1.10-4.58) and experience of violence and/or discrimination due to their sexual orientation or gender identity (OR 2.00; 95%CI: 1.14-3.51).
Conclusions: Study findings reveal a high proportion of PrEP uptake and important socio/behavior/contextual data to target AKP who may be more or less willing to use PrEP, improving provider communication about PrEP and HIV risk, and creating culturally and developmentally appropriate PrEP demand creation materials for AKP.

PEC304

Assessing the cost of PrEP delivery in Mexico: results from the ImPrEP study

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Background: Implementation of pre-exposure prophylaxis (PrEP) programs have been limited, particularly in Latin American countries. Understanding the cost of PrEP delivery targeting priority populations is essential to inform national HIV programs.
This work aims to describe the cost composition and variation of Mexico's PrEP demonstration project (ImPrEP), which provides PrEP and STI tests through trimestral visits.
Methods: We conducted a retrospective costing study from the provider perspective within the ImPrEP study. We developed a costing framework to obtain the cost of all key activities to provide PrEP through two types of platforms: one public HIV clinic and three non-governmental organizations (NOGs). We obtained input from program budgets, expenditure records, and staff interviews.

Costs were classified into three categories: drugs, laboratories, and personnel. We estimated annual numbers of PrEP patients served in 2019 from program data from the four facilities between June and November 2020. We report the cost per client-year and per visit.

Results: During 2019 PrEP was delivered to 1,228 participants. All together attended 5,511 visits. The annual cost per client-year was $1,484 and the cost per visit $184. The annual unit cost was substantially lower in public health services ($760) than NGOs ($1,824). After removing drugs, unit cost declined to $242 in the HIV clinic and $974 in NGOs. Drugs, personnel, and laboratory costs comprised 50%, 38%, and 12% of program costs, respectively. Cost composition was different between service delivery platforms – drugs accounted for 70% of the cost in the HIV clinic and 55% in NGOs. Personnel cost had a higher relative weight in cost composition in NGOs (42% vs. 19%).

Conclusions: PrEP costs vary substantially depending on the service delivery platform. Drug costs accounted for half of the annual cost per client. To our knowledge, this is one of the first studies in Latin America assessing the cost of PrEP provision using primary data. Our results could help to inform PrEP scale-up in Mexico and other contexts.

PEC305

Importance of accounting for ART costs saved in the long term when estimating HIV pre-exposure prophylaxis (PrEP) cost-effectiveness: a modeling study informed by the ImPrEP demonstration project

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Background: Evaluating the cost-effectiveness of PrEP under real world conditions in low- and middle-income countries is key to informing scale up. In Peru, from 2018-2020, the ImPrEP demonstration project enrolled 1954 men who have sex with men (MSM) and 275 transgender women (TW) in public sexual health clinics, providing rich data to inform an HIV epidemic and economic model of PrEP impact.

Methods: ImPrEP data on PrEP uptake, retention and adherence informed our dynamic compartmental model representing HIV transmission and PrEP impact among 4 groups: gay-identified MSM, bisexual/heterosexual-identified MSM, male sex workers and TW. We performed a micro-costing analysis of adding PrEP to services provided by public sexual health clinics, including ongoing costs of PrEP drugs, laboratory tests and equipment, transport and infrastructure. We estimated the cost-effectiveness of scaling up PrEP among 20% of MSM/TW between 2022-2030, both ignoring and accounting for ART costs saved. To recognize that averting infections between 2022-2030 would reduce future ART costs, we also considered a longer timeframe from 2022-2060 (with no PrEP post 2030).

Results: Scaling up PrEP to 20% of MSM and TW between 2022-2030 could avert 26% (95%CI: 22%-32%) of new HIV infections. One year of PrEP provision was costed at $680, versus $510 for one year of ART. The cost per DALY averted was $3,953 (95%CI: $2,041-$7,278) when ignoring ART costs saved and $3,922 (95%CI: $2,022-$7,228) when accounting for them over 2022-2030. These are within the WHO threshold of 1 GDP/capita ($6,941) and the Peru specific threshold estimated by Woods ($7,747). Accounting for ART costs saved between 2030-2060 reduces this estimate to $1,988 (95%CI: $1,135-$4,039), approaching the more stringent threshold estimated by Ochaleck ($1300) based on the correlation between changes in health expenditure and mortality/morbidity in Peru.

Conclusions: Achieving 20% PrEP coverage among MSM and TW in Peru would significantly reduce HIV incidence and would be cost-effective under established thresholds. Accounting for ART costs saved between 2030-2060 halves the cost per DALY averted, highlighting the importance of acknowledging the long-term benefits of prevention. PrEP implementation by the Ministry of Health would benefit from existing infrastructure and economies of scale, likely lowering the cost per year.

PEC306

Low PrEP uptake among gay, bisexual, and other men who have sex with men in five Asian countries: results of the Asia Pacific MSM Internet Survey

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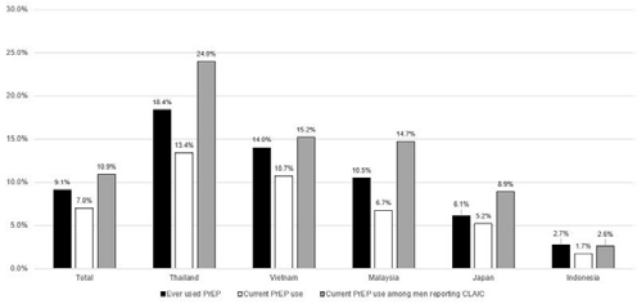
Background: PrEP is highly effective at preventing HIV infection among gay, bisexual, and other men who have sex with men (GBM). However, across Asia, PrEP programs are limited, and uptake is highly variable.

Methods: An online cross-sectional survey targeting GBM in Indonesia, Japan, Malaysia, Thailand, and Vietnam was conducted from May 2020–January 2021. Factors independently associated with current PrEP use were determined by multivariate logistic regression.

Results: We recruited 10,953 HIV-negative/untested GBM who reported ≥1 male sexual partners in the previous year (Japan=5,856; Vietnam=2,413; Thailand=1,172; Indonesia=930; Malaysia=582).

Overall, 65.3% had heard of PrEP (Thailand=83.9%; Vietnam=74.9%; Malaysia=74.2%; Japan=63.3%; Indonesia=23.1%), 9.1% had ever used PrEP and 7.0% were currently using PrEP. Of the 4,368 men reporting any condomless anal intercourse with casual partners (CLAIC) in the previous year, 10.9% were current PrEP-users. There was substantial variation by country (Figure). One-quarter of 989 PrEP-experienced respondents stated COVID-19 had made it harder to access PrEP (Indonesia=64.0%; Malaysia=37.7%; Thailand=36.4%; Japan=21.1%; Vietnam=16.8%).

Compared to non-PrEP-users, current PrEP-users were more likely to have higher income (adjusted odds ratio [AOR]=2.29, 95% confidence interval [CI]=1.57-3.35, p<0.001), >20 male partners (AOR=2.36, 95%CI=1.74-3.21, p<0.001), group sex (AOR=1.84, 95%CI=1.51-2.23, p<0.001), HIV and STI testing in the previous year (AOR=5.4, 95%CI=4.07-7.17, p<0.001 and AOR=2.86, 95%CI=2.23-3.68, p<0.001, respectively), and experienced stigma in healthcare settings (AOR=1.43, 95%CI=1.03-1.99, p=0.032). They were less likely to be bisexual-identified (compared to gay-identified; AOR=0.77, 95%CI=0.59-0.99, p=0.039). STI diagnosis in the previous year, education, and age were not associated with current PrEP use.



Figure

Conclusions: Although slightly higher among those at elevated risk, PrEP use overall was very low. Challenges in improving awareness of PrEP remain, especially in Indonesia. COVID-19 had disrupted access for some. It is critical that PrEP be scaled up consistently across Asia and steps taken to address sexuality-related stigma in healthcare settings.

PEC307

HIV recent infection test-based incidence as a counter-factual for new PrEP trials

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Background: Clinical trials of new PrEP agents are challenging because it is not ethical to include a placebo-only group. Innovative ways to evaluate new PrEP modalities are needed without impractically large sample sizes (SS) required for non-inferiority trials. HIV recent infection testing algorithms (RITAs) such as the limiting antigen avidity assay (LAg) plus viral load (VL) could be used to derive a "counter-factual" incidence estimate (CFIE) using specimens from untreated, HIV-positive people identified during screening, to which on-PrEP incidence can be compared. The feasibility of this approach is partly dependent on the SS needed to ensure adequate power, which is impacted by RITA performance, the number of recent infections identified, the expected efficacy of the intervention, and other factors.

Methods: SS (number of persons screened) required to support detection of an 80% reduction in incidence (null hypothesis: 50% reduction) were calculated based on a test statistic of log incidence ratio (https://github.com/feigao1/samplesize_RA) in different populations, and assuming: 4th generation Ab/Ag testing to identify HIV-positives, 90% enrollment, 90% recency testing success, two years of follow-up on PrEP, significance level 0.05 and power 0.8. Subtype-specific mean durations of recent infection and false recent ratios (FRR) for the LAg + VL RITA were derived from pooled calibration data.

Results: Required SS for three key populations were modeled: women aged 14-17 years or >18 years in South Africa (subtype C), and men who have sex with men in the USA (subtype B). SS for these three populations were 2882, 5463, and 2327, respectively. These SS are comparable to the number of participants in recent phase 3 PrEP trials.

Conclusions: CFIEs based on recent infection testing can facilitate next-generation PrEP trials, at least in high incidence populations for which RITAs have been calibrated, and where the efficacy of the intervention is expected to be very high. SS may not be feasible in populations with lower incidence, where the FRR is higher (e.g. subtype D), or if PrEP efficacy is expected to be lower. Despite these limitations, generation of a CFIE based on recency assays appears to be feasible, offers high statistical power, and is nearly contemporaneous with the on-PrEP population.

Microbicides (including vaginal and rectal microbicides)

PEC308

Castanea Sativa Mill. bark extract (ENC®) inhibits R5 and X4 HIV-1 strains infectivity *in vitro*

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Background: The development of alternative strategies in Pre-Exposure Prophylaxis (PrEP), such as topical microbicides, might be crucial to prevent or reduce HIV transmission at level of genital and rectal mucosa. We analysed the antiviral activity of the partially purified *Castanea Sativa Mill. bark extract* (ENC®), a natural molecules consisted of over 78% hydrolysable tannins, in cell cultures infected with different HIV-1 strains.

Methods: Attachment, pre-attachment and post-attachment assays were performed to investigate ENC® related antiviral mechanisms *in vitro*, using HIV-1 strains with different tropism.
HIV-1_{Bal}, HIV-1_{Ada}, HIV-1_{J} (R5 strains), HIV-1_{C} (R5 strain isolated from HIV-1 positive cART naïve patient) and HIV-1_{IIIb} (X4 strain) (5ng/ml HIV-1 gag p24), were pre-incubated with scalar concentrations (20, 10, 5 µg/ml) of ENC®, then added to activated PBMCs. ENC® antiviral effect was determined measuring HIV-1 gag p24 in cell supernatant at day 7 post-infection (pi) using an ELISA kit (Biomerieux) and was compared with untreated control. In addition, in a dilution assay, the compound was pre-incubated with viral strains and diluted 50-fold to reduce ENC® concentration below the level capable of preventing HIV infection. Moreover, ENC® cytotoxicity was evaluated by analysis of the lactate dehydrogenase (LDH) levels.

Results: In the first set of experiments, the antiviral activity of ENC® on HIV-1 replication was evaluated. In the attachment assay, ENC® (20, 10, 5 µg/ml) significantly ($p<0.05$; Two-tailed Student test) decreased HIV-1 gag p24 content in cellular supernatant at day 7 pi respect to untreated control, irrespective of the HIV-1 strain employed.
Pre and post-attachment assay were performed to determine the stage of the viral replication cycle at which ENC® interferes with the infection. No inhibition was observed by these experimental approaches. These results suggesting that the antiviral effect might be related to a direct interaction between virus and compound during extracellular phase. Finally, ENC® was not cytotoxic at the concentrations tested.

Conclusions: ENC® shows a significant antiviral activity against all HIV-1 strains tested, it is safe and free of side effects in vitro. Accordingly, could be an attractive candidate microbicide against HIV-1 infection and may be interesting to examine its antiviral mechanism using a human cervicovaginal histocultures model.

Vaccines

PEC309

Global and regional estimates for subtype-specific therapeutic and prophylactic HIV-1 vaccines

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Background: Global HIV-1 genetic diversity forms a major obstacle to the development of an HIV vaccine. It may be necessary to deploy subtype-specific HIV-1 vaccines in individual countries according to their HIV-1 subtype distribution. We aimed to estimate the global and regional need for subtype-specific HIV-1 vaccines.

Methods: We determined the proportions of different HIV-1 subtypes and recombinants circulating in each country through a systematic review and global survey. We took into account the genetic composition of HIV-1 recombinants and the different genome segments (gag, pol, env) that may be incorporated into vaccines.

We modelled different scenarios according to whether countries would employ subtype-specific HIV-1 vaccines against 1) the most common subtype; 2) subtypes contributing more than 5% of HIV infections; or 3) all circulating subtypes.

Results: For therapeutic vaccines targeting the most common HIV-1 subtype in each country, 16.5 million doses of subtype C vaccine were estimated globally, followed by subtypes A (14.3 million) and B (4.2 million). A vaccine based on env required 2.6 million subtype E doses, and a vaccine based on pol required 4.8 million subtype G doses.

For prophylactic vaccines targeting the most common HIV-1 subtype in each country, 1.9 billion doses of subtype A vaccine were estimated globally, followed by subtype C (1.1 billion) and subtype B (1.0 billion). A vaccine based on env required 1.2 billion subtype E doses, and a vaccine based on pol required 0.3 billion subtype G doses. If subtype-specific HIV-1 vaccines are also directed against less common subtypes in each country, vaccines targeting subtypes D, F, H and K are also needed and would require up to five times more vaccine doses in total.

Conclusions: To provide global coverage against the most common HIV-1 subtype circulating in each country, subtype-specific HIV-1 vaccines need to be directed against subtypes A, B and C. Vaccines targeting env would also need to include subtype E and those targeting pol need to include subtype G.

Novel delivery systems (e.g., rings, implants, transdermal systems)

PEC310

Three approaches to forecasting potential numbers of dapivirine ring users for HIV prevention among women in sub-Saharan Africa

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Background: The monthly dapivirine vaginal ring for HIV prevention was recommended by the World Health Organization in January 2021 as an additional prevention choice for women at substantial risk of HIV infection. As countries prepare to introduce the ring pending regulatory approvals, stakeholders need to estimate potential numbers of users for planning purposes. We utilized three approaches to estimate the range of possible users across thirteen sub-Saharan African countries with generalized HIV epidemics.

Methods: The user quantification approaches are outlined in the table below. Scale-up of ring implementation was assumed to start in the following years and countries: (2022): Kenya, South Africa, Zambia, Zimbabwe; (2023): Eswatini, Lesotho, Mozambique, Namibia, Uganda; (2024): Botswana, Malawi, Rwanda, Tanzania.

The potential user population was assumed to be sexually active, HIV-negative women ages 18-45. Low, moderate, and high estimates of ring uptake relative to oral PrEP were derived from results of a discrete choice experiment previously conducted during the TRIO study: stated preferences for a monthly vaginal ring relative to daily oral tablets varied based on relative efficacy of the two products and country of respondent.

The unmet need estimate represents the maximum potential size of the user population based on market research conducted in South Africa, Zimbabwe, Kenya, Uganda, and Malawi and applied to all 13 countries.

Approach	Description of Approach	Scale-up Years	TRIO Data
Oral PrEP trends	uses assumptions about ring uptake relative to oral PrEP and applies them to PEPFAR trends for oral PrEP scale-up in each country by end 2026	ring initiations follow trend of oral PrEP initiations, with reported oral PrEP initiations from 2016 related to ring initiations starting in 2022, 2023, or 2024 by country as indicated above; ring initiations counted through 2026 for all countries	used to estimate # of ring initiations for every oral PrEP initiation
Oral PrEP targets	uses assumptions about ring uptake relative to oral PrEP and applies them to UNAIDS 2020 World AIDS Day Report-derived oral PrEP targets for adolescent girls and adult women by end 2026	S-shaped scale-up curve starting in the indicated year and peaking 5 years later; ring initiations are counted through 2026 for all countries	used to estimate # of ring users for every oral PrEP user in 2025 target year
Unmet need	applies uptake projections from market research in 5 countries to estimated size of HIV negative female population, ages 18-44, in 2026 across all countries	scale-up trend not applied	not used

Results: Total projected ring users across the 13 countries, 2022-2026, estimated by the 3 approaches, are reported below.

Approach to Estimate Numbers of Ring Users	Low Estimate	Moderate Estimate	High Estimate
Oral PrEP trends	7,300	140,000	420,000
Oral PrEP targets	140,000	2.7 Million	8.1 Million
Unmet need	-	-	44 Million

Conclusions: Despite using the best evidence available, the uncertainty around the scale of potential future use of the dapivirine ring is considerable, ranging from a minimum of 7,300 to a maximum of 8.1 million projected users by 2026, out of a total potential user base of 44 million across 13 sub-Saharan African countries.
Nonetheless, these estimates have already informed planning by USAID. Additional data on product preferences, speed of rollout, and rates of uptake are required before these projections can be further refined.

PEC311

Discreetness and pain avoidance as central drivers of preferred characteristics in an HIV prevention implant among women in Zimbabwe and South Africa

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Background: Women's preference for HIV prevention products varies with current circumstances, life stage, and geography. Thus, eliciting women's feedback at the preclinical stage is critical to increase user-centricity, facilitate product development, roll-out, and uptake. We conducted this study to inform developers of women's preferences for selected HIV PrEP implant attributes.
Methods: We purposively selected 48 women aged 18-30 in Soshanguve, South Africa and Harare/Chitungwiza, Zimbabwe to complete in-depth interviews based on the following characteristics: parity, implant experience, and engagement in transactional sex. Interviews included an "Ideal Product Activity" (IPA) where participants selected preferred product attributes from a pre-determined set of options (implant length, number of rods, duration, flexibility, biodegradability) and discussed the rationale for these choices. Transcripts were used to populate a matrix for thematic analysis.
Results: Mean age was 25 years; 21% were nulliparous, 54% were implant experienced, and 44% had recently engaged in transactional sex. The most salient themes around IPA choices were discreetness and avoiding pain. Discreetness was a major driver in selecting preferred implant attributes (e.g., to escape anticipated contraceptive/HIV stigma) and was tied to various related factors such as flexibility, scarring, visibility, palpability. Nevertheless, a minority of participants (n=11) interested in monitoring implant use preferred attributes that would increase its palpability/visibility. Avoidance of pain was associated with biodegradability (to avert the removal process), number of rods inserted, length, and flexibility. Negative associations with contraceptive implants influenced many of the PrEP implant preferences due to anecdotes about difficult implant removals and unpleasant visits to healthcare facilities. Those associations drove interest for a biodegradable implant (tempered by concerns about unfamiliar material), and the longest duration offered (2 years) to avoid the need for future clinic visits.
Conclusions: Participant preferences were driven by maximizing discreetness and avoiding pain, resulting in different attribute choices depending on which were equated with these priorities. Pervasive mention of negative experiences with contraceptive implants and concerns about unfamiliar biodegradable materials highlight key issues to address during upcoming clinical phases.
Strategies that address such concerns while capitalizing on the interest for minimal pain and maximum discreetness must be taken into consideration when planning clinical trials.

PEC312

Next generation 3D-printed intravaginal rings for prevention of HIV and unplanned pregnancy

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Background: Half a million women are infected with HIV each year and half of all pregnancies are unplanned. There is an urgent need for control and prevention of these global health crises since current preventative daily oral dosing regimens lack efficacy due to low patient compliance. Intravaginal rings (IVRs) are an effective drug delivery platform that provides prolonged drug release.
However, conventional IVR manufacturing lacks control over user preferences, drug choice, and drug release kinetics. Thus, we propose to elicit Continuous Liquid Interface Production (CLIP), a state-of-the-art 3D printing technology that harnesses ultra-violet light and photopolymerization to develop next generation multipurpose prevention technology (MPT) IVRs. Geometric complexity enabled by CLIP can provide controlled and near complete drug release of multiple, chemically discrete drugs.
Here, we report the development of the first 3D printed MPT IVR for prevention of HIV and unplanned pregnancy.
Methods: IVRs are generated in a computer aided design (CAD) software and printed in SIL 30 (silicone-polyurethane) resin on a M1 printer (Carbon, Inc.). Our target MPT IVR will contain the highly potent antiretroviral drug Islatravir (EFdA) and the NuvaRing combination hormones, etonogestrel (ENG) and ethynyl estradiol (EE). The triple drug combination IVR was evaluated for in vitro release kinetics. IVRs (n=4) were placed in 200 mL of simulated vaginal fluid and incubated at 37°C. Sample aliquots (1 mL) of release media were collected at preset time intervals and analyzed using high performance liquid chromatography (HPLC) to quantify drug concentration.

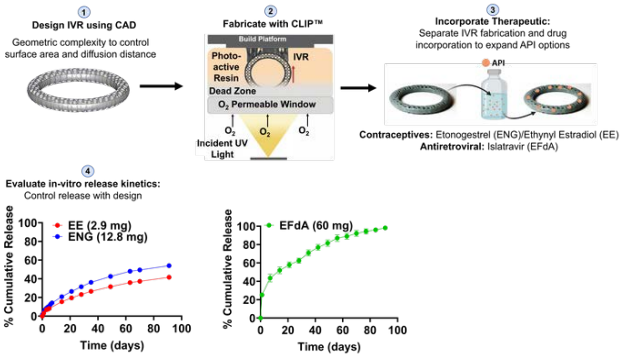

Figure 1. (1) Design IVRs using CAD. (2) Fabrication with CLIP. (3) Load IVRs with drug after fabrication. (4) In vitro release kinetics of ENG/EE (blue/red) from a single human-sized solid IVR. EFdA (green) release kinetics from a macaque-sized solid IVR (i.e. ENG/EE and EFdA are not formulated together.)

Results: Our results demonstrated the ability to (1) fabricate geometrically complex 3D printed IVRs using CLIP, (2) formulate ENG/EE and EFdA in CLIP IVRs, and (3) achieve sustained and clinically translatable release kinetics of all drugs for at least 90 days (Figure 1).

Conclusions: CLIP IVRs elicit design-enabled controlled and targeted drug release kinetics and demonstrate potential for MPT IVR development.

PEC313

Biodegradable polymeric solid implants for ultra-long-acting delivery of single or multiple antiretroviral drugs

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Background: Long-acting (LA) pre-exposure prophylaxis (PrEP) formulations that can provide sustained drug release over weeks or months can potentially enhance compliance to prophylactic therapies and reduce the incidence of new HIV infections.

Methods: Ultra-long-acting (ULA) biodegradable polymeric solid implants (PSIs) were fabricated using a simple, scalable three-step process that combines

(a) phase inversion of a drug/polymer solution to form an initial in-situ forming implant,

(b) micronization of dried drug-loaded solid depots, and

(c) compression of the micronized drug-loaded solid powder.

These PSIs can accommodate one or more antiretrovirals at high drug content (up to 85 wt%) in a single implant. PSIs of Dolutegravir (DTG) and Rilpivirine (RPV) were fabricated and tested in vitro and in vivo for safety and pharmacokinetics.

Results: Single and combination drug PSIs exhibited sustained drug release kinetics in vitro for 180 days or longer. In vivo pharmacokinetics studies in BALB/c mice (n=5/group) showed that a single subcutaneous implantation of a DTG-RPV combination drug PSI (278 mg/kg DTG, 296 mg/kg RPV; 20 mg PSI tablet) can effectively deliver DTG and RPV over 180 days with concentrations above the 4X PA-IC90 for each drug.

The mean Cmax for DTG and RPV (n=5) were 3.11 ± 0.29 µg/mL and 4.32 ± 0.29 µg/mL respectively, and the calculated AUCall (µg*day/mL ± standard error, n=5) were 330.85 ± 21.53 and 83.06 ± 4.61 for DTG and RPV respectively. In vivo safety studies in BALB/c mice (n=7/time point) showed that subcutaneous administration of single or co-drug PSIs did not induce any toxicity or adverse site reaction both systemically and at the implantation site over 6 months.

More importantly, these PSIs are biodegradable and do not require removal post use, however, if treatment termination is required these PSIs can be removed rapidly to terminate the treatment.

Conclusions: This is the first report on a multi-drug PLGA-based solid implant that is fabricated by a phase inversion and compression process. This fabrication process is simple, scalable, and does not require high heat, high pressure or use of high volumes of organic solvents. The fabricated PSIs are highly tunable, ultra-LA, and contain high drug loading to provide translatable to human drug doses for HIV PrEP/ART.

HIV self-testing

PEC314

Effect of a regular self-testing kits distribution intervention on HIV testing and sexual-behavioral outcomes among MSM in China: a stepped-wedge randomized controlled trial

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Background: Around one third of MSM have never tested of HIV globally. HIV self-testing (HIVST) has been widely accepted as an approach for hard-to-reach MSM.

Methods: In this stepped-wedge, non-blinded randomized controlled trial, eligible MSM recruited from four cities were randomly assigned to the intervention. This procedure continued every 3 months until all groups crossed over from control (standard of counseling) to intervention (online HIVST kits distribution). This study was conducted from August 2018 to December 2019. Generalized linear models were used to analyze the study results.

Results: A total of 560 MSM with 140 in each group enrolled, 69.3% were less than 30 years old and 83.2% had a college or higher degree. Among 465 (83.0%) completed at least one follow up, 394 (70.4%) completed the 12-month four-round follow-up and 317 (68.2%) used HIVST. 1,556 HIVST packages were delivered by mail and 1,407 (90.4%) photos of self-testing results returned. Among returned results, 1,162 (82.6%) were used by 560 study MSM and 244 (17.4%) for 182 male partners by HIVST secondary distribution. Twelve MSM were diagnosed as HIV infection and 4 of them were HIV seroconverted during the follow up. HIV positive identification was higher among male partners by HIVST secondary distribution than study MSM (4.9% vs. 2.1%). The intention-to-treat analysis showed a higher probability of receiving HIV testing (estimated risk ratio [RR]=9.21, 95%CI 5.92-14.33), and increased HIV test frequency (estimated risk difference [RD]=0.89, 95%CI 0.82-0.96), and decreased number of condomless anal intercourse (RD=0.46, 95%CI 0.31-0.62) during the intervention periods as compared to the control periods. While there was no effect on the number of male partners between intervention and control periods. Moreover, through secondary distribution of HIVST, the intervention period had increased self-reported proportion of HIV testing (RR=2.23, 95%CI 1.46-3.40) and the frequency of HIV testing (RD=0.26, 95%CI 0.15-0.38) among male partners of MSM participants.

Conclusions: HIVST was an effective approach in increasing HIV testing of MSM and change their CAI. It can also elevate HIV testing of MSM's male partners trough secondary distribution of HIVST. HIVST should be further extended to scale up HIV testing uptake and safe behaviors among MSM.

PEC315

Testing together behaviors in secondary distribution of HIV/syphilis self-testing program among men who have sex with men in China

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Background: HIVST is recommended as a promising way to increase the HIV testing uptake among MSM. Partners testing together with HIVST kits were common in HIVST programs. However, limited data was reported on testing together behaviors with social network contacts beyond partners. The objective of the study is to understand the testing together behaviors among both sexual networks and social networks among MSM in an HIVST secondary distribution program.

Methods: Data were collected among MSM in China from June 2018 to November 2019. Eligible participants (referred to as "indexes") finished a baseline survey and applied self-test kits. Indexes were encouraged to distribute the self-test kits to other people (referred to as "alters"). Indexes finished a three-month follow-up survey and provided information on the distribution of the self-test kits. Alters were invited to conduct an online survey on the usage of self-test kits after they returned the photographed testing results. The primary outcomes of this study were the testing together behaviors of indexes and alters.

Results: A total of 371 indexes and 264 alters were included in our analysis. After three months, 138 indexes successfully motivated others for HIVST and the majority of them (107/138, 77.5%) tested together with at least one alters. Around half of the alters (138/264, 52.3%) reported testing together with indexes. More self-kits were distributed to gay friends than sexual partners and more untested men were reached by friends than sexual partners. Indexes and alters who had ever tested for HIV were more likely to test together (aOR = 2.03, 95% CI: 1.07-3.86); (aOR = 1.75, 95% CI: 1.05-2.93). Alters who had one sexual partner in the past six months (aOR = 3.40, 95% CI: 1.77-6.53), used condom in the last sex (aOR = 2.44, 95% CI: 2.11-5.37), and were stable sex partners of indexes (aOR = 7.33, 95% CI: 2.41-22.29) were more likely to test with indexes.

Conclusions: Our study demonstrated the differences on distributing HIVST among sexual networks and social networks. The social network-based approach is essential in promoting testing together and HIV status disclosure among MSM.

PEC316

Identification of key influencers for secondary distribution of HIV self-testing among Chinese MSM: a machine learning approach

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Background: HIV self-testing (HIVST) has been rapidly scaled up in several countries, but additional strategies are needed to enhance case finding. Secondary distribution has people apply for multiple kits and pass these kits to people in their social networks, but identifying key influencers can be difficult.

This study aimed to develop and validate an innovative machine learning approach to identify key influencers among men who have sex with men (MSM) for HIVST secondary distribution in China.

Methods: Indexes applied for HIVST kits for distribution. Alters were those who received these kits. We defined some indexes as key influencers in three types:

1. key distributors who are more likely to distribute more kits;
2. key promoters who can contribute to finding first-time testing alters;
3. key detectors who can help to find positive alters.

In our identification system, four machine learning models (logistic regression, support vector machine, decision tree, and random forest) were trained to predict key influencers for secondary distribution. An ensemble learning approach was adopted to combine the predictions of these four models for the final prediction.

A simulation experiment was run based on ensemble machine learning identification results compared with human identification (i.e., self-reported leadership scales cut-off method) to validate the higher intervention efficiency of our approach.

Results: A total of 309 indexes in the HIVST distributed kits to 269 alters. Our ensemble model outperformed human identification, exceeding by an average accuracy of 11·0%. Additionally, if identifying the same number of key influencers such as key-distributors, the ensemble machine learning could distribute 18·2% (95% CI: 9·9%-26·5%) more kits, find 13·6% (95% CI: 1·9%-25·3%) more first-time testing alters, and 12·0% (95% CI: -14·7%-38·7%) more positive-testing alters than the human identification approach. Simulation experiments also revealed that the intervention efficiency of ensemble machine learning model increased by 17·7% (95% CI: -3·5%-38·8%) than self-reported scales cut-off method.

Conclusions: We built machine learning models to identify key influencers among Chinese MSM population who were more likely to engage in HIVST secondary distribution and our novel approach outperformed the conventional human identification approach.

PEC317

Awareness, acceptability and factors associated with willingness to indicate HIV self-testing among health care providers from HIV specialized care services in Northeast of Brazil

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Background: The largest gap in Brazil is for the initial 90-90-90 UNAIDS goals, 90% of people living with HIV know their HIV status. The inclusion of the HIV self-testing (HIVST) at the Brazilian National Health System (SUS) has been a recent effort to increase HIV early diagnoses. The engagement of health care providers (HCP) to promote HIVST in HIV/AIDS clinics is essential to make HIVST even more accessible to most at risk populations. We aimed to investigate the awareness, acceptability and factors associated with the willingness to indicate the HIVST among HCP in Northeast Brazil.

Methods: A cross sectional study with HCP in 29 HIV/AIDS specialized care services from 21 cities from Bahia state, Northeast of Brazil. The services were selected using a conglomerate sampling scheme in one phase, and the HCP by convenience sampling. Sociodemographic, occupation and behavior data were collected using a structured questionnaire between October 2019 and March 2020. Adjusted logistic regression models are used to estimate odds ratio (aOR) and 95% confidence intervals (95%CI).

Results: Most of the 252 HCP were women (78.2%), between 35 and 50 years old (54.4%), with college degree education (84.5%), nurses with college degree (25.8%) and high school degree (11.9%), pharmacists (12.3%) and physicians (11.9%). The HIVST awareness, acceptability and willingness to indicate it were: 79.8% (95%CI: 74,3-84,3), 55.2% (95%CI: 48,9-61,2) and 47.1% (95%CI: 40,9-53,4), respectively. Only 13.5% of HCP received some training on ATHIV and 23% reported having knowledge of its offer in SUS. The main reasons to no indication were: concerns about suicidal risk (75.4%), wrong reading of results (68.4%) and self-aggression due to a positive result (61.5%). Factors associated with the willingness to indicate an HIVST were: HIVST acceptability (aOR= 9.5; 95%CI: 4.5-19.7), agreement to use it on yourself (aOR= 4.5; 95%CI: 1.6-12.2), diagnostic confidence (aOR= 5.7; 95%CI: 2.3-12.7) and consider the general public eligible for HIVST (aOR= 2.9; 95%CI: 1.2-6.6).

Conclusions: Although the HIVST awareness among HCP was high, acceptability and willingness to indicate it was moderate. It is needed to increase HIVST training among HCP in Brazil, and demystify concerns related to this technology.

PEC318

Mailout HIV self-testing: overview of the GetaKit initiative in Ottawa, Canada

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Background: Access to HIV testing and sexual health resources has been limited in Ontario as a result of the province's COVID-19 response. However, people continue to engage in sexual contact with new partners, presenting an ongoing risk of HIV transmission and a continued need for HIV testing. To address this gap, a team of nurses at the University of Ottawa and Ottawa Public Health, in collaboration with staff from Ottawa ASOs and the OTHN, launched a mail-out HIV self-testing project entitled 'GetaKit'.

Description: GetaKit sought to assess the outcomes associated with an Internet-based ordering system of an HIV self-test kit in Ottawa, Canada, including HIV diagnosis rates and linkage to care. As of July 20, 2020, eligible participants (≥18 years old, HIV-negative, not on PrEP, not in a HIV vaccine trial, living in Ottawa, no bleeding disorders) could register via www.GetaKit.ca to order kits. GetaKit utilised a status-neutral approach to testing, providing counselling to all clients and linking clients with the appropriate care, either confirmatory testing and treatment or prevention (PrEP).

Lessons learned: As of December 2020, 825 persons completed the eligibility screener; 63.9% (n=527) were eligible. Of eligible participants, 275 completed baseline surveys and 259 ordered a test. Approximately 26% (n=68) of participants had no prior HIV testing or were unsure of testing history. Approximately 66% (n=171) of participants belonged to a priority group for HIV testing, including members of gbMSM, Black, and Indigenous populations. We have results for approximately 70% (n=182) of participants who ordered a kit: none were positive, 143 were negative, 36 were invalid, and 2 "preferred not to say". 61.3% (n=159) patients were referred for PrEP.

Conclusions/Next steps: Our results indicated the effectiveness and acceptability of a mail-out HIV self-test kit in Ottawa, Canada. HIV self-testing ensured testing and prevention among regular and new testers while other sexual health resources were closed. Mailout HIV self-testing has the potential to increase access to HIV testing in Ontario.

PEC319

Factors associated with the successful distribution of HIV self-tests through routine clinical settings in Lusaka, Zambia: a cohort study

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Background: This study evaluated secondary distribution of HIV self-tests (HIVST) to reach individuals underserved by standard testing approaches.

Methods: Individuals (≥16 years) accessing antenatal care (ANC) or antiretroviral therapy (ART) services at two peri-urban public health facilities in Lusaka, Zambia between 11th November 2019 and 31st July 2020 were offered an HIVST kit for distribution to their partners. Interviews were conducted on the day of HIVST collection and at clinic visits 1 month later. Partners were interviewed 3 months after distribution. Logistic regression analyses assessed whether kit use was associated with characteristics of the distributor or their partner.

Results: In ANC, 508 individuals accepted HIVST for distribution, of whom 457(90.0%) were re-interviewed after 1 month. At this time, successful HIVST distribution was reported by 398(87.1%) of the respondents and 342(74.8%) reported HIVST use by their partner. Of 243 male partners interviewed at 3 months, 194(79.8%) reported HIVST use, 6(3.1%) had a reactive result and 4 initiated ART. Reported use after secondary distribution was higher if this was the first pregnancy (OR=2.52, 95%CI 1.23 – 5.18) or the partners were aged under age 35 (OR=3.61, 95%CI 1.69-7.74).

From ART clinics, 122 individuals (66.4% male) accepted HIVST kits of whom 85(69.7%) were re-interviewed at 1 month. Successful HIVST distribution was reported by 74(87.1%) respondents, with 55(64.7%) reporting HIVST use by their partner. Of 58 partners interviewed at 3 months 44(75.9 %) reported HIVST use, 9(20.5%) of these had a reactive result and 5 initiated ART.

The most common reason given for non-distribution (39/59(66.1%) in ANC and 5/11(45.5%) in ART was that the partner was elsewhere in the country.

Conclusions: Secondary HIVST distribution showed potential to reach people living with HIV (PLHIV) unaware of their status. The yield of newly identified PLHIV was higher for kits distributed from ART than in ANC clinics, although participation was lower.

Further optimisation, including integration into contact ("index") testing systems may be achievable. In ANC, targeted recruitment of women in their first pregnancy may lead to higher yields. More flexible delivery methods may be needed to reach partners temporarily absent and to engage older male partners.

PEC320

Introducing HIV self-testing (HIVST) among key populations in West Africa: a baseline qualitative analysis of key stakeholders' attitudes and perceptions in Côte d'Ivoire, Mali, and Senegal

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Background: HIV self-testing (HIVST) is a way to improve HIV status knowledge and access to HIV testing. Since 2019, the ATLAS project has introduced, promoted, and delivered HIVST in Côte d'Ivoire, Mali, and Senegal, in particular among female sex workers (FSW), men who have sex with men (MSM), people who use drugs (PWUD), these key populations being particularly vulnerable to HIV and stigmatized in West Africa. Stakeholders involved in HIV testing activities targeting key populations are essential for the deployment of HIVST. Here, we analyze their perceptions of the introduction of HIVST in their countries.

Methods: A qualitative survey was conducted from September to November 2019 within three months of HIVST distribution initiation. Individual interviews were conducted with 60 stakeholders (Côte d'Ivoire, 19; Mali, 20; Senegal, 21). Semi-structured interviews were recorded, translated when necessary, and transcribed. Data were coded using Dedoose© software for thematic analyses.

Results: In the three countries, stakeholders express enthusiasm and willingness to introduce HIVST for several reasons. HIVST is considered able to reduce stigma, preserve anonymity and confidentiality, especially for MSM and PWUD; reach key populations that do not access testing via usual strategies and HIV+ key populations; remove spatial barriers; save time for providers and users, notably for FSW; and empower users with autonomy and responsibility. HIVST is noninvasive and easy to use. Secondary distribution of HIVST seems appropriate for reaching partners of MSM, with confidentiality. However, stakeholders expressed doubts about key populations' ability, particularly PWUD, to correctly use HIVST kits, ensure quality secondary distribution, accept a reactive test result, and use confirmation testing and care services. They also mentioned that FSW might have difficulties redistributing HIVST to their clients and partners.

Conclusions: HIVST is considered an attractive strategy to improve access to HIV testing for key populations. The doubts about users' capacities could be a matter of reflective communication with stakeholders before HIVST implementation in other western African countries.

PEC321

HIV Self-testing among Male People Who Inject Drugs in Iran; the Rostam study

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Background: HIV testing services are available and free for people who inject drugs (PWID) in Iran, but only one-fourth of adult male PWID had been tested for HIV. While PWID face barriers to HIV testing at health facilities, new strategies like HIV self-testing (HIVST) present a possible solution. In this study, we assessed the knowledge and attitudes of PWID toward HIVST and its feasibility among PWID in Iran.

Methods: Through respondent-driven sampling from 7/2018-2/2020, 343 male PWID (aged≥ 18 years, injected drugs in the last 3 months) in Tehran and Kerman were invited to a survey of risk behaviors, HIV testing including assessment of their knowledge and attitudes toward HIVST. To assess the feasibility of HIVST, we offered HIVST to 38 male participants in Tehran study site in 2020. One trained staff (i.e., observer) used a video tutorial to demonstrate on how to do HIVST, then observed participants doing the HIVST and used a checklist to record their ability to do the HIVST.

Results: Median age was 43.2 years. Most (92.2%) of PWID never heard about HIVST, 100% never used HIVST before, and 67.5% said its likely they use the HIVST if offered. Out of the 38 PWID in who were offered an HIVST, all (100%) accepted to do the self-test. PWID self-reported 1(2%) positive, 6 (16%) invalid, 30 (80%) negative and 1 (2%) was unable to read the HIVST results. The observer reported 0 positive, 5 (13%) invalid, and 33 (87%) negative HIVST results. The observer found most PWID (71% to 94%) perform the HIVST steps correctly (Figure 1). Most PWID agreed to distribute HIVST to their sex partners (47%) and drug use/injecting partners (84%).

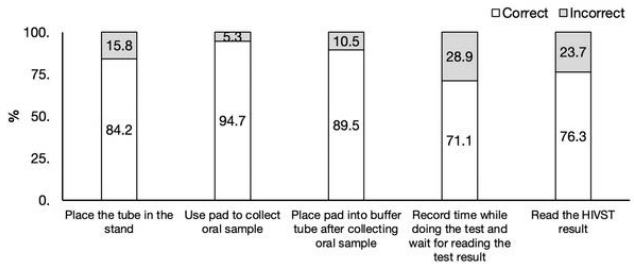

Figure 1. The ability of people who inject drugs to use HIV self-test

Conclusions: Male PWID are likely to use HIVST and distribute it to their partners; however, proper training and assistance to interpret correctly the test results are needed.

PEC322

Factors associated with the willingness to pay for HIV self-testing among transgender women in Northeast Brazil

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Background: HIV self-testing (HIVST) is simple and easy to use and it provides new opportunities for testing outside health services. It could help to overcome testing barriers among transgender women (TGW) such as stigma and discrimination, anonymity or confidentiality concerns, increasing accessibility and frequency of testing.
We aimed to assess factors associated with the willingness to use an HIVST if available for sale in drugstores among TGW.

Methods: A cross sectional study was conducted among TGW in three large capital cities of Northeastern Brazil in 2016/2017 (DIVAS-Northeast study). A total of 864 participants 18 to 65 years old were recruited using Respondent Driven Sampling (RDS), completed a questionnaire with sociodemographic, sexual behavior, violence and discrimination information. For this analysis, we excluded participants that previously knew to be HIV positive.
The outcome was willingness to use an HIVST if available for sale in drugstores. Adjusted odds ratio (aOR) and 95% confidence intervals (95%CI) were estimated through logistic regression. Results were weighted by the RDS-II estimator.

Results: Seven hundred sixty-three TGW were included in this analysis; mean age was 27.2 years (SD 8.8), 78.7% self-identified as black or racially mixed, 54.4% had less than 8 years of schooling and 83.4% were willing to use an HIVST if available for sale in drugstores. Experience of discrimination in health services (aOR 0.48; 95%CI 0.26 – 0.88) was negatively associated with willingness to use an HIVST. Higher monthly income (aOR 2.44; 95%CI 1.33-4.51), unprotected receptive anal intercourse with commercial sex clients in the last 30 days (aOR 1.91; 95%CI 1.09-3.34) and willingness to use HIV pre-exposure prophylaxis (aOR 2.82; 95%CI 1.39- 5.73), increased the odds to use an HIVST.

Conclusions: Willingness to use an HIVST if available for sale in drugstores was high and associated with risky behaviors during commercial sex. Higher income appeared as a facilitator to TGW pay for an HIVST. Experience of discrimination in health services could be a barrier for acquiring HIVST, other strategies for HIVST distribution should be considered, also in combination with other prevention methods such as PrEP. These findings add to needed information for scaling up HIVST for TGW in Brazil.

PEC323

Can we improve HIV self-testing outcomes through digital data capture? A retrospective review of the HIVST Challenge Fund Project in Kenya

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Background: The 2018 KENPHIA report indicated that only 79.4% Kenyans know their HIV status. Following the introduction of the HIVST modality to accelerate access to HIV testing for unreached subpopulations, questions regarding optimal strategies to ensure timely linkage to post-testing persist.

This paper explores if digital data management enhances support and result reporting among HIVST clients.

Description: Beginning October 2019 PS Kenya, a Kenyan NGO, implemented HIVST program that delivers targeted free HIVST kits through Community Based Organizations (CBOs).

At inception of the project, between October 2019 to March 2020, paper-based tools were used by the CBO members to capture key indicators. Completed forms were mailed back to PS Kenya for transcription and feedback shared with HTS providers for follow up. As from April 2020, this process was automated to Health Information System (DHIS 2) using android application. CBO entered data directly into DHIS2 using tablets making data accessible to HTS providers for immediate follow up.

Turnaround time (TAT) was computed by deducting the distribution time from follow-up initiation time. Proportion of clients reached was calculated as a percentage of clients who consented for follow-up. We defined reach as clients that were contacted and responded to the calls or messages sent. Finally, positivity was computed by comparing HIV positive results and all self-test results.

Lessons learned: Between October 2019 and March 2020, the TAT averaged 10 days. Of the 12,719 clients who opted for follow up, only 1,152 (9%) were reached. Overall positivity was estimated at 0.7%.

From April to September 2020, TAT reduced to an average of 1.5 days. Of the 31,416 clients who opted for follow up, 10,908 (35%) were reached (26% improvement from previous period) with a positivity of 4.2%.

The difference in proportions in reach with paper-based data entry and digital data entry were found to be statistically significant (P-value <0.05).

Conclusions/Next steps: Digital data capture shortens follow-up TAT and early contacting enables clients to share results and obtain timely support. Programs should consider digital data capture to increase efficiency.

PEC324

Preliminary results of AmanBol: HIV self-testing program for MSM and transgender persons in Kazakhstan

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Background: Over 60% of new HIV infections in 2018 are estimated to occur among men who have sex with men (MSM) (Kazakhstan's National AIDS Center (NAC)). MSM and transgender persons remain among the least covered groups by HIV testing and treatment programs with only 7.8% HIV testing coverage for MSM (NAC, 2020) across Kazakhstan due to persisting discrimination and stigma.

Description: Funded by Elton John AIDS Foundation (EJAF) and implemented by GHRCCA, AmanBol (2019–2021) is the first HIV self-testing (HIVST) program in the region, dedicated to providing service for MSM and transgender persons in Kazakhstan. AmanBol aims to provide 10,320 HIV self-tests in 3 years for MSM and transgender persons by using web-based solutions such as social networks and automation to gain access to the community. The main services provided include delivering HIV self-tests, providing online support, and publishing articles on sexual and mental health on the website. The programme collaborates with the available post, taxi, local, and national LGBT NGOs/initiatives for confidential, safe, and targeted service.

Lessons learned: Since the project started in 2019, 7,315 tests were delivered, 5,048 feedback responses received, 165 positive results reported, 93 clients linked to care, website viewed 266,000 times. Calculations are based on self-reports by the participants and Google analytics.

One of the biggest achievements was to gain access to marginalized MSM and transgender communities using social media and creating demand for HIVST by providing information and using marketing tools. With a 5-person team, the project was able to test an equivalent of 11% of the estimated MSM population.

This was possible due to the following components:

- Effective and optimized SMM;
- User-friendly interface and language;
- Applying marketing and remarketing tools;
- Automation of database by using CRM;
- Automation of communication using Messagebird and Telegram;
- Proactively requesting feedback from the participants;
- Creating trustworthy experience by securing any personal data;

Optimizing operational processes and outsourcing them as much as possible.

Conclusions/Next steps: The EJAF-funded Amanbol pilot HIVST project showed feasibility and acceptability of HIV self-testing among MSM and transgender persons in Kazakhstan and might be replicated for other Central Asian countries through NGOs.

PEC325

The cost effectiveness and optimal configuration of oral HIV self-test kit distribution in South Africa: a model analysis

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Background: HIV self-testing (HIVST) has been shown to be acceptable, feasible and effective in increasing HIV testing uptake. Novel testing strategies are critical to achieving and maintaining the UNAIDS target of 95% HIV-positive diagnosis by 2030 in South Africa and globally.
Methods: We modelled the impact of six HIVST distribution models (fixed-point, taxi ranks, workplace, partners of primary healthcare (PHC) index cases, partners of pregnant women, primary PHC distribution) in South Africa over 20years (2020-39), using data collected alongside the Self-Testing AfRica (STAR) Initiative. We modelled two coverage scenarios: A) 1 million HIVST kits (current) or B) up to 6.3 million kits (target) distributed annually. Incremental economic costs (2019USD) were estimated from the provider perspective; outcomes were based on surveys of a subset of kit recipients and modelled using the Thembisa model. We calculated the cost-effectiveness of each distribution model compared to the status-quo distribution configuration favouring primary PHC distribution, and optimised using a fractional factorial design.
Results: The largest impact resulted from secondary distribution to partners of PHC index cases; however, it was one of the least cost-effective models (Figure 1). Workplace distribution was cost-saving ($52-$76 million), but had moderate epidemiological impact (Figure 1). Optimisation produced the largest epidemiological impact for the following distribution configurations: 50-70% through PHC index cases; 0-18% each through fixed point, taxi ranks, workplaces; 0-9% each through partners of pregnant women and primary distribution to PHC clients. An optimised scale-up of distribution to 6.3 million tests would result in a ~3-fold increase in life years saved (LYS) compared to a scale-up of current distribution patterns (216,000 vs 75,000 LYS).

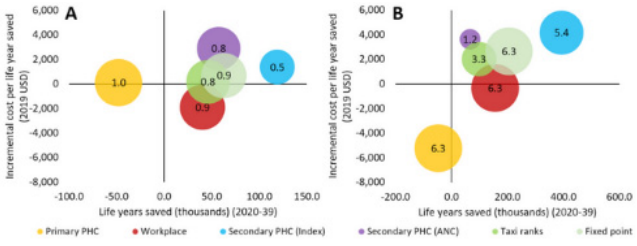

Figure 1. Cost-effectiveness of redistributing all HIVST to different distribution model compared to a baseline status-quo distribution, 2020-39. Impact on incremental cost and life years saved for distributing 1 million HIVST annually (A), and for distributing up to 6.3 million HIVST annually (B). Balloon size represents the total number of HIVST distributed annually.

Conclusions: Optimisation-informed distributions have the potential to vastly improve the impact of HIVST. Using this approach, HIVST can play a key role in improving the long-term health impact of investment in HIVST, and assist in catching up testing targets post-COVID-19.

PEC326

Impact of a combination HIV testing package on couples' HIV testing and female awareness of male partner HIV status among pregnant women in Lusaka, Zambia: A randomized trial

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Background: Compared to partner notification services (PNS) alone, PNS plus secondary distribution of HIV self-test kits (HIVST) increased HIV testing among male partners of HIV-positive and HIV-negative women in Lusaka, Zambia. We evaluated whether this combination testing intervention also increases couples' HIV testing (CHTC) or female awareness of male partner HIV status.
Methods: Between October 2019 and May 2020, pregnant women who had not tested for HIV with their partner in their current pregnancy were enrolled into parallel randomized trials in Lusaka, Zambia, based on HIV-positive (n=116) or HIV-negative (n=210) status. Within each trial, women were randomly assigned to receive PNS alone (control) or PNS plus HIVST (intervention). At the 30-day follow-up visit, participants reported partner HIV testing behaviors and knowledge of partner HIV status. In this secondary analysis, probability differences (PD) and Wald 95% confidence intervals (CIs) were estimated to compare uptake of CHTC and female awareness of partner status between randomization groups using an intent-to-treat approach with the woman as the unit of analysis.
Results: At enrollment, few participants reported ever receiving CHTC with their partner, and most were unaware of their partner's HIV status. 86% of HIV-positive women, and 95% of HIV-negative women, returned for the follow-up visit. There was no evident effect of the intervention on uptake of CHTC among HIV-positive (PD:5.2, CI:-6.7, 17.1) or HIV-negative (PD:3.4, CI:-6.5, 13.3) women (Figure). Among HIV-positive women, female awareness of partner status was greater in the intervention than control group (PD:30.4, CI:13.6, 47.2). This effect was present but less prominent among HIV-negative women (PD:8.6, CI:-1.0, 18.2).

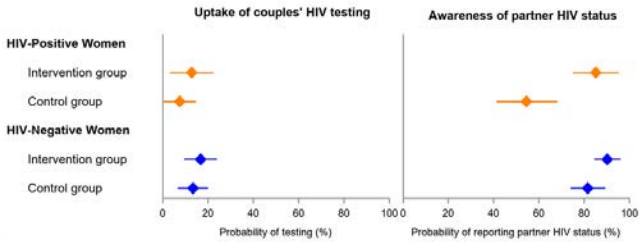

Figure. Uptake of couples HIV testing and awareness of partner HIV status in two parallel randomized trials

Conclusions: Adding HIVST to PNS increased female awareness of male partner HIV status but had limited effect on uptake of CHTC compared to PNS alone. Modifications to the combination intervention will be necessary to promote uptake of CHTC in this context.

PEC327

Mexico must promote HIV self-testing: evidence from a survey of 11,000 Mexican MSM

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Background: HIV in Mexico disproportionately affects MSM with HIV prevalence of 20.7% in cross-sectional studies and only 33.9% diagnosed. In May 2018, the Mexican Government included HIV self-testing (HIVST) in its promotion of differential detection strategies. However, few actions have been implemented and HIVST remains unavailable in Mexico. To illustrate the importance of Mexico remaining committed to HIVST, we conducted a study to describe the Mexican MSM demand for HIVST and estimate its potential public health impacts.

Methods: Within a 2017 online sexual health survey of adult Mexican MSM, those who did not report a previous HIV diagnosis were asked about their willingness to buy an HIVST from a pharmacy. Multivariable logistic regression assessed demographic and behavioral factors associated with willingness to buy an HIVST (yes versus no/maybe). To estimate the impact of HIVST, we assumed that the prevalence of MSM who had never been tested and the prevalence of MSM in Community Detection Center (5.8%) are similar. The analysis was based on UNAIDS's estimates of undiagnosed PLWH in Mexico and a 1.2 million MSM population.

Results: Among 11,183 participants, median age was 26 years old (SD=7.8), 34.5% (3,858/11,183) had never been HIV tested, and 21.9% (2,453/11,183) were tested >12 month prior. The vast majority (88.0%; 9,839/11,183) said they would buy an HIVST from a pharmacy. Never testing (OR = 1.4, CI: [1.2, 1.7]), testing >12 months (OR = 1.5, CI: [1.2, 1.8]) were associated with willingness to buy an HIVST. No sexual behaviors were associated with willingness to buy an HIVST. Among those never tested, 89.2% (3,442/3,858) were willing to buy an HIVST kit. Using an estimated population of 1.2 million MSM in Mexico we estimated that HIVST could potentially lead to 18,000 new HIV diagnoses, among MSM that have never been tested before. Availability of HIVST could potentially reduce one-third of the estimated diagnostic gap (18,000/55,000).

Conclusions: Mexican MSM demand for HIVST is exceptionally high, even if HIVST must be bought from a pharmacy. This high demand emphasizes that the implementation of HIVST policy by Mexico is very likely to have substantial population-level effects on HIV prevention and care of Mexican MSM.

Prevention for co-morbidities (e.g., TB, viral hepatitis)

PEC328

Evaluation of isoniazid preventive therapy received by children living with HIV in Nigeria

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Background: Childhood tuberculosis (TB) remains a global public health threat despite being preventable and curable. It forms a highly lethal partnership with HIV and is even grimmer in highly endemic poor resource countries like Nigeria with mortality rate thrice than the general HIV population. Isoniazid (INH) preventative therapy (IPT) is the most cost-effective option in Nigeria, a low-resourced, TB-highly endemic country for prevention of childhood TB. We aimed to determine the IPT completion rate and predictors of hepatotoxicity of INH among children living with HIV and receiving care in public hospitals in Sokoto, Nigeria.

Methods: This was a four-year (January 2016-December 2019) chart review of 1476 children (0-18 years) receiving HIV antiretroviral therapy (ART) and accessing IPT in tertiary hospitals in Sokoto, Nigeria. Regression models were used to determine predictors of IPT completion and the development of hepatotoxicity. The exclusion criteria were those with pre-existing grade 1 elevations of alanine aminotransferase (ALT), insufficient data to determine exposure or outcome and those with irretrievable case files respectively.

Results: A total of 1476 children accessed HIV/AIDS care in the ART clinics within the study period. 429 children living with HIV/AIDS initiated on IPT, 244 (56.9%) successfully completed IPT. Age and socioeconomic status were the strongest predictors of IPT completion rate. Majority were females (58.7%) and lives in urban (55.5%). 37 (18%; n=205) were found to have their ALT raised to grade 1 level (47.5-95 U/L) with median (IQR) being 71 (53-87) U/L. HIV clinical status predicted INH-induced hepatotoxicity. The median (IQR) time to raised ALT among those who completed 6 months of IPT was 15.5 (12.5-18) weeks. About three out of every five participants completed their six month course of IPT and deaths were reported in 3.5%. 84% (205/429) of them were followed up for 4587.5 person-weeks with 18.0% (37/205) developing grade 1 elevations in ALT at an incidence rate of 42.1 per 100 person-years.

Conclusions: IPT completion rate was sub-optimal and incidence rate of developing grade 1 liver injury was low among the study cohort. We recommend that liver enzymes be monitored especially for those with advanced HIV disease.

PEC329

Human Papilloma Virus (HPV) vaccination uptake in HIV patients: challenges during COVID-19 pandemic in Michigan, USA

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Background: HPV is strongly associated with cancers of cervix, vagina, vulva, penis, anus, and rectum. In 2019, WHO identified vaccine hesitancy as top 10 global threats and planned to increase the HPV vaccine cover-

age. In June 2019 Advisory Committee on Immunization Practices (ACIP) in United States recommended shared clinical decision-making regarding HPV vaccinations in adults aged 26 through 45 years. The goal of this project was to evaluate the uptake of HPV vaccination and challenges in the HIV patients at Beaumont Hospital.

Methods: HIV+ patients (ages 18-45) who received care in the Infectious Disease Clinic at Beaumont Hospital were provided a questionnaire on HPV vaccine as part of routine care. Anecdotally patients in this clinic were not routinely offered the HPV vaccine prior to implementation of this student-led quality improvement project. The results of 9 items questionnaire, demographic data and HPV vaccination uptake, were analyzed from August 2019 to December 2020

Results: Thirty-two participants completed the questionnaire of which 12 participants confirmed interest in receiving vaccination and 9 subsequently received the HPV vaccination at the time of analysis (Figure 1). Of note, two other participants had received vaccination previously. 78% of the participants were males and the mean age of the participants was 33.6 years (SD: 5.6) (Table 1).

Age Mean (SD)	33.6 years (5.92)
Gender Male (%)	25 (78%)
Race (%)	Caucasian (34.4%), African American (56.3%), Other (9.3%)
Are you aware of the virus that causes genital warts, cervical cancer?	Yes (87.5%), No (9.4%), Don't Know (6.3%)
Are you aware that HPV-related cancers are preventable?	Yes (89.7%), No (10.3%), Don't Know (0%)
Are you aware that a vaccine for HPV is available	Yes (82.8%), No (13.8%), Don't Know (3.4%)
Do you know if your insurance covers the HPV vaccine?	Yes (34.5%), No (24.1%), Don't Know (41.4%)
Did you receive Influenza vaccine	Yes (46.7%), No (43.3%), Don't Know (10%)
Would you be interested in talking about HPV vaccine	Yes (42.9%), No (42.9%), Don't Know (14.2%)
If you have not been vaccinated would you like to get vaccinated today	Yes (42.3%), No (42.3%), Don't Know (15.4%)

Table 1:

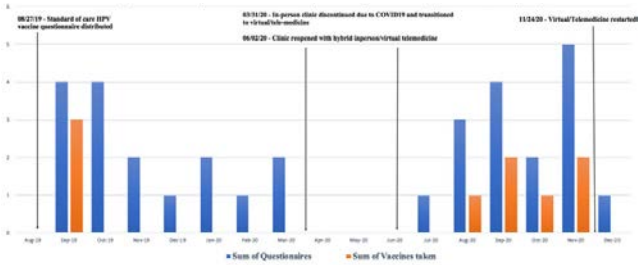

Figure 1: HPV questionaire completed and HPV vaccine uptake in August 2019 through December 2020 (N=32)

Conclusions: The study was limited by transition to tele-medicine clinic during COVID19 pandemic surge. However, it highlighted need for patient-provider discussions to improve HPV vaccination uptake, understand insurance coverage and patient's perception of the vaccine cost to optimize HPV vaccine uptake.

HIV prevention adaptations during COVID-19

PEC330

Maintaining high-yield HIV testing activities in Zambia during the COVID-19 pandemic

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Background: The first case of COVID-19 in Zambia was reported on March 18, 2020; by October 2020, total cases rose to 16,325. At the start of the pandemic, the Ministry of Health established a partial lockdown across the country, which was lifted in May. HIV care and treatment facilities implemented innovative strategies to maintain HIV testing services. In preparation for the second COVID-19 wave, we describe interventions deployed as part of the CIRKUITS program and its effect on testing yield.

Description: CIRKUITS community health workers (CHWs) completed training on COVID infection prevention measures and received personal protective equipment (PPE). CIRKUITS deployed CHWs to hotspot areas and communities with high HIV burden, and organized demand creation activities to support HIV testing. When a HIV positive client was identified, CHWs conducted partner notification services and index testing, and distributed HIV self-test kits to partners. CHWs escorted newly identified HIV positive clients to an appointment at the health facility, as walk-in appointments were not allowed. We examined routinely collected aggregate data from January 2019 to September 2020 across 122 health facilities and their communities in Eastern, Western, and Lusaka Provinces. Descriptive analysis and tests of trend were performed.

Lessons learned: Overall HIV positivity yield remained stable from January 2019 to September 2020. No significant decrease in the number of clients tested (p=0.861) or HIV positive clients (p=0.362) was shown during this period. No significant change on the testing yield trend was observed (p=0.930) overall or by testing modality (p=0.12 for Index, p=0.14 for voluntary counseling testing, p=0.93 for other modalities) (Figure 1).

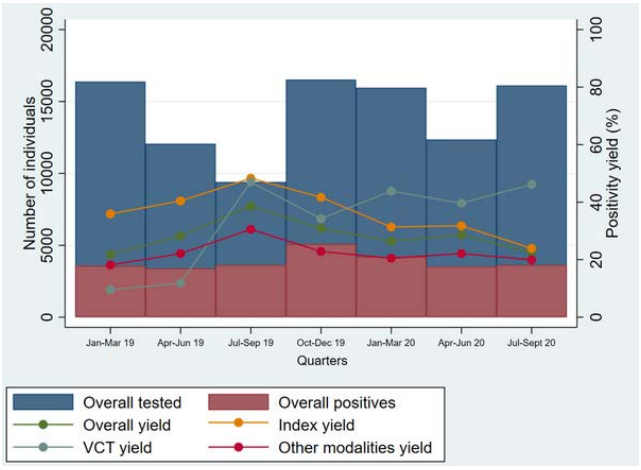

Figure 1

Conclusions/Next steps: CIRKUITS has rapidly adapted to the COVID-19 pandemic to prevent disruptions in HIV services. Training of CHWs and provision of PPE enabled CHWs to carry out community service delivery. By utilizing index testing, HIVST, and facility appointments, high positivity yield was maintained during pandemic times.

PEC331

Impact of COVID-19 pandemic and pandemic response on cisgender men who have sex with men (MSM) and transwomen in a PrEP cohort from Brazil, Peru and Mexico - ImPrEP study

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Background: The COVID-19 pandemic and control measures have likely impacted Latin-American MSM and transwomen's lives, although impact may vary according to country responses (e.g. Brazil had no lockdowns and provided telemedicine, while Peru had strict lockdowns). ImPrEP is an ongoing PrEP demonstration study for MSM and transwomen in Brazil, Peru and Mexico. We report results from a cross-sectional assessment among ImPrEP participants during the COVID-19 crisis.

Total	Brazil 1712 (53.3)	Peru 901 (28.1)	Mexico 598 (18.6)	Total 3211	p-value
Impact of COVID-19 pandemic in personal life					
Medium, very low or low	803 (46.9)	324 (36.0)	286 (47.8)	1413 (44.0)	<.001
Very high or hig	909 (53.1)	577 (64.0)	312 (52.2)	1798 (56.0)	
Challenges during COVID-19 pandemic (yes)					
Sallary/job reduction	752 (43.9)	642 (71.3)	350 (58.5)	1744 (54.3)	< 0.001
Transportation availability	380 (22.2)	348 (38.6)	76 (12.7)	804 (25.0)	< 0.001
Access to daily medication	74 (4.3)	412 (45.7)	194 (32.4)	680 (21.2)	< 0.001
Unable to maintain social distancing	490 (28.6)	67 (7.4)	122 (20.4)	679 (21.1)	< 0.001
Access to health care	90 (5.3)	334 (37.1)	55 (9.2)	479 (14.9)	< 0.001
Access to hand sanitizer	203 (11.9)	59 (6.5)	92 (15.4)	354 (11.0)	< 0.001
Access to food	97 (5.7)	154 (17.1)	34 (5.7)	285 (8.9)	< 0.001
Access to mental health support	105 (6.1)	71 (7.9)	57 (9.5)	233 (7.3)	0.016
Mental Health during COVID-19 pandemic					
PHQ-2 ≥ 3 (likely major depressive disorder)	580 (33.9)	217 (24.1)	107 (17.9)	904 (28.2)	<.001
Alcohol use during COVID-19 pandemic					
Increased	363 (21.2)	29 (3.2)	77 (12.9)	469 (14.6)	
Decreased	339 (19.8)	264 (29.3)	141 (23.6)	744 (23.2)	<.001
Same	522 (30.5)	291 (32.3)	149 (24.9)	962 (30)	
No alcohol use	488 (28.5)	317 (35.2)	231 (38.6)	1036 (32.3)	
Illicit drug use during COVID-19 pandemic					
No use	1196 (69.9)	804 (89.2)	283 (47.3)	2283 (71.1)	
Increased	149 (8.7)	17 (1.9)	64 (10.7)	230 (7.2)	
Same frequency	168 (9.8)	43 (4.8)	136 (22.7)	347 (10.8)	<.001
Initiated new illicit drugs	19 (1.1)	3 (0.3)	16 (2.7)	38 (1.2)	
Decreased frequency	152 (8.9)	26 (2.9)	76 (12.7)	254 (7.9)	
Started using illicit drugs	28 (1.6)	8 (0.9)	23 (3.8)	59 (1.8)	
Sex during COVID-19 pandemic					
Increased	90 (5.3)	26 (2.9)	39 (6.5)	155 (4.8)	<.001
Same	607 (35.5)	364 (40.4)	174 (29.1)	1145 (35.7)	
Decreased	1015 (59.3)	511 (56.7)	385 (64.4)	1911 (59.5)	
Number of sexual casual partners					
No	609 (35.6)	352 (39.1)	210 (35.1)	1171 (36.5)	
Only one	98 (5.7)	60 (6.7)	14 (2.3)	172 (5.4)	<.001
2 to 5	468 (27.3)	259 (28.7)	84 (14)	811 (25.3)	
> 5	537 (31.4)	230 (25.5)	290 (48.5)	1057 (32.9)	
Condomless receptive anal sex with casual partner (yes)	653 (38.1)	251 (27.9)	259 (43.3)	1163 (36.2)	<.001
Steady partner					
No	667 (39)	435 (48.3)	209 (34.9)	1311 (40.8)	
Yes, HIV negative	565 (33)	202 (22.4)	226 (37.8)	993 (30.9)	
Yes, HIV positive undetectable VL	330 (19.3)	86 (9.5)	90 (15.1)	506 (15.8)	<.001
Yes, HIV positive detectable/unknown VL	24 (1.4)	45 (5)	28 (4.7)	97 (3)	
Yes, HIV unknown	126 (7.4)	133 (14.8)	45 (7.5)	304 (9.5)	

Methods: ImPrEP participants were invited to complete a questionnaire on impact of the pandemic and control measures on personal life, mental health, sexual behavior and PrEP use. Participant characteristics were compared across countries using chi-square tests. Logistic regression models adjusted by age, gender and education were used to assess factors associated with stopping PrEP use during the initial pandemic period.

Results: From August/2020 to January/2021, 3211 individuals completed the questionnaire; median age 31 years(IQR:26-37). The majority were MSM (95%), non-white (71%) and education >secondary school (79%). The impact of the COVID-19 crisis was differential by country, considering personal life, mental health, sexual behavior and PrEP use. Peruvian participants reported higher impact of COVID-19 pandemic on personal life, including economics, access to food, and challenges in accessing health care. Brazilians had higher reports of mental health issues, including increased substance use. More Mexicans reported decreasing in sex, although their number of casual partners and condomless receptive anal sex remained higher than Brazil and Peru (Table). A total of 1070(33.3%) stopped PrEP in that period. Being from Peru (aOR:9.25[95%CI:7.48-11.47]) or Mexico (aOR:5.15[95%CI:4.10-6.49]), not having an HIV+ steady partner (aOR:1.34[95CI:1.07-1.67]) and not having sex during that period (aOR:1.72[95%CI:1.30-2.28]) increased the odds of stopping PrEP use.

Conclusions: MSM and transwomen in a PrEP cohort from Latin America were highly affected by the COVID-19 pandemic, but differences were observed across countries, likely resulting from both baseline characteristics and country-specific COVID-19 control measures.

PEC332

Unassisted and assisted HIV self-testing among female sex workers, men who have sex with men, and priority populations before and during COVID-19 and political conflict in Mali

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Background: The USAID-funded EpiC Mali project supports the provision of HIV prevention and treatment services to key populations (KPs) (female sex workers (FSW) and men who have sex with men (MSM) and priority populations (PPs) (non-KPs at high risk). In collaboration with the UNITAID-funded ATLAS project, KP peer navigators create demand at hot spots, offer HIV self-testing (HIVST) following risk assessment and as part of index testing, and navigate individuals to confirmatory testing and treatment sites. In March 2020, Mali government issued a one-month curfew followed by other restrictions to control COVID-19, and political unrest, until September 2020.

Description: In October 2019, EpiC Mali began distributing HIVST kits to hard-to-reach KPs and PPs for unassisted use to increase case detection. During COVID-19 restrictions and political conflict, HIVST was further expanded to continue reaching high-risk KPs and PPs, in compliance with COVID-19 prevention measures, through contactless distribution, but now with increased provider assistance, and phone-based results follow-up.

Lessons learned: From October 2019 to September 2020, 11,579 HIVST kits were distributed. HIVST returns increased from 15% before COVID-19/political conflict to 72% post COVID-19/political conflict, particularly among

Population	October 2019–March 2020 (Pre-COVID-19/Political Conflict)							
	HIVST kits distributed	HIVST returned	HIVST returned (%)	HIVST reactive	HIVST reactive (%)	HIVST reactive and confirmed positive	Total HIV positive (including reactive HIVST confirmed positive)	Reactive HIVST confirmed positive contribution to total HIV positive
FSWs	5,034	687	14%	39	6%	39	673	6%
MSM	847	116	14%	10	9%	10	151	7%
PP	130	81	62%	2	2%	2	214	1%
Total	6,011	884	15%	51	6%	51	1,265	4%

Population	April–September 2020 (during COVID-19/Political Conflict)							
	HIVST distributed	HIVST returned	HIVST returned (%)	HIVST reactive	HIVST reactive (%)	HIVST reactive and confirmed positive	Total HIV positive (including reactive HIVST confirmed positive)	Reactive HIVST confirmed positive contribution to total HIV positive (%)
FSWs	4,550	3,328	73%	154	5%	115	1,042	11%
MSM	939	627	67%	39	6%	37	202	18%
PP	79	57	72%	22	39%	22	303	7%
Total	5,568	4,012	72%	215	5%	174	1,693	13%

Population	October 2019–September 2020 (Complete Time Period)							
	HIVST distributed	HIVST returned	HIVST returned (%)	HIVST reactive	HIVST reactive (%)	HIVST reactive and confirmed positive	Total HIV positive (including reactive HIVST confirmed positive)	Reactive HIVST confirmed positive contribution to total HIV positive (%)
FSWs	9,584	4,015	42%	193	5%	154	1,715	9%
MSM	1,786	743	42%	49	6%	47	353	13%
PP	209	138	66%	24	17%	24	517	4.6%
Total	11,579	4,896	42%	266	5%	225	2,958	8%

PEC332 Table 1. HIVST cascade, October 1, 2019–September 30, 2020

KPs, although baseline return rate for PPs was four times higher than for KPs. The overall reactivity rate remained constant over time (KPs: 6%; PPs: 5%), but it decreased among MSM and increased among PPs. The contribution of HIVST to total HIV case finding increased from 4% to 13% (p<0.01; OR 3.24; CI 2.36–4.45) (Table 1).

Conclusions/Next steps: COVID-19 and political conflict provided the impetus to shift HIVST from unassisted to assisted, resulting in a fivefold increase in return rates and a continued high reactivity rate. Decreased reactivity among MSM could be due to less targeted HIVST kit distribution, while high baseline return rate and high reactivity rate at follow-up among PPs requires further analysis. The increased contribution to overall case finding highlights potential of HIVST, particularly when emergencies arise.

PEC333

Maintaining Voluntary Medical Male Circumcision (VMMC) services amid COVID-19 outbreak in Gambella Region, Ethiopia

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Background: VMMC reduces the risk of HIV acquisition for men by about 60% and is recommended as an additional option for HIV prevention. The federal ministry of health has prioritized VMMC in the Gambella region of Ethiopia which has the highest HIV prevalence (6%) and low rates of male circumcision (47%), setting ambitious doubling of VMMC targets from prior year to 40,792 from October 1, 2019 to September 29, 2020. We examined the effects of COVID-19 pandemic on these activities.

Description: By the end of March, the program had reached only 40.7% (16,604) of the annual target and then was paused due to COVID-19 outbreak for 20 and 53 days at public and refugee facilities, respectively. ICAP in collaboration with the Gambella Regional Health Bureau (GRHB) resumed VMMC activities using a phased approach, carefully weighing the risk and benefit on an ongoing basis. Prior registration and appointment system were introduced, infection prevention and control (IPC) supplies were distributed and triaging undertaken while adhering to mitigation measures. The program disseminated VMMC and COVID-19 awareness and prevention messages through posters, radio announcements and the community mobilizers.

Lessons learned: VMMC services resumed successfully despite the ongoing COVID-19 epidemic. By end of September 2020, 33,483 males were circumcised, 82% of the target, majority (77%) were in the priority age (15-29 years), and 98% returned for follow-up visit with low adverse event rate (0.39%).

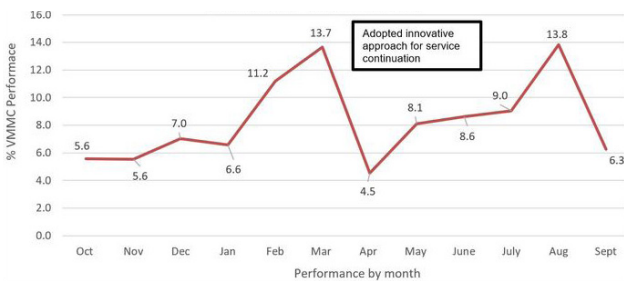

Figure. VMMC performance by month (Oct 1, 2019 - Sept 29, 2020)

Conclusions/Next steps: Modifying demand creation approaches and establishing appointment systems with strict adherence to IPC practices enabled the maintenance of VMMC services during the COVID-19 outbreak.

PEC334

Expanding youth-friendly HIV self-testing services during COVID: a qualitative analysis of a crowdsourcing contest in Nigeria

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Background: HIV self-testing (HIVST) among youth is an effective and confidential approach to enhance uptake. However, optimal strategies for delivering HIVST are limited, and the COVID-19 pandemic has disrupted facility-based HIV testing services. This qualitative study aimed to find common themes in a virtual World AIDS Day (WAD) crowdsourcing open call for youth responses on how to promote HIV self-testing among young people in Nigeria during COVID-19 measures.

Methods: From October to December 2020, the 4 Youth by Youth WAD 2020 crowdsourcing open call was held virtually due to the COVID-19 pandemic. The open call followed WHO standardized steps. Nigerian youth participants aged 10-24 years old submitted ideas online through Google form or email to answer the question: "How will you promote HIV self-testing among young people during COVID19 measures?" Data and responses from each submission were analyzed, and proposed ideas were closely examined to identify common themes. Four independent reviewers judged each submission based on Desirability, Feasibility, and Impact on a 9-point scale (1-9 with nine as highest).

Results: The virtual WAD open call received a total of 156 entries, with 82% (128) through Google form and 18% (28) by email. Twenty submissions received an average total score of 7.5 or above. The steering committee ultimately selected three finalists. Three prominent themes were identified from the open call submissions to promote HIVST through: 1) digital approaches (such as gamification and photo-verification system) to decentralize testing beyond facility-based sites while adhering to COVID-19 safety measures; 2) community leaders and social influencers (such as religious and youth leaders) to build trust in HIV testing services; and 3) mobile service delivery through existing infrastructures/platforms (such as mobile health clinics, churches, schools, and health facilities) to sustain HIVST service delivery post-COVID-19 era.

Conclusions: The open call engaged a large, diverse number of youth through virtual connections. The open call participants proposed a variety of approaches and ideas to improve the uptake of HIVST for the HIV susceptible youth in Nigeria.

PEC335

HIV pre-exposure prophylaxis (PrEP) care in a LGBTQ community-based sexual health and wellness clinic after COVID-19 restrictions

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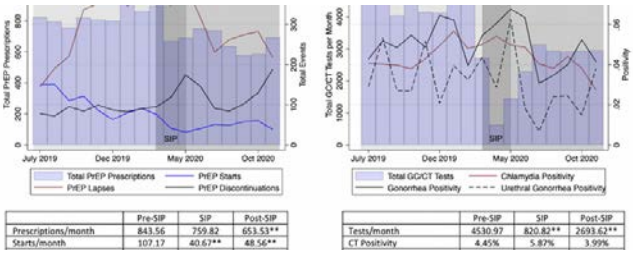
Background: We describe the impact of different phases of the COVID-19 epidemic on PrEP care at Magnet, a San Francisco community-based sexual health clinic.

Methods: We used electronic medical record data for patients with any active PrEP prescription from 7/1/2019-12/4/2020. We examined PrEP initiations, PrEP lapses, PrEP discontinuations, and gonorrhea/chlamydia (GC/CT) testing during three periods: 1) prior to shelter-in-place (pre-SIP) orders in 3/16/2020; 2) during SIP (3/16-5/13/2020), and; 3) post-SIP through database closure. During SIP, in-person visits were available only for new PrEP enrollments, symptomatic STI testing/contacts, and PrEP refills were provided without requiring in-person visits for up to 6 months. We assessed differences between periods and by age and race/ethnicity using chi-squared tests.

Results: Of 3,616 PrEP patients, median age was 32, 94.1% were cis-gender men, 22.4% were Latinx, 4.3% were Black, and 16.6% were Asian. PrEP initiations decreased by 62.2% during SIP and rebounded post-SIP, but only reached 45.1% of pre-SIP levels (Figure 1). PrEP lapses increased by 79% during SIP, while PrEP discontinuations increased by 21%, occurring more frequently in younger patients (p=0.003). Post-SIP, PrEP initiations decreased in Asian patients (p=0.021);among Latinx patients PrEP initiations (p=0.007), discontinuations (p=0.032) and lapses (p<0.003) increased. GC/CT testing post-SIP reached 59% of pre-SIP levels (Figure 2). Compared with pre-SIP, gonorrhea positivity decreased (5.1% vs 4.4%, p=0.004). There were 2 new HIV diagnoses among PrEP patients post-SIP, and 4 prior to SIP.



	Pre-SIP	SIP	Post-SIP
Prescriptions/month	843.56	759.82	653.53**
Starts/month	107.17	40.67**	48.56**

	Pre-SIP	SIP	Post-SIP
Tests/month	4530.97	820.82**	2693.62**
CT Positivity	4.45%	5.87%	3.99%

Conclusions: PrEP initiations decreased post SIP, but without disparities in age or Black/Latinx ethnicity. GC/CT testing and positivity decreased post-SIP. Further investigation is needed to evaluate the impact of lower HIV/STI prevention services on these syndemics.

Innovative HIV prevention interventions

PEC336

Test-and-Share Model: An Innovative HIV Prevention Strategy for Key Population in 16 Chinese Provinces

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Background: HIV testing rates are suboptimal among key population. Test-and-Share may be a useful model for increasing HIV testing and retaining privacy protection.

Methods: An innovative HIV prevention model ('Test-and-Share'), developed by AIDS Healthcare Foundation (AHF) in cooperation with Chinese health facilities, provides active HIV testing and serostatus sharing in 16 Provinces since April 2019. The image of an authorized anonymized HIV test report and a palmprint generate an exclusive personal health QR code. Participants are encouraged to share the QR code to disclose serostatus and encourage sexual partners to be involved in the Test-and-Share model and to test regularly thereafter, practicing safe sex behaviors.

Results: 2,759 HIV-negative or status unknown individuals from high-risk populations joined the Test-and-Share model in 2019. Median age of the participants was 28 (IQR, 22-36 years), 71.8% (1,981/2,759) had at least received college education and 50.8% (1,402/2,759) had a monthly income between 450-1,400 US dollars. At recruitment 3.9% (108/2,759) were diagnosed with HIV. For the rest 12.4% (330/2,651) HIV-negative recruitment participated in regular Test-and-Share with 1-4 follow-ups. One seroconverted during the (third) follow-up. Among the 37.9% (1,045/2,759) first time testers, HIV prevalence was 3.3% (34/1,045), 6.4% (15/233) among men who have sex with man (MSM) and 3.9% (12/307) among heterosexual high-risk population. Compared to three months before Test-and-Share, frequency of HIV serostatus disclosure to partners increased by 18.0% (61.4% vs. 43.4%, χ^2=29.5, p<0.0001) and receiving HIV-status from partners increased by 17.5% (48.1% vs. 30.6%, χ^2=36.0, p<0.0001).

Conclusions: HIV Test-and-Share is an innovative, effective prevention strategy for accessing of key populations, particularly for people who have never tested of HIV. It increases active HIV testing and sharing ones serostatus among high-risk populations in China.

PEC337

How task shifting improved HIV index testing performance in Liberia

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Background: The USAID and PEPFAR funded EpiC project, led by FHI 360, collaborates with the National AIDS and STI Control Program (NACP) in Liberia to scale up index testing to improve HIV case finding. Initially, index testing was led by existing clinical staff, but not systematically offered to all people living with HIV (PLHIV). Moreover, acceptance and willingness to refer contacts was low among those offered index testing, so we used task shifting to improve the results.

Description: EpiC introduced index testing services in Liberia in October 2019 through 17 health facilities and nine civil society organizations (CSOs). An assessment of quality standards done in April 2020 helped identify areas for improvement. Based on results, EpiC and NACP launched an intensive optimization strategy, which included task shifting index testing services to 21 newly identified and trained counselors. Standardized service delivery tools, conducted trainings, and mentorship for 39 clinical staff were introduced to address identified gaps.

Data from pre-optimization, when services were led by existing clinical staff (October–December 2019) were compared to post-optimization, when services were led by dedicated index testing counselors (October–December 2020).

Lessons learned: During pre-optimization, 1,329 PLHIV were offered index testing counseling. Only 63% accepted index testing; 77% of contacts elicited were tested (Table 1).

Case finding among contacts was 23%, and 77% of them were linked to treatment. During post-optimization, 3,583 PLHIV were reached with index testing counseling resulting in higher acceptance (83%), increased uptake of HIV testing among partners elicited (86%), and better linking to treatment (98%).

Although case finding was lower (17%), the number of PLHIV offered index testing increased threefold and the absolute number of HIV cases identified nearly doubled.

Period	Known HIV positive clients reported to clinic	New HIV diagnosis	PLHIV offered index testing	Number accepted index testing	Number contacts elicited	Number partners eligible for testing	Number tested for HIV	Number found HIV positive (%)	Number linked to treatment (%)
Pre-optimization (October-December 2019)	851	478	1329	839 (63%)	1164	1125	871 (77%)	201 (23%)	155 (77%)
Post-optimization (October-December 2020)	2817	766	3583	2959 (83%)	2738	2528	2170 (86%)	367 (17%)	360 (98%)

Table 1: Uptake of index testing

Conclusions/Next steps: Strategic human resource optimization for index testing, including task shifting to dedicated counselors and providing training, mentorship, and standardized tools can significantly improve index testing performance. The collaborative relationship between EpiC and NACP was critical to the success. Beyond technical and financial resources, advocacy among leadership and health professionals is needed to accelerate implementation.

PEC338

Informing the future health economics research agenda for biomedical HIV prevention technologies: identifying gaps in evidence and proposing future directions

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Background: Nearly all existing HIV prevention technologies require continued usage, creating implementation challenges and recurrent costs. Developing interventions that provide longer-term protection is a priority and several products are in the pipeline. Understanding drivers of cost-effectiveness, impact and user preferences early in development can shape product characteristics with long-term implications. Accordingly, we mapped existing and ongoing health economic evidence on biomedical HIV prevention technologies and identified evidence gaps to inform the development and adoption processes for new technologies.

Methods: We reviewed published evidence on (1) cost and cost-effectiveness (n=87), (2) impact modelling (n=43) and (3) quantitative preference elicitation (n=35) through systematic literature reviews for (1) and (2), and secondary analysis of an existing review for (3). To capture yet-to-be-published research we mapped ongoing projects through an online survey with researchers working in these areas. We identified key study characteristics (e.g. technologies, populations, geographies) and methodological approaches.

Results: We found that oral PrEP was the most commonly-researched biomedical prevention technology, followed distantly by other forms of PrEP (e.g. rings or injectables). Few studies explored vaccines. Almost none explored broadly neutralising antibodies (bNAbs). Most studies focussed on low- and middle-income countries (LMICs), especially Eastern and Southern Africa. South Africa and Kenya were overrepresented. Few studies were conducted in Latin America or Asia, and almost none in the Middle East or West/Central Africa. Impact modelling and cost-effectiveness studies in LMICs often focussed on general populations, while most preferences studies looked at key populations, especially female sex workers and men who have sex with men. The latter were underrepresented in Africa. Yet-to-be-published research followed similar patterns and nearly all concentrated on LMICs.

Costing studies rarely collected primary data and mostly focussed on direct costs. Cost-effectiveness and preference research seldomly explored service integration or differentiated delivery modalities. Preference studies enrolled participants largely through convenience sampling (rather than random sampling), recruiting by demographic characteristics instead of behavioural/risk factors. Limited research explored vertical transmission or transmission through injection drug use, intervention combinations, or uptake and adherence factors.

Conclusions: We will use this evidence to propose a health economics research strategy which can inform decision-making in the development of new prevention technologies.

STI diagnosis, treatment and prevention

PEC339

Acceptability of self-sampling for HIV/STI testing in MSM

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Background: Regular HIV/STI testing in men who have sex with men (MSM) is recommended for promoting HIV/STI prevention and enabling timely treatment. It is hypothesized that self-sampling may increase the uptake of testing on a regular basis. This study aimed to assess the acceptability of the self-sampling process in MSM.

Methods: In a one-year cohort study in Hong Kong, participating MSM were asked to test for HIV/STI at 3-monthly intervals. At each visit, participants self-collected urine, pharyngeal and rectal swabs for nucleic acid amplification testing for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG). With the assistance of research staff, participants self-collected fingerprick samples for syphilis point-of-care tests and dried blood spots (DBS) for HIV antibody tests.

Through a monthly survey, participant's perception of the self-sampling process was scored (between 1 as "strong disagree" and 10 as "strongly agree") for its convenience, level of discomfort, confidence in performing self-sampling correctly, and accuracy of the self-collected sample in reflecting the true infection status. Correlations between perception items and with time (testing episode) were examined using Spearman's rho.

Results: Between August 2019 and December 2020, we recruited 207 MSM, including 449 person-time followups. A total of 433 (99.3%) rectal swabs, 433(99.8%) pharyngeal swabs, and 430(99.8%) urine specimens were correctly collected by self-sampling for laboratory testing. The average (±standard deviation) self-sampling scores reported in the corresponding month was 7.1±2.6 (n=188) for convenience, 7.0±2.6 (n=187) for confidence, 7.2±2.6 (n=186) for accuracy, and 4.0±2.7 (n=183) for discomfort.

The score of each perception item was not significantly correlated with time. However, convenience was positively correlated with confidence ($r=0.85$, $p<0.001$), and accuracy ($r=0.80$, $p<0.001$). Confidence was also positively correlated with accuracy ($r=0.88$, $p<0.001$). Level of discomfort was negatively correlated with convenience ($r=-0.22$, $p=0.003$), confidence ($r=-0.26$, $p<0.001$), and accuracy ($r=-0.20$, $p=0.008$).

Conclusions: Self-sampling for HIV/STI testing is feasible and generally acceptable. Despite discomfort during self-sampling, participating MSM were confident in collecting specimens correctly, felt the process was convenient, and believed that the test results from self-collected specimens could show their true infection status. Their perception was supported by the high proportion of correctly collected samples.

PEC340

Syphilis among key population in Indonesia: 25 years of STI control program

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Background: Sexually Transmitted Infection increased risk of HIV transmission. Syphilis rate among Female Sex Workers (FSW) in Indonesia was up to 22% from 1994-2004.
Description: Indonesia has initiated STI surveillance since 1987 through the sero-surveillance in FSW. The STI control program itself was marked with implementation of STI service models in 1995, at 3 sites in 3 provinces. The model includes the collaboration with CSO for outreaching key populations and behavior change intervention, STI screening and treatment of symptomatic infection. Screening was performed with TPHA and RPR, followed by treatment of syphilis cases with Benzatin Penicillin.
In 2003, NAP expanded STI service through establishing STI trainers in 12 provinces, and by 2006, all provinces had the STI trainer teams. These trainings were followed by trainings of health facilities and establishment of STI services. Continuous NAP effort has resulted in STI services expansion from 257 services in 2012 to 6029 in 2020. Consistent condom use was increased in FSW from 27% in 2002 to 68% in 2018, whereby in MSM was 37% in 2004 to 51% 2018, and 43% in 2004 to 62% 2018 among Transgender.
Lessons learned: Indonesia STI trend estimation exercise was conducted by NAP, supported by WHO and Avenir, resulted in reduced incidence of syphilis in FSW from 24.3/1,000py in 2005 to 7.8/1,000py in 2020, and MSM (TG is included) from 16.9/1,000py to 3.8/1,000py.
Conclusions/Next steps: Indonesia's HIV/STI prevention efforts have helped to reduce the prevalence and incidence of syphilis in key populations. In order to end HIV and STI in 2030, Indonesia will continue to scale-up STI services, strengthen screening and management of STI cases, as well as continue to emphasize condom promotion.

Strategies to increase HIV testing and linkage to the prevention cascade

PEC341

Improving HIV Index-contacts testing (ICT) through Intimate Partner Violence (IPV)-Risk assessment questionnaire and ICT national App at selected health facilities in Haiti: challenges, mitigation and implications for the National AIDS Control Program

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Background: In Haiti, women predominantly attend clinics and thus are more likely to be informed of their HIV status. There is no policy/legal requirement making HIV disclosure to sex partners mandatory, which makes index contacts testing [ICT] totally voluntary. In regards to that reality, the National AIDS Control Program (PNLS) along with its partners collaboratively adapted the ICT national guidelines from WHO's SOP on ICT. However, fear of stigma/discrimination and possible intimate partner violence [IPV] remain a major barrier to effective ICT. We present here the outcomes of an intervention aiming at increasing ICT contribution to overall HIV testing services (HTS) and positivity rate at selected health facilities in Haiti.
Description: Following a literature review we adapted an IPV-risk assessment questionnaire that uses an introductory script and standardized questions and integrated it as part of the elicitation process of ICT. The questionnaire was administered to all index-patients/clients. The findings helped address the concerns expressed regarding potential domestic violence related to ICT procedures. We then advised index-patients/clients on the most appropriate contacts' tracing options to prevent potential adverse events directly related to index testing. Furthermore, providers and community health workers [CHWs] received training and weekly technical assistance to ensure the implementation of the national ICT App, which allows timely monitoring/tracking of contacts eligible for tracing and HIV testing notably those unaware of their status.
Lessons learned: During the first quarters of FY20 (Q1-Q3), the proportion of contacts tested for HIV among those listed by index-patients was low at 32% (n=137/423) with a positivity rate of 14% (n=19/137); following the implementation of the IPV-risk assessment questionnaire and the use of ICT national App in FY20Q4, the proportion significantly increased to reach 88% (n=158/180) in FY21_Q1 including a HIV-positivity rate of 30% (n=47/158). Additionally, our weekly review of ICT data has helped monitor progress on ICT App and address challenges timely. Furthermore, we had no reported IPV cases related to ICT.
Conclusions/Next steps: The adapted IPV-risk-assessment questionnaire contributed to improve ICT at the selected facilities and led to an increase in HIV positivity rate while no domestic violence was reported; such strategy may help PNLS improve HTS nationally.

PEC342

GetaKit and the prevention cascade: understanding the impact of HIV self-testing on linkage to prevention services in Ottawa, Canada

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Background: The GetaKit HIV self-testing initiative launched in July, 2020. The initiative primarily sought to assess the feasibility, accessibility, and impact of a mail-out HIV self-testing program in Ottawa, Canada. The secondary objectives of the initiative were to assess the impact of the program on linkages to confirmatory testing and care, and prevention services (PrEP). GetaKit was led by a team of nurses at University of Ottawa and Ottawa Public Health, in collaboration with staff from Ottawa ASOs and the OHTN.
Description: As of July 20, 2020, eligible participants (≥18 years old, HIV-negative, not on PrEP, not in a HIV vaccine trial, living in Ottawa, no bleeding disorders) could register via www.GetaKit.ca to order kits. Testing kits were mailed to clients' homes in Ottawa. The initiative utilized a status-neutral approach, providing follow-up for all clients to connect them with either confirmatory bloodwork or HIV prevention (PrEP). Participants who reported a negative or non-reactive test result were contacted by an ASO staff member or member of the Ottawa Public Health team for follow-up and linkage to PrEP and other services.
Lessons learned: As of February 2021, 388 eligible participants completed baseline surveys and 259 ordered a test Approximately 43% (n=167) of eligible participants reported negative test results. Of those 167 participants, approximately 69% (n=115) belonged to HIV priority groups and were offered PrEP. Participants had an optional 6-month window to con-

tact the Ottawa Public Health team to initiate PrEP after follow-up. Immediate PrEP uptake was approximately 20% (n=23). Other STIs, as well as the need for HAV, HBV, and HPV vaccines, were identified among the participants who initiated PrEP.

Conclusions/Next steps: Our findings indicate that HIV self-testing is an effective gateway for HIV and other sexually transmissible and blood-borne infection prevention services; including PrEP access among persons who otherwise wouldn't have considered it, vaccination, and STI identification and treatment of asymptomatic infections. HIV self-testing is therefore a promising tool in increasing linkage to the prevention cascade.

PEC343

Feasibility and outcomes of tracing women who disengage from targeted health services for female sex workers in Zimbabwe

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Background: The Sisters with a Voice programme provides comprehensive HIV and sexual and reproductive health services for female sex workers (FSW) across 57 clinics in Zimbabwe. Although many women engage with these services only once, little is known about unmet needs among those disengaging. The Sisters programme piloted an approach for tracing women who had not returned for more than six months.

Methods: In one programme site, we identified 134 women who attended between January 2018 and June 2019 but did not return before September 2020. Attempts were made by trained outreach workers to trace these women. Confidentiality of participants was maintained by using verification questions to check identity. Home tracing consisted of up to five home visits. If unsuccessful, this was followed by phone tracing and asking other FSW and peer educators about their whereabouts. We compared tracing outcomes by age, education, marital status and HIV status at first entry.

Results: Some 114/134 women (85.1%) had either a home address or phone number held by the clinic system. Of these, 60 (52.7%) were successfully traced: 25 via home visits, 23 via phone tracing, 10 via engagement with other FSW and peer educators and 2 were determined to have died. Out of the 58 women who were alive, 2 had data missing. Of the 56 women who provided information, 31/56 (55.4%) were still active in sex work, and 50/56 (89.3%) reported that they still required Sisters' services. Reasons for disengaging (multiple responses allowed) included having migrated (31; 55.4%), other work commitments (5; 8.9%), and harassment by providers at clinics (3; 5.4%). Those aged 25+ years were more likely to be successfully traced than those aged <25 years (odds ratio 2.36, 95% confidence intervals 1.06-5.25).

Conclusions: Our findings demonstrate the feasibility of a community level tracing intervention for FSWs, and suggest HIV programmes should retain contact information of FSW guardians/friends for tracing. Over half of disengaged FSWs could not be traced; these were more likely to be younger. The next step for this programme activity will be to determine the percentage of women who re-engaged with the programme following tracing efforts.

PMTCT, including services for vulnerable populations

PEC344

Strategies used in countries with successful mother-infant pair tracking

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Background: Globally, new infant HIV infections continue for several reasons, including undiagnosed maternal infections and interruptions in maternal treatment. This abstract examined programmatic data, identifying countries with high coverage rates of Early Infant Diagnosis (EID) and HIV-exposed infants (HEI) final outcome (FO) ascertainment, and highlights the programmatic strategies being implemented.

Methods: Routinely collected programmatic data from 14 U.S. Agency for International Development (USAID)-supported PEPFAR countries from October 2019 to September 2020 (fiscal year [FY] 20) were used to assess 2-month EID coverage and 18-month FO ascertainment. Top performers were identified as those countries having the highest recorded EID 2mo coverage and FO ascertainment.

Results: The average EID2mo and FO ascertainment for the 14 countries was 65.1% and 58.6% respectively. Eswatini, Lesotho, Nigeria and South Africa achieved the highest rates of EID2mo, ranging from 82.0% to 96.5%, and FO ascertainment, ranging from 70.3% to 86.5%. All four countries implement community and facility mentor mother programs and provide clients with mHealth services, appointment reminders, and joint mother-infant pair services. Three countries implement birth cohort monitoring registers. Only Lesotho and Eswatini use continuous quality improvement approaches (CQI). Finally, only Lesotho incorporates point-of-care (POC) EID and only South Africa includes birth testing.

Conclusions: Top performing countries implemented a combination of strategies to promote continuity of treatment for mother-infants pairs along the PMTCT cascade, including using mentor mother programs, establishing mother-infant pair clinics and utilizing mHealth. However, only Lesotho is using POC machines to ensure rapid turnaround times, which may be contributing to Lesotho's high performance in both EID 2mo and FO; while only South Africa is implementing routine testing at birth and 10 weeks, which may be contributing to South Africa having the highest EID2mo coverage. Further analyses are needed to understand to what degree these interventions contributed to the outcomes of the PMTCT programs in these countries, and if additional innovative strategies are needed.

PEC345

Prevention of mother-to-child transmission (PMTCT) of HIV outcomes in infants of women who received Option B+ care during pregnancy in routine healthcare settings

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Background: Mother-to-child HIV transmission (MTCT) rate estimates in Tanzania remained high at 11% in 2019 despite high (92%) anti-retroviral therapy (ART) uptake for the prevention of MTCT (PMTCT) under the World Health organization (WHO) Option B+.

Methods: We conducted a prospective cohort study of 23,834 pregnant women with HIV enrolled in Option B+ care from 2015-2017 in routine healthcare settings of Dar es Salaam, Tanzania. Mother-infant pairs were followed up for 2+ years postpartum until October 2020. The primary study outcome was MTCT (a positive HIV test by the end of breastfeeding assessed by polymerase chain reaction (PCR) or antibody test at infant's 18+ months of age), or infant death. After exclusion of those who lacked data on the primary outcome, 9,968 mother-infant-firstborn pairs were analyzed. We used random effects Poisson regression with exchangeable correlation and robust error variance to compare MTCT rates across clinical and socioeconomic characteristics, reporting risk ratios (RR) and 95% confidence intervals (CI).

Results: At enrollment to PMTCT care, 6,602/ 8,124 women (81.3%) were in their second or third trimester, 2,993/ 9,935 (30.1%) had advanced HIV disease and 4,625 (46.4%) had started ART prior to index pregnancy. By the end of follow-up, at 18+ months, 154 (1.54%) infants were confirmed HIV positive and 295 (2.96%) infants had died without confirmed HIV status. Using a complete case analysis (n =6,549), the risk of MTCT or infant death was higher among women who started PMTCT care late [RR (95%CI) = 1.43 (1.00, 2.05) and 1.97 (1.30, 2.98) for second and third trimester, respectively, versus first]. Single mothers had lower risk of MTCT or infant death [RR (95%CI) = 0.74 (0.56, 0.99)] compared to married or cohabiting women. Mother's age, advanced HIV disease, starting ART before index pregnancy, ART regimen and infant sex had no significant influence on MTCT or infant death.

Conclusions: Implementation of Option B+ has greatly improved MTCT outcomes among infants of women who remain in PMTCT care in Tanzania. There is a need, however, to improve early uptake of PMTCT services and complete follow-up of mother-infant pairs to the end of the PMTCT period.

PEC346

Determinants of HIV-free survival in the era of lifelong universal antiretroviral therapy (ART): pooled analysis of PEAWIL and IMPROVE studies, Lesotho

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Background: We assessed factors associated with HIV-free survival (HFS) among HIV-exposed infants, pooling data from two Lesotho cohorts in the universal ART era.

Methods: PEA-WIL, an observational study (6/2014-9/2018), and IMPROVE, a randomized trial (7/2016-7/2019), enrolled HIV-positive pregnant women attending antenatal care (ANC) in Lesotho under universal ART guidelines, with mother-baby follow-up through 12-24 months postpartum, to evaluate a facility-based intervention package to improve patient care. There was no significant difference in HFS between arms, so arms were combined. Kaplan Meier analysis was used to estimate mortality and HFS rates, censoring for loss to follow-up or withdrawal; multivariate logistic regression was used to identify factors independently associated with HFS.

Results: A total of 1,205 HIV-positive women were enrolled in combined cohorts; median maternal age was 28 (IQR:24–32) years and 80.1% were married/living with a partner. At delivery, 99.3% of women were receiving ART. Of 1,178 (96.4%) live births, 8.4% were preterm, 97/1,103 (17.9%) had a birth weight <2500 g, and 91.4% were breastfed at birth with 35.9% breastfed for ≥6 months. Estimated 2-year HFS was 93.4% (95%CI 92–95%) (Figure)—most rapid decline from birth-6 months, plateauing at age 1 year. In adjusted analyses, HFS was significantly associated with maternal age (≥25 vs. <25 years) (aOR 2.4, 95% CI 1.4–4.3), HIV disclosure to partner (aOR=2.0, 95% CI 1.04-3.8), gestational age at birth (>37vs≤ 37-weeks) (aOR=3.7, 95%CI 1.6–8.4), and breastfeeding for ≥6 months (aOR=2.4, 95%CI 1.2-5.0). In a multivariate model with birth weight instead of gestational age, birth weight <2,500 g was associated with lower HFS (aOR=0.4, 95%CI 0.2–0.8).

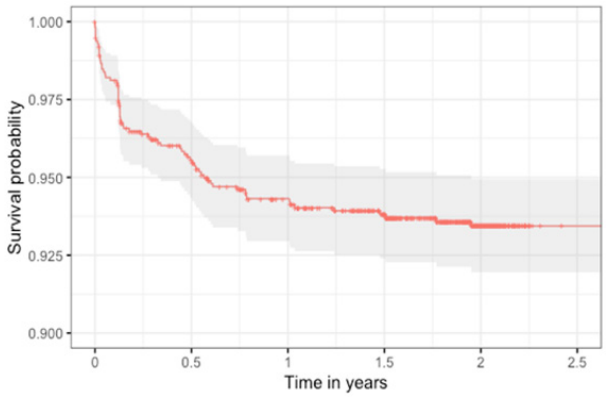

Figure. Kaplan-Meier showing HIV free survival of HIV exposed infants in Lesotho

Conclusions: In an era of universal ART in pregnant women, higher HFS was associated with older maternal age, partner disclosure, and breastfeeding for at least six months; while lower in infants born preterm or low birth weight.

PEC348

The importance of surveys to complement program data in informing modeled Mother to Child HIV transmission (MTCT) estimates and identifying and addressing hidden program gaps: a case study of Uganda

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Background: As recommended by World Health Organization, we reviewed program, survey, and modelling data to identify gaps, track progress toward elimination of mother to child transmission (MTCT), and assess impact of expanded access to program interventions.
Methods: We compared early (at first early infant diagnosis test and/or 4-12 weeks) and final (18 months) transmission from Uganda's cross-sectional nationally-representative household survey (Population-based HIV Impact Assessment, UPHIA, Aug. 2016-Mar. 2017); national PMTCT Impact Evaluation (PMTCT IE, Sept. 2017-Jul. 2019); facility-reported program data (Health Management Information System, HMIS); and annual Spectrum modelling (2015-18) that incorporates routine pregnancy surveillance, expected births, and program data. UPHIA MTCT estimates were derived from 320 HIV-exposed infants <18m of age. PMTCT IE included 23,314 infants aged 4-12 weeks from immunization clinics at 206 nationally-representative health facilities; 11,564 were followed up over 18m for final transmission.
Results: Early transmission declined in program data (5.1% to 3.8%) and Spectrum-modelled estimates (4.79% to 2.95%) (Figure 1). Final transmission significantly dropped in program data (7.4% to 4.6%) and Spectrum estimates (9.84% to 6.29%), but modelling suggests programs miss substantial transmission. UPHIA demonstrated high early (14.8% [CI 3.19-26.47]) and final (15.6% [CI 6.08-25.03]) transmission but was not powered for these estimates. PMTCT IE demonstrated the lowest early (2.1%) and final (2.8%) transmission, with greater cohort retention (82%) versus program data (72%).

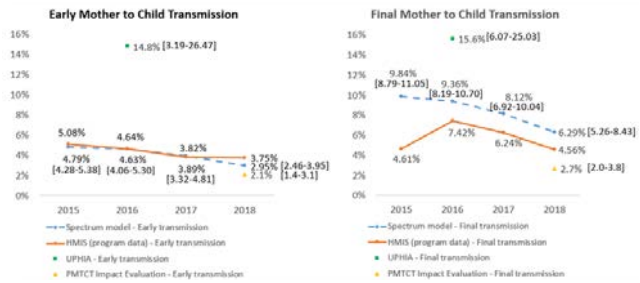

Figure 1.

Conclusions: MTCT decreased from 2015-2018, demonstrating impact of programmatic improvements and access to PMTCT interventions, although estimates differed by methodology. Despite wide confidence intervals, UPHIA uniquely captured higher transmission among HIV-positive women not accessing care (i.e., not in program data). PMTCT IE demonstrated reassuring low transmission among mother-infant pairs accessing care, even at facilities without comprehensive PMTCT services. This work emphasizes the need to compare multiple data sources to estimate MTCT and identify and address gaps in access and utilization of healthcare services.

Integration of family planning and HIV services

PEC349

State-level clustering in PrEP implementation factors among family planning clinics in the Southern United States

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Background: Availability of PrEP-providing clinics is low in the Southern US. Little is known about factors influencing PrEP implementation in Southern states, which vary in state-level policies. We explored state-level clustering of organizational constructs relevant to PrEP implementation in family planning (FP) clinics in the Southern US.
Methods: We surveyed providers and administrators of publicly-funded FP clinics not providing PrEP in 18 Southern states (Feb-Jun 2018, N=414 respondents from 224 clinics). The Consolidated Framework for Implementation Research (CFIR) informed construct selection, including readiness to implement PrEP and others previously associated with PrEP readiness: PrEP knowledge/attitudes, implementation climate, leadership engagement, and available resources. We analyzed each construct using linear mixed models with fixed effects for state, provider, and clinic-level covariates, and a random effect for clinic. A principal component analysis of the resulting construct-specific, state-level fixed effects (8 states excluded due to insufficient data) identified 6 principal components, which were inputted into a K-means clustering analysis to examine state-level clustering.

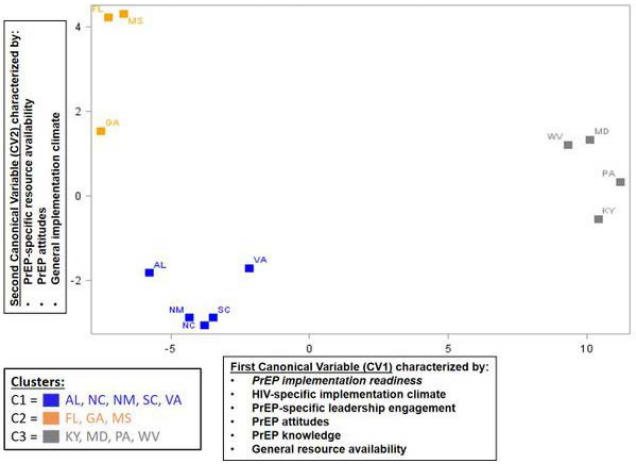

Figure 1. Clusters of 12 Southern US states stratified by first (CV1) and second (CV2) cononical variables derived from CFIR construct-specific, state-level fixed effect estimates

Results: Three clusters (C1-3) were identified with 5, 3, and 4 states, respectively (Figure 1). Canonical variable 1 (CV1; x-axis) separated C1 and C2 from C3 and was primarily driven by PrEP readiness, HIV-specific implementation climate, PrEP-specific leadership engagement, PrEP attitudes, PrEP knowledge, and general resource availability. Canonical variable 2 (CV2; y-axis), which distinguished C2 from C1, was primarily driven by PrEP-specific resource availability, PrEP attitudes, and general implementation climate. All C3 states had expanded Medicaid, compared to 1 C1 state (none in C2).

Conclusions: CFIR constructs relevant for PrEP implementation exhibited state-level clustering, suggesting that tailored strategies could be used by clustered states to improve PrEP provision in FP clinics. Medicaid expansion was a common feature in states within C3, which could explain the similarity of their implementation constructs. The role of Medicaid expansion and state-level policies on PrEP implementation warrants further exploration.

PEC350

Couples' preferences for a dual-purpose product to prevent both HIV and pregnancy: results of a discrete choice experiment (DCE) in Uganda and Zimbabwe

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Background: End-user input at early-stage development of biomedical prevention strategies may optimize their design to ensure high uptake and adherence. Male partners are key influencers in women's product use yet seldom are included in woman-centered prevention research. In MTN-045/CUPID, we interviewed couples to assess their preferences for hypothetical dual-purpose, HIV and pregnancy, prevention (DPP) products.
Methods: Between January-November 2020 we enrolled 400 couples (self-reported HIV-negative women aged 18-40 and their male partners) in Kampala, Uganda and Chitungwiza, Zimbabwe. Using an experimental design, the DCE asked couples to choose between two hypothetical DPP products in a series of 9 choice questions assessing the following attributes: form (oral tablet, vaginal film/insert, vaginal ring); dosing (precoital, daily, weekly, monthly); menstruation (heavier bleeding, spotting, unchanged); side effects (stomach cramps/nausea: rarely, frequently); return to fertility (immediate, 3-, 6-months); vaginal environment (wetter, drier, unchanged). Random-parameters logit models estimated preference weights and relative importance [RI].
Results: Couples' average relationship duration was 5 years (range 0.25 – 21 years); females were younger than males (mean: 26 vs. 31). Most couples cohabitated, with Zimbabwean couples more commonly married (88% vs. 20%). DPP product preferences differed significantly by country. Ugandan couples highly valued effect on the vaginal environment, showing a strong preference for increased vaginal wetness (RI=2.5, 95% CI: 1.8, 3.2). Zimbabwean couples' choices were influenced by menstruation and side effects (RIs=1.3, 95% CI: 0.9, 1.6) as well as dosing frequency (RI=1.2, 95% CI: 0.8, 1.6). Couples in both countries strongly preferred monthly over daily dosing. Ugandan couples also showed interest in precoital dosing. While product form was relatively less important, on average, couples preferred an oral tablet over a vaginal ring.
Conclusions: Preferred characteristics of DPP products varied substantially by country. Effects of the product on the body (e.g., side effects, vaginal environment) were relatively more important than product form or dosing frequency, signaling an openness to new product forms and more frequent dosing if preferred characteristics of other attributes were achieved. Differing tolerances for product side effects should be considered during development, alongside leveraging cultural preferences to increase the attractiveness of a DPP product.

PrEP and pregnant women

PEC351

Motivations and concerns regarding PrEP use during pregnancy: associations with decisional regret and one-month PrEP adherence among pregnant women in Lilongwe, Malawi

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Background: Pre-exposure prophylaxis (PrEP) is a promising tool for HIV prevention during pregnancy. With increasing rollout in antenatal settings, counseling strategies to help pregnant women make decisions about PrEP use are needed. Understanding women's motivations and concerns for PrEP use—and how these relate to their feelings about starting PrEP and adherence—are critical to inform these strategies.
Methods: We enrolled 200 HIV-negative pregnant women in Lilongwe, Malawi (June-November 2020) in a pilot trial to enhance PrEP adherence. At baseline, women reported motivations for and concerns about PrEP use, and their feelings about the decision to start PrEP (decisional regret scale). At one-month follow up, 172 women completed an adherence assessment by pill count (analyzed as both percentage and high adherence ≥85%). We assessed bivariate associations of each motivation or concern with decisional regret and adherence (no adjustments for multiplicity).

PrEP use concerns	n (%) n=200	Decisional regret Mean (95% CI)[a] n=200	% adherence Mean (95% CI)[a] n=172	High adherence (≥85%) n(%)[b] n=172
(1) Concerned that PrEP could harm my body	137 (69%)	1.21 (1.15, 1.26)	0.89 (0.86, 0.92)	90 (78%)
No	63 (32%)	1.23 (1.14, 1.32)	0.86 (0.81, 91)	39 (68%)
Yes		*p=0.75*	*p=0.90*	*p=0.19*
(2) Concerned that PrEP could harm the baby I am expecting	128 (64%)	1.19 (1.14, 1.25)	0.88 (0.85, 0.91)	85 (77%)
No	72 (36%)	1.25 (1.16, 1.34)	0.87 (0.84, 0.91)	47 (75%)
Yes		*p=0.36*	*p=0.92*	*p=0.99*
(3) Didn't think I am at risk for HIV infection	170 (85%)	1.20 (1.15, 1.25)	0.89 (0.86, 0.91)	111 (77%)
No	30 (15%)	1.31 (1.18, 1.43)	0.82 (0.74, 0.91)	18 (64%)
Yes		*p=0.03*	*p=0.11*	*p=0.16*
(4) Concerned that my partner(s) would be upset if knew I take PrEP	180 (90%)	1.19 (1.14, 1.24)	0.88 (0.85, 0.90)	115 (75%)
No	20 (10%)	1.41 (1.19, 1.63)	0.85 (0.74, 0.97)	14 (78%)
Yes		*p=0.03*	*p=0.77*	*p=0.99*
(5) Concerned that family/friends would be upset if knew I take PrEP	178 (89%)	1.20 (1.15, 1.25)	0.88 (0.85, 0.91)	115 (75%)
No	22 (11%)	1.30 (1.12, 1.48)	0.86 (0.76, 0.95)	14 (74%)
Yes		*p=0.40*	*p=0.79*	*p=0.99*
(6) Worried people would think I'm HIV-positive if saw me taking PrEP	153 (77%)	1.20 (1.14, 1.25)	0.87 (0.85, 0.91)	97 (75%)
No	47 (24%)	1.27 (1.17, 1.38)	0.88 (0.83, 0.92)	32 (76%)
Yes		*p=0.15*	*p=0.83*	*p=0.99*
(7) Worried people would think I was promiscuous if knew I take PrEP	177 (89%)	1.20 (1.15, 1.25)	0.88 (0.86, 0.91)	114 (76%)
No	22 (11%)	1.30 (1.11, 1.49)	0.84 (0.76, 0.92)	14 (67%)
Yes		*p=0.58*	*p=0.11*	*p=0.42*
(8) Concerned about being able to take a pill every day	161 (81%)	1.19 (1.14, 1.24)	0.88 (0.86, 0.91)	103 (75%)
No	39 (20%)	1.31 (1.17, 1.44)	0.86 (0.78, 0.94)	26 (76%)
Yes		*p=0.23*	*p=0.62*	*p=0.99*
(9) Don't like taking pills	173 (87%)	1.19 (1.14, 1.23)	0.88 (0.86, 0.91)	110 (75%)
No	26 (13%)	1.42 (1.22, 1.61)	0.84 (0.73, 0.95)	18 (75%)
Yes		*p=0.01*	*p=0.31*	*p=0.99*

Table. Association of PrEP concerns with baseline decisional regret and one-month PrEP adherence
[a]p-value for Mann-Whitney Test; [b]p-value for Fishers Exact Test

Results: On average, women endorsed 3.8 motivations (of 7) and 1.7 concerns (of 9). Top motivations included protection from HIV-infection (100%), perceived HIV risk (81%), and partner risk behaviors (73%). Common concerns included harm to their baby (36%) or themselves (32%). Baseline decisional regret was low overall (mean=1.2, range=1-5).

One-month pill counts indicated average PrEP adherence of 88%, with 75% of women achieving high adherence. PrEP use concerns associated with greater decisional regret included: no perceived HIV risk, concerns about partner disclosure, and dislike of pills. None of the motivations or concerns were significantly associated with one-month adherence.

Conclusions: In this pilot study, pregnant women reported high adherence to PrEP one month after initiation. Though participants generally expressed low levels of regret about initiating PrEP, certain concerns about PrEP were associated with greater regret and should be targeted in decision-making counseling.

PEC352

Transitioning integrated antenatal PrEP delivery from research projects to routine clinic staff at 16 clinics in Western Kenya

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Background: The World Health Organization (WHO) recommends pre-exposure prophylaxis (PrEP) for pregnant and postpartum women at high risk for HIV acquisition. PrEP studies among Kenyan pregnant and postpartum women have found high PrEP acceptance within routine maternal and child health (MCH) settings. Transitioning demonstration projects from dedicated research teams to routine clinic staff not employed by studies is a common challenge in scale up and sustainability.

Methods: Following a cluster randomized trial (NCT03070600) comparing approaches for PrEP delivery to pregnant and postpartum women, we documented the active transition process from research teams to routine clinic staff. We utilized the WHO Health Systems Building Blocks Framework to actively transition care and qualitatively summarized the process through debrief checklists and matrices with study staff.

Results: At 16 health facilities in Western Kenya that transitioned from research to routine clinic team delivery of antenatal PrEP in 2020-2021, all 16 successfully continued PrEP delivery for pregnant and postpartum women. The unique contexts at each clinic influenced heterogeneous solutions to how PrEP was successfully continued; at 6, PrEP delivery shifted to HIV care clinics, while at 10 PrEP remained integrated within MCH clinics.

At all facilities, active transfer of medical commodities and tracking systems (PrEP medication, HIV testing kits, health records and registers) and transition of MCH PrEP users from research to routine health staff providers were successful with few noted challenges. Some facilities actively introduced MCH clients to HIV care clinics while others made a passive referral. Processes for ordering PrEP commodities were heterogeneous across facilities through existing procurement mechanisms, but were not impacted by departing study staff.

Challenges arose around how existing health workforce absorbed new PrEP provision duties, adding to already overloaded responsibility lists. Many facilities identified a new PrEP point person to be mentored by departing research staff, typically the nurse in charge of preventing mother-to-child transmission of HIV. At facilities with donor-supported HIV implementing partners (N=11), implementing partner staff generally assumed PrEP delivery roles.

Conclusions: Transitioning PrEP delivery from research to routine clinic teams was successful and yielded heterogeneous solutions to match local context. Health workforce burden remains a challenge.

PEC353

No association between prenatal PrEP exposure and adverse growth outcomes among Kenyan infants: a prospective study

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Background: The World Health Organization (WHO) recommends PrEP for pregnant women at-risk for HIV, yet calls for longer-term safety evaluations. We evaluated infant growth outcomes through 9 months following prenatal PrEP exposure.

Methods: Longitudinal data were analyzed from the PrEP Implementation for Mothers in Antenatal Care (PrIMA) study (NCT03070600). Women enrolled during pregnancy and infant anthropometry was conducted by trained nurses at 6-weeks, 6-months, and 9-months. WHO weight-for-age, height-for-age, and weight-for-height z-scores were calculated; underweight, stunting, and wasting were defined as z-score<-2. This analysis included singleton pregnancies, with a live birth and documented gestational age. Women who initiated PrEP postpartum or HIV-seroconverted were excluded. Infants with prenatal PrEP exposure were compared with PrEP-unexposed infants using multivariate GEE models, adjusting for gestational age, maternal syphilis, and age.

Results: In total, 4019 mother-infant pairs were analyzed (90% of total PrIMA participants). At enrollment, median maternal age was 24 years (IQR 21-28) and median gestational age was 24 weeks (IQR 20-30). Overall, 548 (13.6%) women used PrEP during pregnancy, initiating PrEP at a median of 26 weeks gestation (IQR 22-30); median duration of PrEP use during pregnancy was 11.9 weeks (IQR 7.1-17). Median weight was similar at 6-weeks (5.0 vs. 5.0 kg, p=0.80), 6-months (7.7 vs. 7.8 kg, p=0.04), and 9-months (8.6 vs. 8.6 kg, p=0.50) between groups. There were no differences in median infant length at 6-weeks (55.2 vs 55.0 cm, p=0.70), 6-months (66.0 vs. 66.0 cm, p=0.35), and 9-months (70.5 vs 70.0 cm, p=0.30). Prenatal PrEP exposure was not associated with underweight, stunting, or wasting at any timepoint (Table 1). Results were similar when analyzed separately by trimester of PrEP initiation.

		PrEP Exposed (n=548)	PrEP Unexposed (n=3471)	Crude RR (95% CI)	Adj RR (95% CI) [2]	p-value
6-weeks	Underweight	7 (2.4%)	65 (3.0%)	0.8 (0.4-1.4)	0.8 (0.5-1.5)	0.52
	Stunting	29 (10.1%)	201 (9.5%)	1.1 (0.7-1.6)	1.2 (0.9-1.7)	0.20
	Wasting	14 (5.0%)	121 (5.8%)	0.9 (0.4-1.6)	0.8 (0.4-1.6)	0.51
6-months	Underweight	6 (2.4%)	60 (3.5%)	0.7 (0.3-1.6)	0.7 (0.3-1.5)	0.30
	Stunting	21 (8.3%)	153 (8.9%)	0.9 (0.6-1.3)	1.0 (0.7-1.4)	0.98
	Wasting	7 (2.8%)	67 (3.9%)	0.7 (0.3-1.5)	0.6 (0.3-1.4)	0.26
9-months	Underweight	8 (2.9%)	70 (4.0%)	0.7 (0.4-1.4)	0.7 (0.3-1.4)	0.32
	Stunting	18 (6.8%)	160 (9.4%)	0.7 (0.4-1.2)	0.7 (0.4-1.1)	0.10
	Wasting	8 (3.0%)	60 (3.6%)	0.8 (0.4-1.7)	0.7 (0.3-1.7)	0.47

Table 1. Infant growth outcomes by PrEP exposure (n=4019)

Conclusions: In the largest safety study of PrEP in pregnancy to date, infant growth outcomes through 9 months did not differ by prenatal PrEP exposure.

PEC354

Navigating PrEP use and pregnancy: perspectives among adolescent girls and young women (AGYW) in Tshwane, South Africa

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Background: Adolescence and emerging adulthood are critical periods of vulnerability to HIV for adolescent girls and young women (AGYW) in South Africa. Pre-exposure prophylaxis (PrEP) is an important strategy to reduce AGYW's risk of HIV, however uptake is low, particularly among pregnant AGYW. Understanding pregnant AGYW's experiences with pregnancy and PrEP may inform interventions to improve uptake. Therefore, the purpose of this study was to examine pregnancy outcomes (live birth, still birth, miscarriage, abortion) and PrEP continuation among AGYW in Tshwane, South Africa.

Methods: In PrEPARE, a trial funded by NICHD addressing multi-level barriers to PrEP use and other reproductive health services among AGYW, we enrolled participants who became pregnant over follow-up in a sub-study to examine pregnancy, birth and PrEP use outcomes. All participants were confirmed as non-pregnant at enrollment and at PrEP initiation. We calculated descriptive statistics on pregnancy outcomes and PrEP use from quantitative data from birth outcome tracking interviews and follow-up questionnaires. We analyzed qualitative data from follow-up contacts with participants using a thematic approach.

Results: Of the 450 participants enrolled in the parent study between April 2019 and January 2021, 45 became pregnant between baseline and 9-month follow-up. Pregnancy outcomes to date include 14 abortions, 3 miscarriages, and 14 live births. Sixty percent of pregnant participants (n=27) reported having initiated PrEP prior to conception, while 40% declined PrEP prior to conception and were found ineligible for PrEP during the study. However, nearly all participants (n=12) who reported live births discontinued using PrEP prior to birth. Among the 27 participants who initiated PrEP, concerns related to PrEP use during pregnancy were the primary reasons for discontinuation. Common concerns included: families discouraging PrEP use during pregnancy, fear of PrEP harming infants during pregnancy and breastfeeding, and worries over the co-occurrence of PrEP side effects and pregnancy-related symptoms.

Conclusions: PrEP has the potential to reduce HIV acquisition among pregnant and lactating post-partum AGYW; however, concerns about using PrEP safely during this period may hinder its use. Interventions that address AGYW's concerns, and those of their families, are critical for promoting PrEP continuation.

PEC355

CAP016 PrEP in pregnancy - a phase 2b open-label randomised control safety study of daily oral TDF/FTC when used as pre-exposure prophylaxis for HIV prevention in pregnant and lactating women

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Background: Daily oral TDF/FTC has been widely studied and recommended as a safe option for prevention of HIV in men and women at substantial risk. With limited safety data, TDF/FTC has also been recommended for pregnant women on the assumption that the benefit of TDF/FTC in prevention of HIV outweighs the risk of adverse pregnancy outcomes.

Methods: We conducted an open-label randomized trial of oral TDF/FTC used as PrEP among HIV-1 seronegative pregnant women in South Africa (NCT03227731). Pregnant women were randomised to either initiating oral TDF/FTC in pregnancy (Treatment Arm) or deferred until cessation of breastfeeding (Control Arm).

Women were followed monthly until delivery. Preterm delivery (PTD), very preterm delivery (VPTD), stillbirths (SB), spontaneous abortions (SA), low birth weight (LBW), very low birth weight(VLBW) and neonatal deaths constituted the primary outcome measures to test the hypothesis that TDF/FTC does not increase the risk of adverse pregnancy and neonatal outcomes. TDF levels were measured on DBS once during pregnancy at a visit prior to an adverse pregnancy outcome or at the last visit prior to delivery.

Results: We report pregnancy outcomes for 250 and 247 women in the PrEP and Control arms. The mean(SD) gestational age at randomization were 17.1(5.1) and 17.6(5.3) weeks respectively. PTD(<37 weeks) and VPTD(<34 weeks) rates were 9.2% and 4.0% in the treatment arm and 8.9% and 4.5% in the control arm. Stillbirth rates were 4.0% in the treatment arm and 2.8% in the control arm. There were 22 (9.3%) and 16 (6.8%) LBW (<2500 g) infants in the treatment and control arms. Very LBW (<1500g) rate was 0.8% in each arm. 3 neonatal deaths were reported for the control arm only. TDF was undetectable in 85 (32.7%; 95%CI 27.0-38.8) women in the treatment arm. Median (IQR) TDF level in 175 pregnant women was 417 (171; 644) fmol/punch.

Conclusions: Risk of adverse pregnancy and neonatal outcomes was not higher in TDF-FTC arm than the control arm. Early stopping of accrual due to change in national PrEP policy led to a smaller sample size with resulting loss of power to conclude equivalence between PreP and Standard of care arms formally.

Integration of HIV prevention services into health and other platforms

PEC356

PrEP acceptability, initiation, and continuation within a commercial pharmacy-based PrEP delivery model for adolescent girls and young women in Kenya

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Background: Many adolescent girls and young women (AGYW) at-risk for HIV in Kenya access contraception at commercial pharmacies without interfacing with public sector facilities. Commercial pharmacies could increase options for reaching AGYW at-risk of HIV with PrEP services. We evaluated PrEP acceptability, initiation, and continuation within a pharmacy-based delivery model for Kenyan AGYW.

Methods: From October 2020 to January 2021, PrEP-prescribing nurses were stationed at 3 commercial pharmacies in Kisumu, Kenya. All AGYW (aged 15-24 years) purchasing contraception (emergency contraception [EC], oral contraceptive pills, injectables, implants, condoms) were counseled on and offered PrEP per national guidelines. AGYW who accepted PrEP were provided with a free one-month supply of PrEP pills. We evaluated acceptance among all AGYW offered PrEP; at 30 days after acceptance, we evaluated PrEP use initiation, and plans for continuation among those who accepted PrEP.

Results: We enrolled 237 AGYW clients who were purchasing contraception at pharmacies. EC was the most frequently purchased contraceptive (35%). Median age was 22 years (IQR 19-23), 44% were currently in school, and 33% currently had multiple sexual partners. One-fourth (24%) reported exchanging sex for money or favors and 14% had sex while intoxicated in the prior 6 months.

Overall, 86% accepted PrEP. The most frequent reasons for acceptance were feeling at-risk of HIV (92%) and thinking a partner has other partners (84%). Among AGYW who declined PrEP, low HIV risk perception (75%) and pill burden (53%) were the most frequent reasons for declining. At one-month, 77% who accepted PrEP had initiated PrEP use and 65% planned to continue use.

Among those starting PrEP, 63% were willing to pay for PrEP at commercial pharmacies even if available for free at public sector facilities. Reasons for willingness to pay included convenience, no wait times, less stigma, and anonymity. The maximum amount AGYW were willing to pay for a one-month supply of PrEP was KSH 150.0 (IQR 100-300), approximately USD 1.50.

Conclusions: In this pilot of nurse-facilitated PrEP provision at commercial pharmacies in Kenya, a substantial proportion of AGYW who purchased contraception subsequently initiated PrEP, planned to continue PrEP use, and were willing to pay for PrEP at pharmacies.

PEC357

Opportunities to integrate PrEP into primary care: results of an online focus group study among family physicians in Flanders, Belgium

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Background: Family physicians (FPs) provide a broad range of person-centered health care and prevention services as part of primary care. However, the provision of PrEP in Belgium is currently centralized in specialized HIV clinics. Engaging FPs in PrEP care could help to scale-up PrEP delivery and to reach underserved populations. We currently lack insights into FPs' perceptions of their role in providing PrEP care.

Methods: Family physicians practicing in Flanders were invited to participate in online discussion groups, organized within existing local FP quality circles. We conducted 13 FGDs with a total of 81 participants, between November 2020 and January 2021, using web conferencing technology. In addition, participants completed an online questionnaire assessing socio-demographics and experience with sexual health. Data were transcribed verbatim, and analyzed in Nvivo using a constant comparison approach.

Results: Overall, participants had little PrEP-related knowledge and exposure through their practice, yet were interested to receive more information. While FPs unequivocally agreed that identifying and referring at-risk clients for PrEP fitted their scope of activities, they differed in their perceptions of how to operationalize that role.

Participants regarded their experience with sexual health activities (e.g. screening for sexually transmitted infections), and a low-threshold relationship with their clients, as good opportunities for identifying PrEP candidates and linking them to specialized PrEP care.

Most FPs, however, described a lack of clinical guidelines, absence of a formal referral mechanism, and perceived discomfort in proactively conducting sexual behavior risk assessments as main barriers to identify and refer clients for PrEP. Due to limited familiarity with providing antiretroviral medication, many FPs were hesitant to initiate PrEP independent of specialist advice.

Although some FPs felt comfortable putting clients on PrEP themselves, a collaborative model between specialist physician ('start-up') and FP ('follow-up') was generally identified as an approach towards integrating PrEP into primary care in Belgium.

Conclusions: Despite limited PrEP experience, Belgian FPs in our study clearly saw a role for them in linking clients to PrEP and in ensuring good-quality follow-up, particularly for clients not reached by specialized HIV clinics. Providing additional training and creating FP-specialist collaborations were suggested to increase FPs' engagement.

PEC358

High willingness to pay for PrEP services at retail pharmacies in Kenya

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Background: For models of HIV pre-exposure prophylaxis (PrEP) delivery outside of clinical settings (e.g., retail pharmacies) to be self-sustaining, a fee must be associated with service provision. We collected data on participants' willingness to pay for services associated with pharmacy-based PrEP delivery as part of an ongoing pilot study in Kenya.
Methods: We enrolled pharmacy clients interested in PrEP for HIV prevention at four retail pharmacies in Kisumu and Thika, Kenya. The Ministry of Health supplied PrEP drugs and HIV self-tests free of charge for this pilot and we charged participants a service fee (300 KSH, ~3 USD) for pharmacy-based PrEP initiation, which included counselling, safety assessment, assisted HIV self-testing, and drug dispensing. At enrollment, all participants completed a survey that captured their socio-demographic information, amount spent at a typical pharmacy visit, and future willingness to pay amount per visit for pharmacy-delivered PrEP services. We reported descriptive statistics by age and sex and measured differences using Pearson's chi-squared test.
Results: From December 2020 to February 2021, we enrolled 91 participants in the pilot, of which 57% were females and 45% were <25 years. Participants reported spending a median of 50 KSH (IQR: 0-300 KSH) at a typical pharmacy visit. Almost all participants (97%), were willing to pay for pharmacy-delivered PrEP services and many (43%) were willing to pay more than they were charged (>300 KSH) for these services. There were no significant differences (p<0.05) in willingness to pay for PrEP delivery at pharmacies by age and sex (Figure 1).

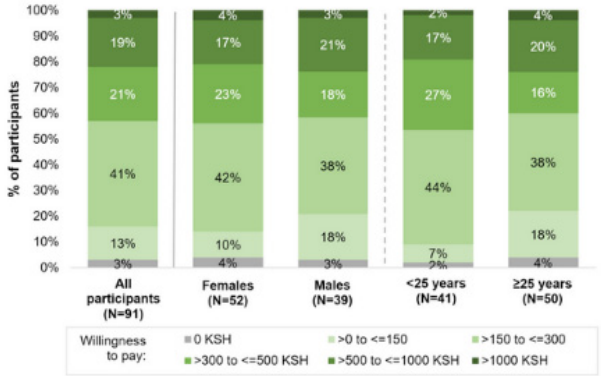

Figure 1. Willingnes to pay for pharmacy-based PrEP delivery among pharmacy clients participating in a pilot study

Conclusions: Clients at retail pharmacies in Kenya are willing to pay for pharmacy-delivered PrEP services and many are willing to pay more than what they were charged for these services in the pilot. These findings indicate both a demand for and the potential sustainability of pharmacy-based PrEP delivery models in Kenya and similar settings.

PEC359

Understanding sexual and reproductive healthcare-seeking and service provision at retail pharmacies in Kenya: opportunities for HIV prevention

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Background: In Kenya, retail pharmacies are ubiquitous and offer a wide range of curative and preventive sexual and reproductive health (SRH) products and services. We conducted qualitative interviews with Kenyan pharmacy providers and clients to understand retail pharmacy-based SRH care-seeking and identify opportunities for integrated delivery of SRH and HIV prevention services.
Methods: From October 2019 to February 2020, as part of a formative research study on pharmacy-based delivery of HIV pre-exposure prophylaxis (PrEP), we interviewed 16 pharmacy providers and 40 pharmacy clients in Kisumu and Thika, Kenya. Eligible pharmacy providers were ≥18 years old, licensed, and providing care at a registered retail pharmacy. Pharmacy clients were ≥18 years old and at risk of HIV (as per a routinely used screening tool). We conducted a secondary analysis of interview data using conventional content analysis.
Results: Provider median age was 33 years (IQR: 27-35) and 44% (7/16) were female; client median age was 25 years (IQR: 22-28), half (20/40) were female, and 83% (33/40) reported using some form of pregnancy prevention, most commonly male condoms, emergency contraception, and contraceptive implants. Participants commonly reported purchasing or selling four types of SRH services: 1) urgent SRH services (e.g., emergency contraception, HIV post-exposure prophylaxis [PEP]); 2) preventive SRH services (e.g., contraception), 3) routine SRH services (e.g., testing for pregnancy, HIV, and other STIs), and 4) recreational SRH services (e.g., testosterone boosters). Client-reported reasons for seeking SRH services at retail pharmacies included convenience, privacy, fair prices, and nice treatment by pharmacy staff. Provider-reported challenges to delivering SRH services included low knowledge and training (e.g., not understanding the difference between PEP and PrEP), regulatory restrictions, drug shortages, and inadequate space to test and/or counsel clients.
Conclusions: Seeking and providing SRH services at retail pharmacies was common among the pharmacy clients and providers in this study, highlighting an opportunity for retail pharmacies to identify candidates for HIV prevention interventions, such as PrEP. Further research is needed to test the feasibility of delivering integrated SRH/HIV prevention services in retail pharmacies in Kenya.

PEC360

High acceptance of incentivised community based HIV and sexual and reproductive health services in adolescents and young people: Results from the pilot phase of the Yathu Yathu trial in Zambia

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Background: Adolescents and young people aged 15-24 (AYP) are at high risk of HIV and other STIs and yet are the least likely to access health facilities. Integrating HIV services with broader sexual and reproductive health services (SRHS) is critical to their health and well-being. Through community-based, peer-led spaces, Yathu Yathu delivers comprehensive, SRHS to AYP in Lusaka, Zambia. Using data from a pilot implementation phase (August 2019-February 2020), we describe attendance to Yathu Yathu hubs by age and sex, and the key services accessed.

Methods: Two urban communities in Zambia (populations ~100,000 each), were sub-divided into 20 zones. Zones were randomized 1:1 to intervention or standard-of-care. Enumerators visited every household. Consenting AYP aged 15-24 were given a loyalty card, called "prevention points card" (PPC). In intervention zones, youth-friendly spaces (hubs) staffed by peer-support workers were established at central locations within the communities. AYP from intervention zones could accumulate prevention points after accessing SRHS at a hub or the local health facility. AYP from control zones only received points after accessing services at the local health facility. Accrued points could be exchanged for rewards.

Results: Over two-thirds of enumerated AYP consented to participate (29,370/40,864=71.8%) with recruitment similar in control and intervention zones. After accepting the PPC, 40.1% (5,962/14,872) of AYP from intervention zones accessed SRHS versus 8.2% (1,181/14,498) from control zones (OR 7.9, 95%CI 7.3-8.5). More AYP aged 15-17 accessed services than AYP aged 20-24. Attendance was higher among females. Among AYP from intervention zones attending hubs, the mean number of visits was 4.4 and most popular services utilized were comprehensive sex education sessions (12,037 visits), educational entertainment sessions (4,778 visits) and HIV-testing (4,605 visits). Over two-thirds of AYP from intervention zones (4,052/5,962, 68.0%) exchanged accumulated points for rewards. Facecloths (4,291), bathing soap (4,146) and toothpaste (3,201) were handed out most frequently.

Conclusions: This early evidence suggests that community-based SRHS, complemented by incentives through loyalty cards, are an innovative strategy to reach AYP and significantly increased access to services compared with standard of care. A future cluster-randomized trial will provide evidence of the impact of the strategy on coverage of HIV services.

Use of the Internet, social media, mobile phones and other e-devices for prevention

PEC361

Test-and-share program: an innovative model for HIV prevention in men who have sex with men in Beijing, China

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Background: The proportion of men who have sex with men (MSM) accounted to over half of newly reported HIV/AIDS cases in Beijing. With the country's scale-up of efforts in HIV/AIDS prevention and control among MSM, HIV awareness rapidly increased (from 15.2% in 2009 to 65.4% in 2015), but condom use did not change significantly.

To address the dissociation between awareness and behaviors among MSM, innovative prevention strategies to facilitate HIV testing and safe sex behavior are crucial.

Methods: The 'Test-and-Share' model to develop active HIV testing and safe sex behaviors was introduced among MSM in Beijing from April to November 2019. An HIV test report from authorized health facility and individual palmprint are required to generate an exclusive personal health QR code, for sharing with people in their social network. Participants record their HIV serostatus through Test-and-Share Platform and share their status to sexual partners.

Results: 486 MSM who are HIV-negative or with status unknown, joined Test-and-Share program in 2019. The median age of the participants was 31 (IQR, 26-37 years), 76.3% (371/486) had at least college education and 39.7% (193/486) had a monthly income > 1,400 USD. At recruitment, 12 (2.5% or 12/486) were HIV positive and 75.0% (9/12) of those were tested as HIV negative before. All 12 were initiated on ART. Of those who were HIV-negative at recruitment, 56.1% (266/474) actively participated in the periodic (max. 4 times) HIV testing during the study period. No-one seroconverted during the follow-up period.

Compared to the three months before Test-and-Share implementation, frequency of receiving HIV status from partners increased by 15.0% (46.7% vs. 31.7%, χ^2=15.7, p<0.0001), whereas serostatus disclosure to partners increased by 5.9%, but without significant difference (63.4% vs. 57.5%, χ^2=2.09, p=0.15).

Conclusions: Test-and-Share program is an effective strategy to encourage active HIV testing and safe behavior among MSM. This highlights the potential for using this model for improving the behaviors consist with knowledge among MSM in China. This model deserves scale-up, as evidenced by efficacy in regular HIV testing and change towards safe sex behavior.

PEC362

A Pilot Study of a Mobile App (UPrEPU) to Self-monitor Daily/Event-driven PrEP Adherence for Men who Have Sex with Men

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Background: UPrEPU app is a self-monitoring tool to improve PrEP adherence regardless of the MSM users' choices of dosing regimens. UPrEPU mobile app accommodates users' need to take either event-driven or daily PrEP, and has an indicator for drug concentration, a sexual and PrEP diary, geo-location of HIV/STI testing, PrEP information and videos. The aims of this pilot study are to evaluate the usability of UPrEPU app and the effectiveness of adherence monitoring.

Methods: HIV-uninfected MSM aged above 20 years who were currently on PrEP or willing to initiate PrEP, able to understand, read, and speak Mandarin Chinese were recruited and followed for four months after enrollment. Usability of this app was measured using the systematic usability scale (SUS). A score above 50 out of 100 indicates acceptable.
The effectiveness of adherence monitoring was analyzed using Cohen's Kappa statistic to calculate the concordance between the numbers of pills taken recorded in the app and the tenofovir and emtricitabine drug concentrations in dried blood spot (DBS) samples in the previous 7 days before the day of blood sample collected.

Results: From May 2020 to October 2020, 35 participants were enrolled and overall retention was 91.4% (32 participants) at the end of study. No participant acquired HIV infection during the 4 months follow-up. During the follow-up period, there were 1872 pill taken records and 569 sex event records in the app. More than half of participants (57.1%) switched between daily and event-driven PrEP (event-driven and no switch: 40%; daily and no switch: 2.9%). UPrEPU app acceptability was high with a mean SUS score of 71.5 (SD: 12.4). Nearly half of participants have a consistent result comparing their self-reported PrEP taken in the app and the DBS concentration (43.8%). The agreement between PrEP taking logs and the result of DBS was moderate (weighted Kappa: 0.42).

Conclusions: The UPrEPU app showed high acceptability in both daily and event-driven MSM PrEP users. The consistency between self-reported PrEP-taking in the app and DBS concentration was not high. Improvement of app features and usability should be further explored to serve as a better self-monitoring tool for PrEP users.

PEC363

Mobile phone ownership is not a barrier to uptake of community-based ART and viral suppression

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Background: Community-based delivery of antiretroviral therapy (ART) increases viral suppression and often requires tracking and tracing of clients living with HIV to coordinate care. Mobile phones are an effective method for communicating with clients and facilitates counseling and coordination of care.
We hypothesized that mobile phone ownership would increase access to a community-based ART and thus increase viral suppression.

Methods: The Delivery Optimization of Antiretroviral Therapy (DO ART) Study in South Africa and Uganda evaluated community-based delivery of ART compared to clinic-based care. During enrollment people living with HIV reported mobile phone ownership and provided their phone number. Care was coordinated using mobile phones, when one was available, but mobile phone ownership or access was not a requirement for study participation.
At study exit (12 months) plasma HIV viral load was determined using the bioMérieux NucliSens assay. These data were used to measure the prevalence of mobile phone ownership and to calculate relative risks of ownership and HIV treatment outcomes using a modified Poisson regression for binary outcomes with robust standard errors, adjusting for potential confounders of age and gender.

Results: Of 1,531 participants, most (84%) owned a mobile phone. There was no significant association between age and mobile phone access (adjusting for gender). Women were 9% more likely to have access to a mobile phone than men when controlling for age (95% CI: 4 - 14). There was no significant association between mobile phone ownership and viral load suppression at study exit a(RR: 1.09, 95% CI: 0.98 – 1.21, p = 0.11), adjusting for age and gender.

Conclusions: Mobile phone ownership is now almost ubiquitous; mHealth can facilitate care for people living with HIV. However, we found no association between viral suppression and mobile phone ownership in the context of high rates of mobile phone ownership in a community-based ART project in South Africa.
Thus, owning a mobile phone may not be a requirement to access community-based ART delivery programs and realize the health benefits of decentralized services. Given that more women than men had mobile phones, mHealth programs requiring access to a mobile phone may unintentionally exclude men.

PEC364

Feasibility and acceptability of HIV prevention mHealth intervention among young men who have sex with men in South Korea

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Background: mHealth interventions have great potential for HIV prevention among men who have sex with men (MSM). MSM are disproportionately impacted by HIV in Korea, with their incidence rate continuing to increase over the past decade. To develop effective HIV prevention mHealth interventions, it is critical to explore feasibility and acceptability of these approaches among Korean MSM.

Methods: We conducted an online study with Korean young MSM (YMSM; ages 18-35) living in the Seoul metropolitan area between September and November 2020. 180 YMSM answered questions related to their technology use, socio-demographic characteristics, HIV prevention behaviors, and sexual behaviors. Descriptive statistics are used to summarize socio-demographic characteristics, health information seeking patterns, and acceptability and willingness to engage in mHealth HIV prevention interventions.

Results: Participants' mean age was 26.5 years (SD=4.2). Most identified as gay (91.7%); less than half (42.2%) reported having a partner. Two-thirds (67.2%) had tested for HIV in their lifetime. Most YMSM in Korea owned a smartphone (99.4%) and searched online for health information including HIV-related topics in the past 12 months (80.4%).

Korean YMSM prioritized the following HIV prevention topics when searching for information online: HIV testing (92.7%), PrEP use (92.7%), living with HIV (86.0%), healthy living (79.2%), safer sex (75.3%), condom use (71.9%), creating social change (69.7%), love & relationships (57.3%), and life skills (52.3%).

When asked what features would be important in an mHealth HIV prevention intervention, participants wanted an application (app) that allowed them to ask questions of HIV care providers (84.3%), locate HIV testing resources (79.8%), order in-home HIV tests (79.2%), engage in telehealth-based counseling (79.2%), participate in discussion boards (71.4%), facilitate user-to-user messaging (70.2%), and read articles on health (56.2%). Less than half prioritized gamification features (42.7%).

Conclusions: Korean YMSM indicate high acceptability for mHealth intervention approaches for HIV prevention. The current absence of mHealth interventions for Korean YMSM combined with rising HIV incidence in this population underscores the urgency of the problem. Tailoring HIV prevention mHealth interventions to focus on HIV testing/care, PrEP, and access to expert resources may contribute to reductions in the HIV disparities observed among YMSM in Korea.

PEC365

WeChat reminders to improve the willingness to undergo voluntary medical male circumcision for HIV prevention among men who have sex with men: a randomized controlled trial

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Background: Evidence from observational studies demonstrates the potential association between voluntary male medical circumcision (VMMC) and lower HIV prevalence among men who have sex with men (MSM). High prevalence of smartphone and WeChat usage provides an unprecedented opportunity for mobile-based health information interventions in China. The objective of this randomized controlled trial was to evaluate the efficacy of WeChat-based health information intervention in increasing the willingness of VMMC for HIV prevention among MSM in China.

Methods: MSM who were HIV-uninfected, uncircumcised and aged 18 or older were recruited between January and March 2019 from six cities in China. During a six-month intervention period, health education information concerning HIV and other sexually transmitted infections(HIV/STIs), foreskin health, and male circumcision, was sent to participants in intervention group twice a week via WeChat. Participants in control group only received information about HIV/STI health education with the same frequency and duration as the intervention group. An online, self-completed questionnaire was used to collect baseline and post-intervention data. The prevalence of willingness to undergo VMMC comparing two groups was assessed after intervention. This trial is registered with Chinese Clinical Trial Registry, number ChiCTR1900020981.

Results: 444 MSM were recruited, 305 of whom self-reported foreskins completely or partially covering glans in the absence of erection, and 319 (155 in intervention group and 164 in control group) of whom underwent the full 6-month intervention. No statistically significant differences in baseline characteristics were found between drop-outs and non-drop-outs. Compared with control group, the proportion of intervention group who perceived that long foreskin would cause premature ejaculation increased significantly (117/155[75.5%] vs 99/164 [60.4%],P=0.004), and that long foreskin would increase the risk of HIV/STI infection increased significantly (123/155[79.4%] vs 101/164[61.6%],P<0.001), and that circumcision could reduce the risk of HIV/STI infection increased significantly (124/155[80.0%] vs 98/164[59.8%],P<0.001) after intervention. But the willingness to be circumcised showed no significant change (46/155[29.7%] vs 43/164[26.2%], P=0.510). Glans can be fully exposed during erection was the main reason for MSM's reluctance to undergo circumcision (243/314,77.4%).

Conclusions: WeChat reminders may not improve the willingness to undergo VMMC for HIV prevention among MSM, but it increased circumcision-related sexual health knowledge.

Behavioural interventions to prevent HIV transmission

PEC366

Improving safety and quality of Safe Male Circumcision (SMC) services in Uganda: adverse events quality improvement collaborative

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Background: In 2010, Uganda introduced Safe Male Circumcision (SMC) as part of its comprehensive HIV prevention package. In 2018, the Monitoring and Evaluation Technical Support (METS) Program in collaboration with the Ministry of Health (MoH), U.S. Centers for Disease Control and Prevention (CDC) and Implementing Partners (IPs), conducted a data quality assessment in 72 CDC-supported SMC sites. The assessment reviewed 177,952 medical records of males circumcised between October 2017 and March 2018. 970 (0.5%) experienced reportable (moderate or severe) adverse events (AE) resulting from SMC. Of which 30% (288) were correctly classified, 51% (499) misclassified, 19% (183) of reportable AEs not classified and only 9% were documented. An adverse event is any medical complication or injury that occurs during or after SMC.

Based on these findings, CDC-supported SMC sites in July 2019 implemented an AE quality improvement initiative aimed at improving safety and quality of SMC services.

Methods: Multi-pronged QI capacity building model for SMC services which included tailored trainings, post-training coaching and mentorship, periodic service and data quality assessments and learning sessions was implemented in 82 CDC-supported sites. Site teams consisting of circumcisers, counsellors, and data officers were trained in Adverse Event (AEs) identification, management, documentation and reporting.

Following the training, multiple on-site mentorship and coaching visits were jointly conducted by central level coaches and IPs during which service and data quality assessments were done using the MoH service and data quality assessment tools.

Results: In July 2020, 7-day follow-up post-SMC was 99% (83,462/84,305) from 80% (73,900/92,000) in September 2018, AE occurrence reduced by 44% from 0.55% (970) to 0.31% (262); AEs correctly classified improved from 30% (288) to 86% (224). The proportion of AEs reported using a site-specific improvised AE form, AE management report and AE grading scale increased from 10% (85/850) in June 2018 to 84% (207/247) in July 2020. Documentation of AE management outcome also improved from 25% (245) to 98% (219) in July 2020.

Conclusions: Collaborative implementation guided by customized AE reporting tools are vital in improving identification, classification, management and documentation of AEs following SMC. A dedicated AE management and documentation tool should be adopted across sites.

Adherence to HIV prevention strategies

PEC367

Demographic factors associated with continuation of oral anti-retroviral HIV pre-exposure prophylaxis at one and three months in Nairobi, Kenya

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Background: The effectiveness of oral anti-retroviral HIV pre-exposure prophylaxis (PrEP) depends on continued adherence over the users' risk period. We sought to determine one and three months PrEP continuation rates, as proxy of adherence, and examine demographic characteristics associated with the continuation.

Methods: Retrospective cohort analysis was conducted using data from thirty University of Maryland, Baltimore (UMB) supported facilities in Nairobi, Kenya. Individuals newly initiated on PrEP, beginning July 2019 through June 2020, were included in these analyses. Continuation rates (prescription refill) at one and three months were computed and logistic regression model was used to estimate odds ratios (OR) and 95% confidence intervals (95% CI) for the association of demographics (age, gender and population type) with PrEP continuation.

Results: Of 1607 individuals who initiated PrEP within the reviewed period, 1192 (74%) were 25 years or older, 1161 (72%) were female and 874 (54%) were female sex workers (FSWs). Overall, continuation rate was 38% and 17% at one and three months respectively. Younger individuals (15-24 years) had continuation rates of 27% and 10%, while key populations (FSW and MSM) had 23% and 9% at one and three months respectively. Compared to younger individuals, those ≥ 25 years were more likely to continue with PrEP, [OR 1.97 (95% CI 1.54– 2.52)] and [OR 2.03 (95% CI 1.44–2.86)] at one and three months respectively. Males had higher odds of continuing with PrEP at month 1, [OR 1.41 (95% CI 1.13–1.76)]. Key population were less likely to continue with PrEP at both one and three months compared to general population individuals in HIV sero-discordant relationships (Table 1).

Demographic characteristics	Month 1 prescription refill		Month 3 prescription refill	
	OR (95 % CI)	P-value	OR (95 % CI)	P-value
Age				
15–24	Ref		Ref	
> 24	1.97 (1.54–2.52)	<.0001	2.03 (1.44– 2.86)	<.0001
Gender				
Female	Ref		Ref	
Male	1.41 (1.13–1.76)	0.0023	1.28 (0.97– 1.69)	0.0846
Population type				
Discordant couples*	Ref		Ref	
FSW	0.17 (0.14–0.22)	<.0001	0.20 (0.15–0.27)	<.0001
MSM/MSW	0.04 (0.02– 0.08)	<.0001	0.05 (0.02–0.13)	<.0001
General population**	0.58 (0.33– 1.00)	0.0514	0.30 (0.14–0.66)	0.0024

Abbreviations: FSW, Female sex worker; MSM, Men who have sex with men; MSW, Men who have sex with men as sex workers (transactional)

* Excluding key population
** Excluding key population and individuals in HIV sero-discordant relationships

Table 1: Predictors of HIV pre-exposure prophylaxis continuation at month one and three in Nairobi, Kenya, 2019 - 2020.

Conclusions: These results show sub-optimal PrEP continuation among younger and key population individuals. Targeted interventions for these two groups are necessary to optimize PrEP continuation in light of national scale-up of PrEP uptake.

PEC368

Persistence on oral pre-exposure prophylaxis (PrEP) among female sex workers in Durban, South Africa from 2016-2020

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Background: In 2016, South Africa became one of the first countries in sub-Saharan Africa to introduce pre-exposure prophylaxis (PrEP) to female sex workers (FSW) as part of the National Strategic Plan. Despite the established efficacy of PrEP to prevent HIV and the advantages conferred by a female-controlled method, uptake and persistence on PrEP by women in both clinical trial and real-world settings has been suboptimal. We utilized programme data to describe persistence on oral PrEP among FSW in Durban, South Africa.

Methods: All FSW initiating PrEP at TB HIV Care in Durban between 2016-2020, were included in these analyses (n=2694). PrEP was provided for free, and women served by TB HIV Care were followed monthly. We examined time from PrEP initiation to discontinuation using Kaplan-Meier curves and a discrete time-to-event data setup. Discontinuation of PrEP was defined as two consecutive monthly visits missed. We stratified analyses by age and year of initiation.

Results: The number of initiations increased each year from 155 (6%) among PrEP-eligible FSW in 2016 to 1224 (44%) in 2020. Persistence was 52% (95% CI: 49%-53%) 1 month after PrEP initiation, 31% (95% CI: 29%-33%) 4 months after initiation, and 16% (95% CI: 14%-18%) 7 months after initiation. A greater proportion of women ages ≥25 years persisted on PrEP compared with women <25 years old at all timepoints (p<0.001). Persistence improved each consecutive year of the programme until 2020 (Figure 1).

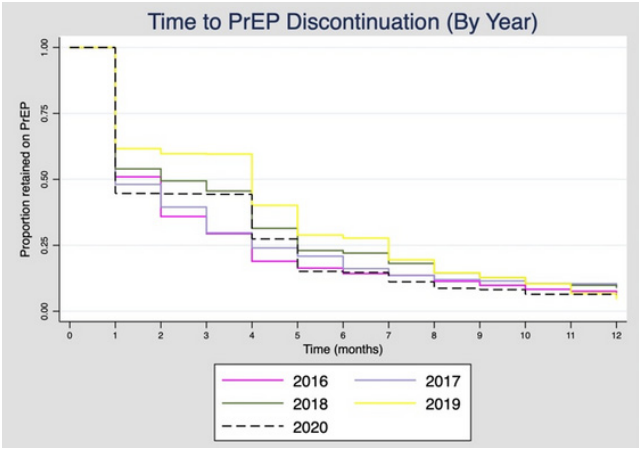

Figure 1. Time to PrEP discontinuation by year among 2694 female sex workers initiating PrEP through TB HIV care in Durban, South Africa 2016-2020

Conclusions: Low levels of PrEP persistence were observed consistent with data among underserved women elsewhere. Encouragingly, the proportion of women persisting on PrEP increased over calendar time, even as the number of women on PrEP and staff workload also increased. The programme introduced several implementation strategies to improve PrEP persistence throughout this period, and further research is needed to understand which specific strategies may have contributed to these year-on-year improvements.

PEC369

Effectiveness of participant-driven follow-up strategy on retention among young female sex workers in Kampala, Uganda

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Background: Poor retention and adherence to study visits and procedures has been cited as one of the greatest challenges in key population and adolescent studies as well as in HIV care and treatment programs. Research suggests that peer influence, self-stigma and anxiety is significantly associated with poor retention in adolescent studies. Peer-led approaches have had a positive impact on retention and we explore additional follow-up strategies from a randomized controlled trial assessing a cognitive-behavioral and structural HIV prevention intervention.

Description: Between November 2016 and February 2019, 644 young female sex workers (YFSWs) were enrolled. Follow-up was scheduled at 6, 12 and 18 months. Initially, participants were requested to attend follow-up study visits on specific days with community workers regularly reminding them about the appointments prior to the visit date. In study week 118 (07 Feb 2019), retention was at 51%, 56% and 63% at month 18, 12 and 6 respectively. We devised strategies to improve retention. In addition to the routine site clinic, we conducted mobile clinics, Saturday clinics and moonlight clinics based on participant preference.

Lessons learned: Between week 118 and week 163 we conducted 53 mobile, 26 Saturday and 09 moonlight clinics. Retention improved from 51% to 72% for month 18 follow-up visit, from 56% to 63% for the month 12 visit, and 67% to 71% for the month 6 visit.

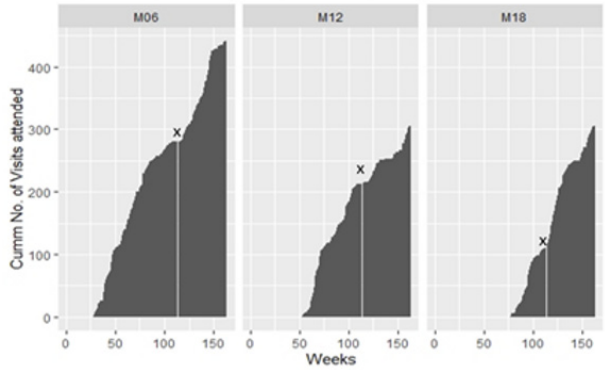

Figure.

Of the 410 study visits, the majority 42% were completed at mobile clinics, 5% were completed at moonlight, 18% at Saturday clinics, and 35% at the site clinic.

Conclusions/Next steps: Providing a range of options is key in improving retention and more so when participant preference is put into consideration. Mobile and moonlight clinics have the potential to improve participant retention in trials targeting YFSWs and could be used in informing programming for service provision to a highly vulnerable at-risk population.

PEC370

Interim feasibility results of a pre-exposure prophylaxis (PrEP) delivery demonstration project among male sex workers in Malindi, Kenya

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Background: Despite overwhelming scientific evidence supporting use of pre-exposure prophylaxis (PrEP) for HIV prevention, the reality of providing PrEP and ensuring adherence remain a challenge for highly marginalized persons in resource poor settings. This study was conducted to evaluate the feasibility and acceptability of a peer-driven, community-based PrEP program for male sex workers (MSWs) in Malindi, Kenya.

Methods: This 15-month demonstration project engaged MSWs ³ 18 years old in Malindi, Kenya via peer-leader led, venue-based sampling (i.e. at local hotspots). Working with a local organization supporting LGBTQIA persons, MSW were screened for eligibility using the PrEP Rapid Assessment Screening Tool (RAST). Eligible participants received were prescribed a monthly and then quarterly supply of PrEP and scheduled for monthly follow-up visits for PrEP refills. Data on PrEP related concerns and perceived barriers to adherence were collected as well as self-reported adherence at a midpoint and final study visit.

Results: Between May 2019 to October 2019, n=200 MSW (mean age = 27.0 years, SD= 6.6 years; range = 18 – 51) met study eligibility criteria and were enrolled in this project and n=195 (97.5%) were retained over the course of the study period. Preliminary results indicate that at baseline, PrEP concerns were about long-term health effects (37%), side effects (38%) and daily adherence (27%). Despite these concerns, on average, >90% of participants returned as scheduled to obtain PrEP refills and self-reported adherence was reported by >80% of participants.

Conclusions: While follow-up and data collection activities are still in progress, important lessons can be drawn from these preliminary findings. First, employing a peer leader model to engage MSW in a PrEP demonstration project was critical to successfully recruiting, enrolling and retaining MSW. Next, by employing a community participatory model based on collaborating with a a local and well-established LGBTQIA support organization, our preliminary findings strongly suggest that locating PrEP delivery services within health service organizations that are sex-worker friendly can significantly facilitate adoption of HIV prevention among male sex workers. Finally, these findings will be important for successfully scaling-up community-based PrEP delivery and sexual health services to MSW in Malindi, Kenya.

Prevention among people living with HIV

PEC371

Changes in HIV outcomes and progress towards epidemic control from 2016 to 2020 in Lesotho: comparing results from two nationally representative surveys

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Background: With the second highest HIV prevalence in the world, Lesotho has made substantial efforts to expand its HIV testing, linkage to care, and treatment programs. We estimated progress towards the Joint United Nations Programme on HIV and AIDS (UNAIDS) 90-90-90 targets using data from the 2016-2017 and 2020 Lesotho Population-based HIV Impact Assessments (LePHIA2016 and LePHIA2020).

Methods: The LePHIA surveys were cross-sectional nationally representative household surveys. Individuals who slept in the household the night before were eligible for participation, which included an interview, HIV testing, and viral load measurement. We estimated the 90-90-90 cascade using self-reported data for adults 15-59 years of age on HIV awareness (First 90), self-reported treatment (antiretroviral therapy (ART)) among those aware (Second 90), and viral load suppression (VLS) (HIV RNA<1000 copies/ml) (Third 90). All estimates were weighted, jackknife variance estimation conducted, and differences between surveys were assessed using a Z statistic distribution. The analysis included 11,682 adults (41% men; 59% women) 15-59 years of age in LePHIA 2016 and 12,718 (42% men; 58% women) in 2020.

Results: HIV prevalence decreased significantly from 25.6% in 2016 to 23.5%, in 2020 (p: 0.0028) and among all age groups including adolescent girls and young women aged 15-24 (11.1% vs 8.5%, p: 0.0074). Among those who tested HIV-positive, there was an increase in awareness of HIV-positive status from 77.2% to 86.4% (p: < 0.0001).Among those aware and on ART, treatment coverage increased from 90.2% to 95.8% (p: < 0.0001), and VLS among those on ART increased from 88.3% to 91.4% (p: 0.0032). At the population level, prevalence of VLS increased from 67.6% in 2016, to 79.9% in 2020 (p: <0.0001).

Conclusions: LePHIA 2020 results demonstrate significant progress in reaching UNAIDS 90-90-90 targets since 2016. With the Lesotho Ministry of Health adopting test and start, index testing, and viral load scale up since 2016, Lesotho has almost achieved the first 90 target and has exceeded the second and third 90 targets, moving the country closer towards HIV epidemic control. These findings position the country well as it aims to achieve the new UNAIDS targets of reaching 95-95-95 by 2025.

Prevention in healthcare and other institutional settings

PEC372

Awareness, beliefs, and barriers to prescribing PrEP among physicians in Brazil and Mexico – ImPrEP study

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Background: In Latin America, pre-exposure prophylaxis (PrEP) is slowly scaling-up. Knowledge and attitudes toward PrEP among physicians providing healthcare for populations engaging in HIV high-risk behavior must be addressed to better implement PrEP in the public health system (PHS).

This study aimed to describe awareness, beliefs, and barriers to prescribe PrEP among physicians from Brazil and Mexico.

Methods: We performed a cross-sectional web-based survey during 2020 as part of the ImPrEP study. Physicians from Brazil and Mexico answered questions about sociodemographic, professional experience, awareness, beliefs, and barriers to prescribe PrEP. We performed a descriptive analysis to highlight the differences between the two countries.

Results: The final sample was 477 physicians: 339(71.1%) and 138(28.9%) from Brazil and Mexico, respectively. In both countries, the majority were male (58.4%[Bra], 55.1%[Mex]), similar median age (Bra: 43 years [IQR:35-54]; Mex: 44 years [IQR:39-51]), worked at public institutions (65.2%[Bra], 95.6%[Mex]), and had more than 20 years as physicians (44.2%[Bra], 35.9[Mex]).

Brazil (79.1%) had more infectious disease specialists than Mexico (16.7%), more respondents aware of PrEP (65.8% vs. 54.4%), and whoever prescribed PrEP (49.1% vs. 31.9%). Their greatest concerns about PrEP prescription were consistent access to PrEP medication (Brazil, 82.9%) and the possibility of increasing risky sexual behavior (Mexico, 87.0%).

The most frequent barriers were the lack of professionals to prescribe PrEP (Brazil, 61.9%) and the belief that users could have limited adherence to a PrEP regimen (Mexico, 71.0%). Conversely, the majority believe that PrEP should be provided by the PHS (92.4% [Brazil], 83.8% [Mexico]).

Conclusions: Although Brazilian and Mexican physicians shared some characteristics and are aware of PrEP and agreed with PrEP provision through the PHS, they have differences in beliefs and concerns toward PrEP prescription. Higher awareness of PrEP and structural barriers to prescribing PrEP reported among Brazilian physicians may be related to PrEP availability at the PHS since December 2017.

Meanwhile, barriers perceived by Mexican physicians are related to users' behavior, suggesting the need for greater dissemination of accurate information about PrEP.

Prevention in people who inject drugs

PEC373

Setting up a Medically Assisted Therapy program for HIV prevention in a resource limited setting: experiences from Uganda

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Background: Globally,13.1% of 11.8 million people living with HIV are estimated to inject drugs (UNAIDS, 2017). The HIV prevalence among people who inject drugs in Uganda (PWID) is high at 17% (UHRN, CHAU report 2017). WHO recommends medically assisted therapy (MAT) as part of a package of interventions to reduce HIV spread and harm among drug users.

The Infectious Diseases Institute (IDI), with PEPFAR-CDC funding, has supported the Ministry of Health (MOH) to set up a MAT program at Butabika National Mental Referral Hospital in Uganda. We describe the processes undertaken to set up this pioneer program.

Description: The process started in May 2019 with establishment of an MoH-led multi-stakeholder task force to oversee the set up and lead development of key program documents and tools with guidance from a Kenyan MAT consultant. With support from the Ugandan community of people who use drugs (PWUD), dialogue meetings were held to map and validate hotspots, define appropriate service delivery models, and understand consumer perspectives in programming. Butabika Hospital was selected to host the MAT center given its mandate to provide mental health services. Task force members conducted a learning visit to established MAT centers in Tanzania to benchmark experiences.

Infrastructural refurbishment and procurement of MAT clinic equipment were undertaken. Import permits were secured, and forecasting and ordering for MAT drugs was done with approval of the International Narcotics Control Board. A ten-day training of key staff was conducted and teams from the PWUD network CSO were trained to screen, prepare and link eligible clients for clinical assessment and enrolment on MAT at the center.

From September to December 2020, 80 PWUD (70 males) were screened and enrolled on MAT. Nine were HIV positive and all were active on ART. Sixty-four (80%) of the PWUD regularly attended daily for their MAT refills.

Lessons learned: Establishment of MAT services is feasible in low resource settings, and acceptability was enhanced by integration with other mental health services. Engagement of multiple local stakeholders and benchmarking from mature regional programs simplified set up.

Conclusions/Next steps: MAT services are acceptable and can be feasibly established to reach PWUD in resource limited settings.

PEC374

Disseminated effects of the initial training and subsequent booster sessions components of the HIV Prevention Trials Network 037 peer-driven intervention on HIV injection risk behavior in people who inject drugs

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Background: Often delivered as packages comprising different components, HIV prevention peer-driven interventions (PDIs) among people who inject drugs (PWID) aim to disseminate risk reduction information and promote behavior change into PWID networks. The disseminated effects (i.e., indirect or spillover; effect on network members from intervention clusters not receiving the intervention from study staff but from peers [indexes] trained as peer-educators compared to those in control clusters) of these interventions and the separate effects of their components are rarely assessed.

We evaluated the disseminated, individual (i.e., effect on peer-educators beyond being in intervention clusters), composite (i.e., effect on peer-educators contrasted with effect among network members in control clusters), and overall (i.e., effect of being in an intervention cluster compared to a control cluster) effects of the components of a social network PDI on the risk of self-reported HIV injection risk behaviors (HIRBs) among PWID.

Methods: We studied 560 PWID from Philadelphia, US, participating in the HIV Prevention Trials Network (HPTN) 037 Study (December 2002-July 2006). Index and their HIV risk networks were randomized to receive (or not) a PDI comprising two components (an initial peer educator training and two subsequent peer educator training booster sessions) delivered to the index only. To estimate the disseminated, individual, composite, and overall effects of each component on subsequent HIRBs risk, we used inverse-probability-weighted log-binomial mixed effects models adjusted by baseline and time-varying known or suspected confounders.

Results: Whereas we observed statistically significant disseminated (Risk Ratio: 0.70 [95% Confidence Interval: 0.52-0.92]) and overall (0.76 [0.61-0.95]) reductions on HIRBs for the time-varying booster sessions, and composite reductions for ever receiving a booster session (0.67 [0.47-0.95]), the initial training only had significant overall effects (0.81 [0.67-0.98]). We found no significant individual effects for any of the components.

Conclusions: Both the PDI initial training and booster sessions reduced HIRBs overall; however, only the booster sessions showed evidence of dissemination from the index to their network members.

Although the individual effects were not significant, and it does not seem to confer additional benefits to indexes, considering the spillover effects shows that the booster sessions were effective. Spillover effects should be routinely analyzed in PDIs.

PEC375

The influence of primary care providers' implicit bias on clinical decision-making for HIV pre-exposure prophylaxis for people who inject drugs

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Background: Pre-exposure prophylaxis (PrEP) is clinically efficacious and recommended for HIV prevention among people who inject drugs (PWID). PrEP uptake remains low among the estimated 72,150 PWID with clinical indications for PrEP in the US. PrEP is not consistently offered as a prevention option by providers who work with PWID, suggesting that providers' implicit and explicit biases may affect their willingness to prescribe PrEP.

Methods: Participants were 186 primary care providers (PCP): physicians – 84%, nurse practitioners – 11%, physician assistants – 5%. PCPs completed a web-based survey including an Implicit Association Test (IAT) measuring implicit bias against PWID, a validated measure of explicit bias against PWIDs, and case vignettes used to assess PrEP prescribing decisions. Patient HIV risk profile (heterosexual man, gay man, and PWID) was systematically manipulated. Primary outcomes included differential response times (D scores) on the IAT as a surrogate for implicit bias, PWID explicit bias scores, and PrEP-related clinical judgments in clinical vignettes.

Results: While a minority of participants (35.5%) reported explicit bias against PWID, a majority (86.5%) of participants showed implicit bias toward PWID. Among all clinicians, mean IAT D score for PWID was 0.59 (p = .0001; SD = 0.41), indicating a strong anti-PWID implicit bias. PWID patients were perceived as less likely to adhere to PrEP, less safety-conscious, and less responsible than heterosexual and gay patients in clinical vignettes. One-third of clinicians thought that PWIDs prescribed PrEP were less likely to enroll in MAT programs, and a quarter believed PrEP use would increase the likelihood of sharing needles among PWIDs. We found no significant correlation between the degree of implicit bias and PrEP prescribing decisions for PWIDs.

Conclusions: This study reports evidence of unconscious (implicit) bias against PWID patients among primary care physicians, implicit bias being more pervasive than conscious (explicit) bias, and potential driving mechanisms of more negative judgment of PWID vs. other patients (perception of PWID patients as less adherent, safety-conscious, and responsible). Implicit PWID bias was not significantly associated with the intent to prescribe PrEP. Future research should assess the implication of biases and test interventions to reduce their impact.

Prevention in adolescents

PEC376

Preparing pediatric providers to PrEP: provider utilization of a best practice advisory and association with PrEP prescription rates

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Background: HIV pre-exposure prophylaxis (PrEP) was FDA-approved in 2018 for use in adolescents; however, many pediatric providers are not yet aware of PrEP. A best practice advisory (BPA) electronic alert is a low-cost intervention that can provide real-time provider clinical decision support to offer PrEP to youth at risk for HIV. The purpose of this study was to evaluate provider utilization of a PrEP BPA in a large academic-community pediatric network and assess the association of the BPA with PrEP prescribing rates.

Description: HIV test orders were altered for patients aged 13 years and older in pediatric ambulatory care settings to include a hard-stop question asking if the patient would benefit from PrEP. If providers answered "Yes" or "Not Sure," the BPA would launch to provide options to open a PrEP initiation order set, refer the patient to an internal PrEP specialist, and/or receive a 15-minute education module. A frequency analysis was done to evaluate provider response to the hard-stop BPA prompt as well as provider choices of BPA follow-up actions. The rate of new PrEP prescriptions for one year after the BPA launch was compared to the same time period the year prior using Pearson's chi-squared test.

Lessons learned: There were 56 distinct providers exposed to the BPA, of which 69.6% (n=39) responded "Unsure" the first time they answered the BPA prompt. 51.8% (n=29) requested the PrEP educational module, 8.9% (n=5) opened the standardized order set, and 3.6% (n=2) referred to a PrEP specialist (Table 1). The PrEP prescribing rate increased from 2.0 prescriptions per 10,000 patients to 5.1 prescriptions per 10,000 patients in the year post-intervention (p=0.045).

	Provider BPA Prompt Response		
BPA Follow-up Action	"Not Sure" (n=39)	"Yes" (n=17)	Total (n=56)
No action taken	16	5	21
Cancel BPA	6	0	6
Order set + educational module	0	5	5
Educational module	15	7	22
Educational module + refer to PrEP specialist	2	0	2

Table 1: Provider BPA prompt response and follow-up actions

Conclusions/Next steps: This study suggests that a hard-stop BPA within an HIV test order that offers clinical decision-making support and provider education can be an acceptable way for providers to learn about PrEP and effective in increasing PrEP prescribing among pediatric providers.

PEC377

Effectiveness of strategies for generating demand for PrEP and combination prevention among adolescent´s men who have sex with men and transgender women in Brazil

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Background: As adolescent men who have sex with men (aMSM) and transgender women (aTGW) face many barriers to HIV prevention, appropriate and effective recruitment strategies are essential. We analyzed the effectiveness of strategies to reach and recruit aMSM and aTGW for HIV pre-exposure prophylaxis (PrEP) and other prevention measures in Brazil.

Methods: PrEP1519 is the first PrEP demonstration study with adolescents done in Brazil. It takes place in three cities (São Paulo, Salvador, and Belo Horizonte) and it includes aMSM and aTGW aged 15 to 19. Participants were actively recruited between March/2019-December/2020 by: peer educators (PE) who engaged with aMSM/aTGW at social venues, in schools, and on virtual platforms and apps; referrals from health services or friends and partners; and NGOs. A cross-sectional analysis of the baseline data from the PrEP1519 cohort was carried out. The outcome variable for the bivariate and multivariate analyses was the recruitment strategy, categorized into virtual and face-to-face. Adjusted odds ratio and 95% confidence intervals (95%CI) were estimated.

Results: A total of 3,675 aMSM and aTGW were reached by the study. Most were recruited via PE virtual strategies (2598/3675=70.7%), followed by PE in face-to-face contact (408/3675=11.1%), direct referrals (335/3675=9.1%), and NGOs (135/3675=3.7%). Of the total number of adolescents reached, 19.8% were enrolled in the cohort (729/3675=19.8%). The most successful strategies for enrolling participants in PrEP involved peer recruitment in virtual settings. There were no differences in the profile of sexual and HIV prevention behaviors across the recruitment strategies. The odds of being enrolled in the cohort through a virtual strategy were greater among aMSM (OR=5.17; 95%CI: 2.07-12.93), with a higher socioeconomic level (OR=6.44; 95%CI: 4.07-10.26), and more education (OR=1.43; 95%CI: 1.00-2.04).

Conclusions: PE were the most effective strategy to reach aMSM/aTGW, with virtual strategies being more effective, especially among MSM. Combining different recruitment strategies allowed for reaching and enrolling aMSM/aTGW with diverse socioeconomic and behavioral profiles. Our findings reinforce the need for recruitment strategies that actively reach out to the population at greatest risk for HIV infection, adopting measures to generate demand for PrEP.

Prevention in transgender populations

PEC378

High rates of sexualized drug use among Brazilian transwomen

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Background: Transwomen are highly vulnerable to HIV worldwide. Sexualized drug use (SDU), i.e., intentional use of illicit drugs before/during sex, may increase their HIV vulnerability. There is no data on SDU among Latin-American transwomen. We aimed to estimate SDU prevalence and evaluate its predictors among key-populations.

Methods: We used an online (advertisements on GSN dating-apps) and on-site (5 PrEP services) survey to enroll 3,924 sexual/gender minorities people (7.1% transwomen, 90.5% men who have sex with men [MSM], and 2.3% non-binary) between October-December/2020. SDU was assessed using the question: "In the last 6 months, have you used any illicit drug before/during sex?" We obtained SDU correlates with logistic regression models.

	SDU (N=1130)	No SDU (N=2794)	p-value
Gender Transwomen Non-binary MSM	 114 (40.7) 30 (33.0) 986 (27.8)	 116 (59.3) 61 (67.0) 2567 (72.2)	<0.001
Recruitment Online Site	 840 (28.7) 290 (29.0)	 2083 (71.3) 711 (71.0)	0.89
Age 18-24 years >24 years	 209 (31.2) 921 (28.3)	 461 (68.8) 2333 (71.7)	0.13
Race White Black/*Pardo*	 631 (29.2) 482 (28.2)	 1532 (70.8) 1226 (71.8)	0.52
PrEP use Yes No	 384 (33.7) 746 (26.8)	 755 (66.3) 2039 (73.2)	<0.001
Binge drinking Yes No	 840 (36.87) 290 (17.6)	 1440 (63.2) 1354 (82.4)	<0.001
Condomless anal sex Yes No	 869 (32.3) 261 (21.1)	 1819 (67.7) 975 (78.9)	<0.001
Self-reported STI Yes No	 241 (38.0) 889 (27.0)	 394 (62.0) 2400 (73.0)	<0.001
HIV risk perception High Low	 307 (35.4) 786 (27.3)	 560 (64.6) 2096 (72.7)	<0.001

Results: SDU prevalence was 28.8% (95%CI27.4-30.2): 40.7% (95%CI:35.0-46.7) for transwomen, 33.0% (95%CI:23.7-43.7) for non-binary, and 27.8% (95%CI:26.3-29.3) for MSM (no difference according to recruitment). Transwomen had 2.43-times increased odds (95%CI:1.74-3.39) of engaging in SDU compared to MSM, regardless of PrEP use (PrEP users: 2.10 [95%CI:1.12-3.92], off-PrEP:2.49 [95%CI:1.67-3.70]). Increased SDU odds occurred among white respondents (aOR:1.21 [95%CI:1.03-1.43]), those from the South/Southeast country region (aOR:1.23 [95%CI:1.02-1.49]), using PrEP (aOR:1.30 [95%CI:1.10-1.54]), reporting binge drinking (aOR:2.75 [95%CI:2.33-3.24]), condomless anal sex (aOR:1.62 [95%CI:1.36-1.94], and high-perceived HIV-risk (aOR:1.46 [95%CI:1.22-1.75]). Among PrEP users, SDU predictors were: South/Southeast origin [aOR:1.63[95%CI:1.16-2.31], binge drinking (aOR:3.04 [95%CI:2.27-4.09] or self-reported sexually transmitted infection (aOR:1.71 [95%CI:1.26-2.33]). Among non-PrEP users, younger age (aOR:1.29 [95%CI:1.01-1.63]), binge drinking (aOR:2.61 [95%CI:2.15-3.19]), condomless anal sex (aOR:1.76 [95%CI:1.43-2.17]), self-reported STI (aOR:1.40 [95%CI:1.08-1.81]), and high-perceived HIV-risk (aOR:1.51 [95%CI:1.23-1.84]) were associated with SDU.

Conclusions: Despite being common among sexual/gender minorities, transwomen had the highest SDU odds. SDU may impact HIV vulnerability among key-populations, including transwomen, and should be addressed in HIV prevention approaches.

PEC379

Factors associated with never testing for HIV among transgender women in São Paulo, Brazil

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Background: Transgender women (trans women) bear a disproportionate burden of HIV globally. Testing is the entry point for receiving antiretroviral treatment (ART) to improve health, well-being and prevent onward transmission. Despite HIV testing and ART being free through the Brazilian public health care system, there may be persistent barriers for trans women learning their HIV status. We examined the prevalence and correlates of never having tested for HIV in a large, community-based study of trans women in São Paulo.

Methods: We analyzed baseline data of the Trans*National cohort study of trans women in São Paulo. Recruitment was from 5/2017 to 7/2019 through a long-chain peer-referral approach. Eligible criteria were ≥18 years, female gender identity different from birth sex, and having a referral coupon. Participants were interviewed face-to-face on demographics, risk behaviors, and HIV testing. Associations between never testing and demographic characteristics were assessed by multiple logistic regression.

Results: From a total of 789 trans women, 56.5% was ≥30 years; 73.2% reported black/mixed race; 62.7% had ≤12 years of formal education; 46.3% earned under the Brazilian minimum wage. Sex work was the main source of income for 50.8%. 9.4% reported never testing for HIV. Over the recruitment period, the frequency of never testing for HIV did not decrease (8.6% in 2017; 10.6%, 2018; 11.8%, 2019). In bivariate analysis, risk factors for never testing were younger age (<30 years, OR 3.79, 95% CI 2.08-6.90) and have never having injected silicon fillers (OR 1.70, 95% CI 1.01-2.85). In multivariate analysis younger age remained an independent risk factor for never testing (aOR3.22, 95% CI 1.72–6.02) adjusting for age, race, income, sex work, education, and filler use.

Conclusions: Although there is free availability of HIV testing in Brazil, almost one in ten trans women have never been tested – higher rates among younger. Discrimination towards trans women in the Brazilian health care system is well documented and may present an important

barrier to HIV testing. Community-based testing initiatives are warranted. Also, prevention strategies that address HIV risk and treatment knowledge are needed to reach young trans women to increase linkage to care and decrease HIV transmission.

Assessing impact of structural interventions and social protection

PEC380

Working with Christian faith-based organisations to prevent HIV/AIDS and unwanted pregnancy in Delta State of Nigeria

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Background: Most people in Africa including Delta State of Nigeria are quite religious often gathering in churches, mosques and other faith-based locations to worship and receive spiritual support. The issue of HIV/AIDS and unwanted pregnancy has become very topical in the African society largely as a result of the stigma, morbidity and mortality associated with the conditions. The role of faith-based organisations in reducing the burden of HIV/AIDS and unwanted pregnancy is still very unclear, even though many of them have members facing such situations. It is against this backdrop that a project to work with Christian faith-based organisations to prevent HIV/AIDS and unwanted pregnancy was carried out.

Description: Health talks were given in Christian faith-based organisations such as churches in Warri-South Local Government Area of Delta State, Nigeria aimed at sensitising them on prevention of HIV and unwanted preganancy, usually on Sunday mornings on a monthly basis. Five churches were visited each month from January to October 2018 making a total of fifty churches. The health talks covered areas such as: Control of HIV/AIDS, Family planning and Prevention of rape. Fliers on Family Planning were distributed.

Lessons learned: Of all the churches visited, The Redeemed Christian Church of God were the most cooperative. Pastors were also advised that hence forth when young people are coming for marriage counseling they must present or have ready on hand tests results including HIV/AIDS test result. The health talks provided the members of the churches visited to ask several questions bordering on the possibility of having an abortion if pregnant after rape, breastfeeding by HIV positive mothers, HIV discordant couples, sensitizing young girls to report sexual abuse, secondary abstinence, and peer pressure.

Conclusions/Next steps: Working with Christian faith-based organisation provided a low-cost opportunity to sensitise a large number of community members in Warri South Local Government Area of Delta State Nigeria on ways to prevent HIV/AIDS and unwanted pregnancy. Advocacy to institutionalize this practice by community health workers in primary health care settings should be embarked upon for sustainability. Government at local, state and national levels in addition to international development partners should make this a priority for support.

Track D

Methodological challenges to scale up and optimization of services

PED381

Differentiated antiretroviral therapy delivery in rural Zimbabwe: mixed-method study

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Background: To promote client-centered care and relieve the strain on health facilities, Zimbabwe adopted differentiated HIV care policies in 2015. However, little is known about the experience of differentiated antiretroviral therapy (DART) delivery in rural areas following the policy adoption.

Methods: We used mixed-methods to collect data at 26 rural HIV facilities in Zimbabwe in 2019. We collected quantitative data on the availability of DART models from each facility. We performed 26 semi-structured interviews among healthcare providers and 6 focus group discussions (FGDs) among clients to elicit their experiences of ART delivery. FGDs included different key populations receiving routine care or enrolled in DART models. We analyzed the transcripts thematically, with inductive coding to identify emerging themes.

Results: Twenty of the 26 facilities (77%) offered at least one of the five differentiated ART delivery models recommended in Zimbabwe: community ART refill group (CARG; 13 facilities, 50%), fast-track refill (8, 31%), family refill (6, 23%), and club refill (1, 4%).

Thirteen facilities (50%) offered only one model. Concerns about confidentiality and privacy, long travel distance to the clinic and travel costs, as well waiting times were the main issues influencing clients' views on DART models (Table).

Clients perceived fast-track as the model that was best adapted to their preferences for privacy, while ensuring shorter visits. In contrast, group refill models such as CARGs, club and family refills were felt to be prone to involuntary disclosure, which could discourage respondents to attend these, although they reduced travel costs.

Providers perceived additional workload when offering facility-based group models, such as CARGs. Mobile outreach clinics were not available in the region due to the lack of dedicated funding.

Theme	Quotes
Confidentiality and disclosure	*"Everything comes back to issues of confidentiality." (client)* *"With HIV most of the people do not want to be known that their children are on [antiretroviral therapy]. So joining a group of people (CARGs or clubs) will be problematic in the sense that some other people cannot keep confidential issues so the whole village will end up knowing." (client)*
Travel and expenses	*"Many patients come from far away and transport cost is usually a problem for them." (healthcare provider)* *"CARGs will [address] issues of distances [to the facility], which for some of us are a challenge." (client)*
Waiting time	*"The long waiting time is a challenge because we will be hungry by the time we walk back, and it will be almost evening." (client)* *"With fast-track you are quickly served and go back home." (client)*

Table: Selection of quotes.

Conclusions: Although DART models were widely available in this setting, most facilities did not offer a choice of models, nor did the majority offer fast-track refill, which was perceived to be the best adapted to clients' needs. Confidentiality, travel expenses, and client waiting times are key elements to consider when planning and rolling out differentiated care.

PED382

A region left behind - the story of the HIV response in the Eastern Mediterranean region: progress, gaps, opportunities

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Background: Eastern Mediterranean Region (EMR) has the slowest response to the HIV epidemic globally. With 420 000 people living with HIV (PLHIV), 44000 new infections and 15000 deaths; epidemic is concentrated among key populations; with 47% and 57% increase in infections and deaths (2019). Half the 22 countries experience protracted emergencies and civil war.

Description: We interrogated Global AIDS Monitoring reports, regional and country reports, policies, UNAIDS estimates, ARV surveys and WHO case reporting. We describe epidemic trends, gaps and reasons for low coverage of testing, ART, and increasing deaths. Data was entered into Excel, with tabulation, cross-tabulation and trend analyses.

Lessons learned: 37% PLHIV identified, 24% on ART and 21% virally suppressed. Ten-fold increase in ART: 100 000 (2019) relative to 19 000 (2010); despite this, marginal ART coverage increase: 8% (2010) to 24% (2019). 1-2% annual increase in case finding: 37% (2019), 32% (2018), 29% (2016) is low compared to increasing infections: 2.6% (2017), 5.4% (2018), 6.8% (2019). Testing inequalities in low risk populations: migrant workers (59.6%), ANC (12.1%), STI, TB and VCT (4.5%), key populations (1.5%); yet cases mainly VCT (53.5%), ANC, TB, STI (21.3%), key populations (6.4%), prisoners (10.4%), 5% migrant workers. Advanced disease increase: 37% (2019), 30% (2018), and 27.3% (2017), and low CD4 coverage (18.8% - 53.6%). 47% viral load testing with 87% suppression (four countries). Regimens for 52318 individuals (Libya, Morocco, Oman, Pakistan, Lebanon, Somalia, Sudan, Syria) show EFV-based: 88% (2019), 93% (2018), 89% (2017); NVP-based: 7% (2019), 5.5% (2018), 7.4% (2017); INSTI: 6% (2019). Second line was LPV-r based: 81% (2019), 79% (2018), 75.6% (2017); ATV-r based: 15% (2019), 17.4% (2018), 17.2% (2017). Policy survey revealed all countries (except Iraq, Libya) have adopted Treat All, implementation varies: 50% - 95% (Sudan, Pakistan, Egypt, Iran), <50% (Somalia), no implementation (Djibouti, Syria). 12-month retention is 79.6% (94% Lebanon - 37.2% Syria).

Conclusions/Next steps: Continued transmission and deaths attributed to advanced disease, slow INSTI uptake, NNRTI use. Growing epidemics need evolving response to counter emergent infections. No catch-up realized as epidemic continues to grow with non-commensurate response. Appropriate resource allocation, differentiated testing and treatment will guarantee optimal HIV response.

PED383

Adoption of differentiated HIV service delivery in Tanzania: from policy to practice

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Background: Tanzania has scaled up differentiated HIV service delivery models (DSDMs) to ensure patient-centered care and mediate challenges arising from increasing client volume. We describe implementation findings of DSDM adoption by health facilities, assessed during a technical assistance (TA) program in Tanzania.

Methods: Facility managers from 60 health facilities across 10 regions of Tanzania participated in cross-sectional surveys during TA visits in June and September 2019. TA consisted of guidelines and tools development, training, regional action planning, and facility-based mentoring. Implementation outcomes included dissemination of job tools and adoption of DSDMs for testing and treatment, including facility-based, population-focused, and community-based services at participating facilities. Data were summarized using counts and proportions, medians and interquartile ranges. Outcomes at first visit were compared to follow-up outcomes using chi-square tests.

Results: Facilities included 10 regional/zonal hospitals (17%), 15 district hospitals (25%), 12 dispensaries (20%), and 23 health centers (38%); the majority in urban settings (n=37, 62%). All managers reported adoption of at least one differentiated testing and ART delivery at their facility. There was an increase in uptake of testing models for key and vulnerable populations (54% at baseline to 70% at follow-up, p=0.06) and implementation of adolescent testing models (85% to 92%, p=0.25). Adoption of facility-based index testing was 100% at both timepoints, and community index testing remained low (10% both timepoints). A significant increase in adoption of treatment DSDMs was observed for mobile populations (17% to 35%, p=0.02).

Adoption of multi-month refill models (100% both timepoints), extended hours for ART refills (87% to 88%) and fast-track refill (82% to 88%) remained high. Community refills by healthcare workers (29% to 35%), and facility-based group refills (9% to 18%) improved but remained low, family refills decreased (49% to 42%). Nearly all facilities had national HIV guidelines (92% to 95%), and operational manual and job aids (58% to 98% for both) available.

Conclusions: As differentiated care scales throughout Tanzania, there is variation in uptake of DSDMs. Population-focused and pharmacy-based models were more readily adopted by health facilities, while challenges persisted, even after technical support, with models requiring community or group delivery.

PED384

Improving access to HIV viral load testing in the northern regions of Cameroon

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Background: Although viral load (VL) services are free in Cameroon since January 2020, access has been limited in the three Northern regions. Only one conventional platform served the regions with four point of care (POC) machines for specimen analysis. Frequent and prolonged reagent stock-outs, limited cold-chain capacity, long distances to health facilities (HFs) and poor roads amplified VL access challenges. We describe the impact of interventions to improve VL access across the Northern regions.

Description: From October 2019, case managers were assigned client cohorts to determine VL eligibility; VL focal persons were appointed in each supported HF for monitoring and results documentation; VL registers were printed and staff trained; the sample transport system was reorganized with establishment of hub-and-spoke laboratories, cold chain was strengthened with use of mobile coolers, solar panel installation and refrigerators.

A new conventional platform was installed and continuous lab staff mentorship was initiated. Backup laboratories were identified to handle VL testing during reagent stock-outs. Retrospective routine data collected quarterly (Q) [Q1:October-December 2019;Q2:January-March 2020;Q3:April-June 2020;Q4:July-September 2020] from 74 ICAP-supported HF were analyzed to determine trends by quarter across the VL cascade.

Lessons learned: The VL coverage increased progressively from Q1(5.9%) to Q4(39.1%) with higher coverage for children (43%) compared than adults (39%) by Q4. The number of VL samples collected increased by 399% between Q1(1,756) and Q2(8,763), but declined by 26% between Q3 (7,382) and Q4(5,412). Return of results also improved from 52% (3,044/5,854) by the end of September 2019 to 74% (17,260/23,313) by September 2020. The average VL suppression was lower for children (57%) compared with adults (77%) and was similar across the four quarters.

Conclusions/Next steps: Despite challenges, there was a significant increase in VL access over the four quarters in the northern regions with Covid-19 slowing down access from Q3. The strategies implemented were successful but need to be streamlined to address Covid-19 related challenges and further scaled up through strengthening identification of eligible patients using the electronic register and increasing the number of POCs across the three regions. Suppression of VL especially for children will be a priority subsequently.

Impact evaluation of differentiated service delivery

PED385

Community-based prevention of mother-to-child HIV transmission increases engagement in antenatal care for women and infants in Zambia: results from the SMACHT project

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Background: While Zambia has made significant progress towards prevention of mother to child transmission (PMTCT) of HIV, gaps remain in uptake of antenatal care (ANC), HIV testing of pregnant women, and linkage to ART. Effective differentiated service delivery interventions are needed to test and link to treatment pregnant women living with HIV (PWLHIV) and ensure follow up of HIV-exposed infants (HEIs) along the early infant diagnosis (EID) cascade.

We report quantitative results from the University of Maryland Baltimore Stop Mother And Child HIV Transmission (SMACHT) project, a community-based PMTCT program implemented in Southern Province of Zambia.

Description: As part of the SMACHT program, community health workers (CHWs) identified pregnant women in the community, provided health education, and escorted them to ANC clinic for continuity of care and HIV testing. CHWs followed pregnant and breastfeeding women (PBFW) to ensure adherence to HIV prevention and treatment. To assess program impact, we conducted a before and after evaluation using routine aggregate programmatic data from the pre-intervention (April 2014 to March 2015), implementation phase (April 2015 to March 2016), and post-intervention period (April 2016 to December 2017) across 41 facilities.

Lessons learned: The number of pregnant women attending ANC increased in the post-intervention period more than six-fold, from 4,799 to 31,503. Early ANC attendance (before 20 weeks) increased from 45% to 48%. Positivity yield among pregnant women increased from 10% to 13%. The total number of PWLHIV in ANC on ART increased from 777 to 9,731. Total number of HEIs identified increased over two-fold, from 2,537 to 5,446 due to an increase in PWLHIV attending ANC. HEIs tested at 6 weeks increased from 1,515 to 2,760. However, there was a decrease in EID coverage at six weeks (60 to 51%) and for 6 and 12 month EID testing.

Conclusions/Next steps: The SMACHT project greatly increased absolute numbers of PBFW attending ANC, as well as HIV-positive women in ANC and HEIs in care. Community PMTCT programs are effective at reaching PWLHIV and their infants, however; additional strategies, including ensuring sufficient test kits, must be deployed to optimize EID coverage and monitor closely baby-mother pairs.

PED386

'Stable patients' need health services too: HIV-related symptoms are common amongst people eligible for less-intensive differentiated service delivery treatment models in Harare, Zimbabwe

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Background: Zimbabwe is scaling up HIV differentiated service delivery (DSD) to better meet the needs of people living with HIV (PLHIV) and to improve treatment outcomes and health system efficiencies. National guidelines support five differentiated ART (DART) models for 'stable' PLHIV, defined as adults who have been on their current ART regimen for ≥ six months, have no current opportunistic infections or acute illness, and have a viral load < 1,000 copies/mL and/or a CD4 cell count of >200 cells/mm^3. Decreased health facility (HF) visit frequency is a characteristic of most DART models, which typically assume patients doing well on ART will neither need nor choose to visit the HF more than 1-2 times a year. Although patients in these models have the option to visit HF more frequently, they may not be aware of indications for non-scheduled visits.

Methods: In the context of a discrete choice experiment to assess DART preferences amongst 'stable patients', we surveyed 500 DART-eligible adults from seven HFs in Harare, Zimbabwe, about their current quality of life, mood, and HIV-related physical symptoms. We used a tablet-based interviewer-assisted survey. Descriptive analyses were conducted using SAS version 9.4.

Results: Participants' median time on ART was 4.1 years (IQR 1.0-7.6); all were virally suppressed and met DART eligibility criteria. 50% were female; median age was 29.5 years (range 24-41). 44% reported HIV-related physical symptoms, 20% rated their quality of life as poor or very poor and 37% reported anhedonia and/or "feeling down, depressed or hopeless" in the past two weeks. Compared to asymptomatic participants, those reporting HIV-related symptoms were less likely to be interested in the Fast-Track model (OR 0.76; CI 0.60-0.98), an individual, facility-based model in which patients go to the HF 2-4 a year to collect ART.

Conclusions: As DART models are taken to scale it is important to appreciate the spectrum of care required by 'stable patients' and the varying needs of DART-eligible PLHIV. All less-intensive models should provide comprehensive care and facilitate *ad hoc* clinical and mental health consultations.

PED387

Scaling up the community eMTCT delivery system during COVID-19 pandemic lock down in Uganda - a case of TASO Gulu, Northern Uganda

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Background: Differentiated service delivery (DSD) model addresses many barriers in HIV care continuum, providing good client retention and virologic outcomes. However, current national guideline recommends DSD for stable clients and excludes pregnant and breastfeeding women (PBFW). During the two years prior to COVID-19 pandemic, TASO Gulu piloted a community eMTCT delivery (CED) system, integrated within community drug distribution points (CDDPs) at three (3) hard-to-reach areas. Initially, the CED system targeted PBFW from hard-to-reach areas in order to address the challenge of missed clinic appointments. Through the CED system, holistic eMTCT package was provided and results showed improved eMTCT outcomes.

Therefore, when public and private transport were banned and gatherings restricted to control COVID-19 infections, TASO Gulu rapidly scaled-up the CED system to 12 more CDDPs bringing a total of 15 CED points for PBFW living 20+ Kilometers from the facility.

Description: At the beginning of April 2020, TASO Gulu identified 284 PBFW living at least 20 Kilometers from TASO Gulu facility. These PBFW were linked to 15 widely distributed CED points within the region. At each CED point, a volunteer mentor mother was identified and empowered to mobilize peers for eMTCT services. During scheduled appointments, the TASO technical staff worked with the mentor mothers to provide comprehensive eMTCT services including clinical review, ART drug refills, counseling, and bleeding for laboratory testing.

Lessons learned: All PBFW from hard-to-reach areas continue to receive eMTCT services from the nearby 15 CED points with 100% acceptability. In addition, there was no infant or maternal mortality, no transfer out, and no loss-to-follow up among PBFW at CED points.

Moreover, at the end of December, six months' viral load suppression among PBFW at CED points was well above the UNAIDS 95:95:95 targets (95.4%) and PCR positivity rate among HEI was below 1.0%.

Conclusions/Next steps: Rapid scale-up of CED system during and beyond the COVID-19 pandemic is acceptable, feasible, and effective. CED system can effectively mitigate barriers to accessing eMTCT services and improve its outcomes. Health systems in low-and middle-income countries should consider the CED system as an alternative strategy to improve access to eMTCT services.

PED388

The effectiveness of community-based multi-month dispensing of antiretroviral treatment with single annual clinical visits for newly stable HIV patients: a pooled analysis of two cluster-randomized trials in Southern Africa

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Background: Multi-month dispensing (MMD) of antiretroviral treatment (ART) is a differentiated service delivery model that is particularly important during COVID-19 to reduce patient load in overburdened healthcare facilities. However, two important current evidence gaps regarding MMD include I) understanding MMD effectiveness amongst those newly stable on ART (commencing MMD <12 months after ART initiation), and II) ART outcomes amongst patients receiving single annual clinical consultations.

To investigate these, we analyzed pooled data from two cluster-randomized trials investigating community-based MMD conducted in Zimbabwe and Lesotho.

Methods: Individual-level data of newly stable adults enrolled between 6–12 months after starting ART having viral load <1000 copies/mm^3 from the two trials were pooled. Each trial had three arms: ART collected three-monthly at healthcare facilities (3MF, control); ART provided three-monthly in Community ART Refill groups (CARGs) (3MC); and ART provided six-monthly in either CARGs or at community-distribution points (6MC). Clinical visits were three-monthly in 3MF and annually in both intervention arms.

The primary outcome was participant retention in ART care and secondary outcomes were viral suppression and number of unscheduled clinic visits 12 months after enrolment. Individual-level regression analyses were conducted by intention-to-treat specifying for clustering and adjusted for country.

Results: A total of 599 participants were included; 212 (35.4%), 128 (21.4%) and 259 (43.2%) in 3MF, 3MC and 6MC, respectively. After 12 months, 198/212 (93.4%), 123/128 (96.1%) and 248/259 (95.8%) were retained in 3MF, 3MC and 6MC, respectively. Retention in 3MC was superior vs. 3MF, risk difference (RD)=4.6% (95% CI: 0.7% to 8.5%) and noninferior in 6MC vs. 3MF, RD=1.7% (95% CI: -2.5% to 5.9%) (prespecified noninferiority RD margin of -3.25%). Viral suppression was similar between arms, 99.3%, 98.6% and 98.1% in 3MF, 3MC and 6MC, respectively, risk ratio=0.98 (95% CI: 0.92-1.03) for 3MC vs. 3MF, and 0.98 (95% CI: 0.95-1.00) for 6MC vs 3MF. Unscheduled clinic visits were not increased in the intervention arms; incidence rate ratio=0.53 (CI: 0.16-1.80) for 3MC vs. 3MF, and 0.82 (CI: 0.25-2.79) for 6MC vs. 3MF.

Conclusions: Three and six-monthly community-based MMD with single annual clinical visits were at least noninferior to standard facility-based care amongst participants newly stable on ART.

PED389

Differentiated HIV care for people using second-line antiretroviral therapy in South Africa: a retrospective cohort study

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Background: People living with HIV (PLHIV) who are receiving second-line antiretroviral therapy (ART) may benefit from differentiated service delivery. We assessed treatment outcomes among PLHIV on second-line regimens in a community ART delivery programme in South Africa.

Methods: We did a retrospective cohort study among PLHIV who were potentially eligible to collect treatment from community pick-up points such as private pharmacies (receiving second-line ART for >1 year, aged >15 years, non-pregnant, no TB co-infection, and viral load < 200 copies/mL in past 6 months), at 59 public clinics between October 2016 to December 2018. We used multivariable logistic regression models to compare the outcomes of viral suppression after 6-18 months, and retention-in-care, between clients referred for community ART versus those continuing at clinics.

Results: Among 171,301 PLHIV aged ≥ 15 years who collected ART in the study period, 5417 (3.2%) received second line ART. After excluding 362 with no baseline viral load, 1887 with baseline viral load ≥200 copies/mL, and 143 who were pregnant/had TB, there were 3025 (1.8%) clients potentially eligible for community ART. Median age was 39.0 years (interquartile range [IQR] 34.0-45.0) and 1603 (65.1%) were women. 430 (17.5%) were referred for community ART. Overall, 2506 (82.8%) had a viral load recorded 6-18 months after their baseline viral load; of these, 2209 (88.1%) were suppressed <200 copies/mL. By study end, 2393 (79.1%) were retained-in-care, 394 (13.0%) had transferred out, and 238 (7.9%) were lost to follow up or died. In separate multivariable logistic regression models adjusted for age, gender and district, clients referred for community ART had higher odds of viral suppression (adjusted odds ratio [aOR] 1.46, 95% CI 1.04-2.10, p=0.036, n=2506) and retention-in-care (aOR 1.44, 95% CI 1.13-1.85, p=0.004, n=3025) respectively.

		Viral load				Retention in care			
		≥200 cps/ml	<200 cps/ml	Univariable OR	Multivariable aOR	Not retained	Retained	Univariable OR	Multivariable aOR
Age	Mean (SD)	38.0 (8.9)	39.8 (9.3)	1.02* (1.01-1.03, p=0.003)	1.02* (1.01-1.03, p=0.003)	39.3 (10.3)	39.7 (9.2)	1.00* (1.00-1.01, p=0.317)	1.00* (0.99-1.01, p=0.393)
Gender	Male	100 (11.5)	768 (88.5)	1	1	214 (20.2)	843 (79.8)	1	1
	Female	197 (12.0)	1441 (88.0)	0.95 (0.74-1.23, p=0.709)	1.00 (0.77-1.29, p=0.985)	418 (21.2)	1550 (78.8)	0.94 (0.78-1.13, p=0.522)	0.95 (0.79-1.14, p=0.594)
District	Urban	281 (12.2)	2023 (87.8)	1	1	584 (20.9)	2209 (79.1)	1	1
	Rural	16 (7.9)	186 (92.1)	1.61 (0.98-2.84, p=0.074)	1.52 (0.92-2.68, p=0.121)	48 (20.7)	184 (79.3)	1.01 (0.73-1.42, p=0.937)	0.97 (0.70-1.36, p=0.847)
Community ART?	No	257 (12.6)	1788 (87.4)	1	1	543 (21.9)	1936 (78.1)	1	1
	Yes	40 (8.7)	421 (91.3)	1.51 (1.08-2.17, p=0.020)	1.46 (1.04-2.10, p=0.036)	89 (16.3)	457 (83.7)	1.44 (1.13-1.85, p=0.004)	1.44 (1.13-1.85, p=0.004)

*OR = odds ratio, aOR = adjusted odds ratio, SD = standard deviation, ART = antiretroviral therapy. *OR for each additional year of age*

Table.

Conclusions: PLHIV receiving second-line regimens who were referred for community ART had better outcomes than clients who continued at clinics.

PED390

Scale-up of multi-month dispensation of antiretroviral therapy among children living with HIV as a COVID-19 mitigation measure and retention strategy, Zambia, 2020

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Background: Prior to the COVID-19 pandemic, children were not prioritized for multi-month dispensation (MMD) of antiretroviral therapy (ART) in Zambia. However, when the first cases of COVID-19 were reported in March 2020, the country's HIV program implemented scale-up of MMD as a mitigation strategy in April 2020 to prevent COVID-19 infections and treatment interruptions by minimizing clinical encounters among persons living with HIV (PLHIV), which included eligible children ≥2 years of age.

Methods: Using de-identified patient-level data from electronic medical records, we analyzed the proportions of children living with HIV (CLHIV) <15 years on ART who were on minimum 3-month MMD (3MMD) from March to Sept 2020. Using program data, we also compared pediatric viral load coverage (VLC) and suppression (VLS) in Zambia between the same time periods. Lastly, we compared lost-to-follow-up (LTFU) rates of CLHIV among those receiving at minimum 3MMD vs. those on <3 months dispensation. LTFU rate is defined as the number of patients who are more than 30 days late to their next scheduled appointment (lost) on a given date divided by the sum of all patients (lost and current).

Results: Prior to the first cases of COVID-19 in Zambia in March 2020, 20,727 (46.5%) of CLHIV were receiving minimum of 3MMD, compared to 27,028 (62.7%) at Oct 2020. Despite scale up of MMD and CLHIV coming less frequently to clinic appointments, VLC was not adversely affected, with 76% coverage in March compared to 78% in Sept 2020. VLS improved as well, with 79% suppressed in March compared to 84% in Sept 2020. Among those receiving at least 3MMD as of Sept 2020, LTFU rate was 5.0%, as compared to 17.4% among those who were not receiving MMD.

Conclusions: Scale-up of 3MMD among CLHIV ≥2 years of age had no adverse impact on their VLC or VLS. It appeared to be an important COVID-19 mitigation strategy that minimized the number of interactions with health facilities and decreased LTFU rates. Provision of 3MMD to CLHIV should be considered an integral retention strategy for the national pediatric HIV program and continue to be scaled up.

PED391

An evaluation of nurse-led Community ART Distribution (CAD) for stable ART clients in Malawi

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Background: Partners in Hope in Malawi recently implemented nurse-led community ART distribution sites (CADs), in which trained ART providers deliver care to stable clients at delivery points in communities. We evaluated retention in care and viral load (VL) suppression in CADs versus facilities in a cohort followed for one year.

Methods: We conducted a retrospective cohort study using medical records from ART clients in care between January 2019 and August 2020 at 4 facilities and their CADs in Malawi. Inclusion criteria included: 1) ≥13 years; 2) ≥12-months on ART; 3) on first-line ART; and 4) undetectable viral load (VL) within 6-months of the cohort entry. Primary outcomes of interest were retention in care over one year (no period ≥60 days without ART) and VL suppression (<1,000 copies/mL) after at least 6-months in the CAD model compared to a facility cohort.

Results: 700 ART clients (350 CAD, 350 facility) were included; median age 43 years (IQR 36-51), median duration on ART of 7 years (IQR 4-9) and 73% female. There were more young people in facility care (7.4% were of ages 13-24 vs 3.0% in CAD) and gender distribution was equivalent between groups (~73% women).

Retention at one year was 92.9% in CADs and 90.6% in facilities (p=0.149). Of clients in CADs, 5.7% (n=20) transferred back to facility-based care. VL results at least ≥6 months after study enrollment were available for 44% of CAD and 38% of facility clients. Among those with VL results, 92.2% of CAD and 94.0% of facility clients had VL suppression at <1,000 copies/mL (p=0.555) (Table).

	Overall		
	CAD	Facility	
	n=350	n=350	*p-value
Outcome	n (%)	n (%)	
Retained	325 (92.9%)	317 (90.6%)	0.149
Transfer Back to Facility	20 (5.7%)	n/a	
Default	3 (0.9%)	6 (1.7%)	0.505
Transfer out	17 (4.9%)	24 (6.9%)	0.26
Death	5 (1.4%)	3 (0.9%)	0.725
Viral Suppression	n=154	n=133	
Suppressed (<1,000 copies/mL)	142 (92.2%)	125 (94.0%)	0.555
	By Gender		
	CAD	Facility	
	Male n=93	Female n=257	Male n=98	Female n=252	*p-value
Outcome	n (%)	n (%)	n (%)	n (%)	
Retained	82 (88.2%)	243 (94.6%)	89 (90.8%)	228 (90.5%)	0.415
Transfer Back to Facility	6 (6.5%)	14 (5.5%)	n/a		
Default	2 (2.2%)	1 (0.4%)	3 (3.1%)	3 (1.2%)	1
Transfer out	5 (5.4%)	12 (4.7%)	5 (5.1%)	19 (7.5%)	0.714
Death	4 (4.3%)	1 (0.4%)	1 (1.0%)	2 (0.8%)	0.464
Viral Suppression	n=47	n=107	n=29	n=104	
Suppressed (<1,000 copies/mL)	44 (93.6%)	98 (91.6%)	27 (93.1%)	98 (94.2%)	0.083
	By Age				
	CAD		Facility		
	<25 years n=11	25+ years n=339	<25 years n=26	25+ years n=324	*p-value
Outcome	n (%)	n (%)	n (%)	n (%)	
Retained	10 (90.9%)	315 (92.9%)	20 (76.9%)	297 (91.7%)	0.052
Transfer Back to Facility	5 (45.5%)	15 (4.4%)	n/a		
Default	0 (0%)	3 (0.9%)	1 (3.9%)	5 (1.5%)	1
Transfer out	1 (9.1%)	16 (4.7%)	5 (19.2%)	19 (5.9%)	0.373
Death	0 (0%)	5 (1.5%)	0 (0%)	3 (0.9%)	n/a
Viral Suppression	n=5	n=149	n=7	n=126	
Suppressed (<1,000 copies/mL)	4 (80.0%)	138 (92.6%)	6 (85.7%)	119 (94.4%)	0.523

*P-values calculate using Chi-square or Fisher's exact tests

Table. Outcomes of clients followed for one year in CAD versus facility-based care

Conclusions: CADs showed high rates of retention and viral suppression over the follow-up period. Further research is needed to understand long-term retention and viral suppression, cost-effectiveness of this model, and whether CADs may benefit certain groups, such as those <25 years.

PED392

Impact of a family-centered care model on viral suppression among HIV-infected children in Migori, Kenya

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Background: Viral suppression (VS) among children 2-9 years old receiving antiretroviral therapy (ART) in Kenya was 68.9% in 2018, substantially below the national trend of 95% by 2030. Kenya guidelines recommend differentiated service delivery (DSD) models and ART optimization to improve VS. In January 2018, University of Maryland Baltimore implemented a family-centered model (FCM), which included: family/caregiver treatment literacy sessions, engagement with peer educators, participation in psychosocial support groups, ART optimization, and linking patients to orphans and vulnerable child support programs. We assessed VS among children 2-9 years before and after FCM-implementation.

Methods: We conducted a cross sectional analysis to assess VS among children receiving ART during the pre-FCM intervention period (September 2016-December 2017) and the post-FCM intervention period (December 2018-September 2020) at 8 UMB-supported facilities in Migori, Kenya. Routinely collected data were abstracted from standardized tools and registers. Generalized Estimating Equations, accounting for repeat measures from the same client, and a 6-month lag period from intervention implementation, were used to generate a multivariable logistic model to assess VS (<400 copies/ml) among children in the pre- and post-FCM intervention periods.

Results: A total of 849 children (57% 6-9 years; 58% female) were included in the pre-FCM period, and 1336 (56% 6-9 years, 56% female) in the post-FCM period. At the time of VL testing in the pre-FCM period, 25% of clients were on Efavirenz(EFV), 42% on Nevirapine(NVP), 32% on Protease Inhibitors(PI) (i.e. ATV/r and LPV/r based regimens) and 1% in other regimens; while in the post-FCM period 7% were on Dolutegravir(DTG), 48% on EFV, 5% on NVP, 38% on PI, and 2% in other regimens. VS was 69% vs. 83% in the pre- and post-FCM periods, respectively(p<0.01). After adjusting for age and sex, children in the post-FCM period were 2-fold more likely to be virally suppressed compared to those in the pre-FCM period (aOR 95% CI 2.2 (1.7-2.7)).

Conclusions: VS was substantially higher among children 2-9 years of age who received the FCM intervention. Differentiated care models designed to better support both clients and their families can improve clinical outcomes among children living with HIV in resource-limited settings.

PED393

Clinical outcomes of community ART distribution: DRC's experience with the PODI+ model

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Background: While ART multi-month dispensation (MMD) has demonstrable advantages to both clients and providers, limited comparative evidence exists between clinically similar HIV-positive clients receiving MMD through different approaches. We assessed clinical outcomes between two clinically stable client groups: one receiving three-month MMD at health facilities (HF) and another receiving MMD through lay cadre-run, community sites ("PODI+") providing ART and other limited services in Kinshasa, DRC.

Methods: Adults receiving MMD through 8 HF or 2 PODI+ sites were enrolled and followed prospectively for one year (September 2018 – August 2020). Data were abstracted quarterly from clinic records; viral load (VL) samples were collected at enrollment and endline. An adherence proxy, ≥ 90% of days during study with medication, was determined using ART pick-up dates and number of doses dispensed across all visits. Retention was defined as attending all four post-enrollment visits within one-month pre- or post-scheduled visit. Differences in endline VL, adherence, retention and return to one-month refills were calculated using odds ratio (OR) and accounting for clustering.

Results: All participants (n=844, median age: 48 years) were virally suppressed at enrollment; 72% were female. Odds of maintaining viral suppression for PODI+ participants were two times greater than for HF participants (97% versus 93.6%, OR: 2.21 95% CI: 1.01, 4.85) with VL results at one year post-enrollment. Censoring participants at time of death (11 HF, 4 PODI+) or early termination (13 HF, 11 PODI+), no statistical differences were found between groups on adherence or retention. More HF clients transferred off MMD for unsuppressed VL/poor adherence, TB or excessive weight loss, but the difference was not significant.

Characteristic	Health Facility Client (n=403)	PODI+ Client (n=441)	Total (n=844)	Odds Ratio (95% CI)
Age at enrollment, median years (IQR)	47 (38-54)	49 (43-56)	48 (40-55)	-
Female, n (%)	286 (71.0)	324 (73.5)	610 (72.3)	-
Suppressed VL result (<1,000 copies/ml), endline	339/362 (93.6%)	391/403 (97.0%)	730/765 (95.4%)	2.21 (1.01, 4.85)
≥ 90% adherence at 3, 6, 9 and 12 month visits	270/394 (68.5%)	306/437 (70.0%)	576/831 (69.3%)	1.07 (0.36, 3.21)
Attended +/- 1 month of scheduled visit at 3, 6, 9 and 12 months	212/403 (52.6%)	223/441 (50.6%)	435/844 (51.5%)	0.92 (0.39, 2.17)
Standard of care transfer	25/403 (6.2%)	15/441 (3.4%)	40/844 (4.7%)	1.9 (0.65, 5.39)

Table.

Conclusions: HIV-positive, clinically stable clients receiving ART MMD through community distribution by lay workers had similar or marginally better clinical outcomes compared to stable clients receiving MMD through HF. While there was high viral suppression across groups, some adherence issues/treatment failure persisted even with clinically stable clients that should be addressed to minimize VL rebound.

PED394

Cost-effectiveness of community delivery of HIV care in South Africa

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Background: The Delivery Optimization of Antiretroviral Therapy (DO ART) Study demonstrated high rates of ART initiation, retention in HIV care over 12 months, and significantly increased viral suppression among men (from 54 to 73%) through community-based delivery compared with clinic-based care. We evaluated the cost-effectiveness and affordability of scaling up community-based ART in South Africa.

Methods: To estimate population-level incidence, prevalence, and mortality, we parameterized a mathematical model for KwaZulu-Natal, South Africa using the clinical outcomes from the DO ART Study. We modelled:

(1) standard clinic-based HIV care and

(2) a home-testing campaign, conducted once every five years, followed by community-based ART for people not reached by clinic care; with loss-to-follow-up, 66% of people living with HIV were virally suppressed under community-based ART.

Uncertainty ranges were generated as the minimum and maximum of 25 best-fitting model parameter sets. We conducted time-and-motion and activity-based micro-costing to evaluate intervention costs. Using modeled health impact and intervention costs, we estimated the incremental cost per Disability-Adjusted Life Year (DALY) averted by 2060 with costs and outcomes discounted 3% per year, and the five-year undiscounted budget required for province-level scale-up.

Results: By 2060, community-based delivery of ART following home testing averts 28% of HIV infections (range: 24-32%), 28% of HIV deaths (range: 27-29%), and 16% of DALYs (range: 12-20%), compared with the standard of care. At scale, the cost per client on community-based ART is US$245 per person-year. The incremental cost per DALY averted is $210 compared to clinic-based care (range: $196-221), which is well below the threshold of $750 from the South African HIV Investment Case. The five-year incremental program cost in KwaZulu-Natal for 2020-24 is $215.0 million, or $43.0 million per year (range: $34.3-47.9 million) compared to the annual DOH HIV budget of $312.0 million for KwaZulu-Natal (Consolidated Spending Report, 2016/7).

Conclusions: Scale-up of community-based ART requires an additional 14% initial investment but is highly cost-effective, preventing over a quarter of HIV cases and deaths. Costs could be further reduced through 6 monthly ART refills. Scaling up community-based ART has potential to cost-effectively and affordably decrease HIV incidence, disability, and death in high prevalence South African settings.

PED395

Does onsite HIV self-testing enhance linkage to care? A case study of HIVST Challenge Fund Project in Kenya

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Background: Globally, only 81% of people living with HIV know their status (UNAIDS, 2019). In Kenya, 27.5% of men aged 15 to 64 living with HIV do not know their status compared to 17.3% among their female counterparts (KENPHIA, 2018). Knowledge of HIV status is critical to entry and initiation of lifelong ART which ensures quality of care for individuals who are HIV positive. In 2016, WHO published guidelines on HIV self-testing. There is limited data to demonstrated methods that optimize linkage to care. These abstract compares linkage to treatment and care clients who tested on-site and those tested off-site.

Methods: In 2019, HIVST Challenge Fund Project trained young women and men aged 20 to 34 years as peer educators to distribute HIVST. During the distribution recipients can either opt to test at the point of distribution or take away the kits. Clients willing to test onsite are offered private spaces to test themselves. Clients who test through on-site strategy and report reactive results are immediately offered confirmatory testing by trained HTS providers. For those who are confirmed HIV positive, linkage to ART treatment is facilitated through real-time escort by HTS providers to facilities of choice.

Results: Between April 2020 to October 2020, 18467 people tested onsite. Of these 288 (1.6%) reported positive results, 270 (94%) were confirmed positive and 237 (88 %) were initiated on treatment and care. 7349 opted to test off -site. Of these, 289 (4.0%) reported positive results, 66 (23%) confirmed their results and 44 (67%) were initiated on treatment and care. Persons testing on site were more likely to be initiated on treatment as compared to testing off site (P-Value <0.005).

Conclusions: On-site HIV self-testing is a promising approach as it enhancing linkage to care and treatment among HIV positive clients. The approach can be tested in a wider scale in rigorous studies.

PED396

Optimizing transitioning to differentiated service delivery key approach to achieving (UNAIDS) 90-90-90 treatment targets in Kogi State, Nigeria

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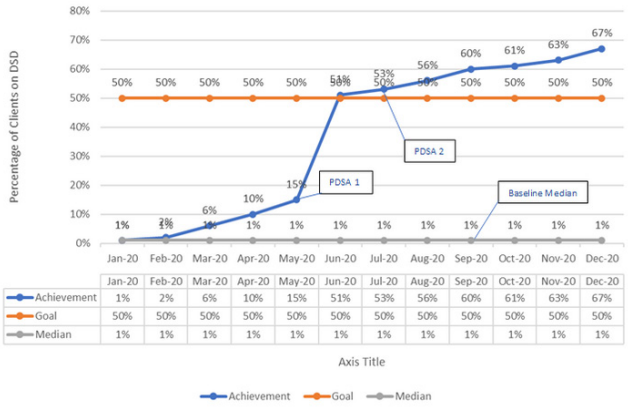
Background: Differentiated service delivery (DSD) was developed to combat suboptimal long-term retention in HIV care and to better titrate limited health systems resources to patient needs, primarily in low-income countries. Despite the knowledge and the numerous benefits of DSD, the facility data show that only 1% of the clients have been transited over 1 year ago. The quality improvement method aimed at optimizing the DSD of client load in a treatment center from 1% to 50% over a period of 12months.

Methods: A facility team carried out root-cause analysis using the 5 whys. This revealed that lack of staff commitment, lack of stipend for volunteers and unexpected shortage of commodity were some of the factors limiting DSD optimization. Interventions addressing the identified root-causes were implemented in two PDSA cycles starting from

January 2020. The first cycle included setting up DSD-volunteer group leaders and provision of stipends for volunteers while the second cycle ensured the availability of ARVs and clients' follow-up. Both the community and facility based DSD models were adopted.

Results: The facility had an total current client load of 1007 at the end of the project. Optimization started from 1%. A strident growth in the client's optimization was noticed after the first PDSA cycle from 15% to 50%. This was followed by sustained improvement to a peak of 67% which was above the project set target. This has helped in improving the treatment retention from 51% to 71%.



	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20
Achievement	1%	2%	6%	10%	15%	51%	53%	56%	60%	61%	63%	67%
Goal	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Median	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%

Figure. Clients transitioning to DSD in the health facility

Conclusions: Implementation of 2 PDSA cycles successfully led to a significant improvement in the proportion of clients opting for DSD models beyond the set target of 50%. To bridge the future gap between transitioning with aim of improving retention, this approach should be considered.

PED397

Differentiated prevention testing and art delivery for modified general populations and key populations in Nigeria: a documentation of best practice models

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Background: Nigeria's HIV epidemic affects all population groups and geographic areas of the country. Key populations (KP) are disproportionately impacted by this epidemic, the IBBSS 2014 revealed the following HIV prevalence among Key Populations: Female sex workers(FSW): brothel-based FSW (19.4%); and 8.6% among non-brothel based FSW; men who have sex with men(MSM) (23%) and People who inject drugs(PWID) (3.4%).

This study, with funding from funding from International AIDS Society, sought to document the success or otherwise of the differentiated service delivery (DSD) for KPs in Nigeria.

Methods: This study was a cross sectional study which utilized focus group discussions and key informant interviews for data collection. The target participants for this study included: PWID, FSW, MSM DSD beneficiaries, MSM and FSW key opinion leader, health care workers (HCWs), State AIDS program coordinator, and State Agency for the Control of AIDS in three selected states. Research Assistants were trained centrally for uniformity. The data was transcribed and analyzed using a constant comparison analysis technique.

Results: The study revealed that the trainings of the HCWs were adequate and relevant. Due to these trainings, HCWs were perceived to be more KP-friendly and more professional in the services they provided, waiting time at the ART clinics also reduced due to the differentiated service delivery models.

Participants also said that ARVs were always available at the OSS facilities. All participants belong to and participate in a support group. Some of the support groups are KP-led and gender differentiated while others are not.

The models of Differentiated Service Delivery implemented across the states included the Facility based model, the Out-of-facility model and the Client managed group models. Sources of finances included government and other donors. The DSD implemented in each state had a positive influence on loss to follow up among KPs.

Conclusions: Conclusively, the DSD models have improved service delivery in the study sites, reduced waiting times at the ART clinics, improved KP-friendliness among HCWs, and increased demand for ART services among KPs. Therefore, it is suggested that DSD models be scaled up to national level in order to improve ART service delivery across the country.

Provider and facility determinants of outcomes

PED398

Trust in the PrEP provider is associated with accurate self-reported PrEP adherence among adolescent girls and young women in sub-Saharan Africa

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Background: Trust is the cornerstone of patient-provider communication, including about pre-exposure prophylaxis (PrEP). Accurate reporting of PrEP adherence by adolescent girls and young women (AGYW) in sub-Saharan Africa is important for providers to determine who needs adherence support. It is not known if trust in the PrEP provider is associated with concordance between patient-reported and tenofovir diphosphate (TFV-DP) levels, an adherence biomarker.

Methods: HPTN 082, an open-label PrEP demonstration study, enrolled 451 AGYW (ages 16-25 years old) from 2016-2018 in Cape Town and Johannesburg, South Africa, and Harare, Zimbabwe. At month three, participants' responses to indicators of trust were dichotomized as '*agree*' (strongly-agree/agree) versus '*disagree*' (neither/disagree/strongly-disagree). Patient-reported adherence response to 'In the past month, how often did you take the tablet?' was dichotomized as '*high*' (every day/most days), and '*low*' (some days/not many days/never).

Objective evidence of adherence was defined as '*high*' if TFV-DP ≥ 700 fmol/dried blood spot (DBS) punch, and *'low' if* < 350 fmol/punch. Log odds of concordant adherence (high patient-reported and high TFV-DP) and concordant non-adherence (low patient-reported and low TFV-DP)

relative to discordant non-adherence (high patient-reported and low TFV-DP) were modeled as linear functions of trust, using multinomial logistic regression.

Results: Of 427 (95%) AGYW who initiated PrEP, 354 (83%) had month three TFV-DP and patient-reported adherence data. Most responses were 'agree' for the trust indicators: 'trusting relationship with PrEP provider' was 86%; 'let PrEP-providers know if missed doses' was 78%; and "I know how to contact the PrEP providers if I have problems or questions about PrEP" was 85%. Nearly 50% were 'discordant non-adherent', 31% were 'concordant adherent', and 20% were 'concordant non-adherent'. AGYW who reported strong trusting relationships with their PrEP providers had increased odds of 'concordant adherence' than 'discordant non-adherence' (aOR 3.72, 95% CI 1.20-11.51, $p = 0.02$). All three trust indicators had non-significant lower odds of being 'concordant non-adherent' than 'discordant non-adherent'.

Conclusions: Drug levels provide an objective marker of PrEP adherence and identify AGYW who over-report PrEP adherence. When there is high-level of trust in the PrEP providers among AGYW, there is concordance between patient-reported adherence and biomarker concentration of PrEP.

PED399

Comparison of anti-retroviral treatment (ART) failure by health-facility level prior to widespread availability of laboratory-based monitoring in east Zimbabwe

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Background: Decentralization of HIV services from district hospitals to local clinics is a key strategy used to support implementation of expanded ART eligibility in Zimbabwe. We investigated access to laboratory-based (CD4 and viral load (VL)) monitoring at smaller health centres, and whether access to care at decentralised facilities is associated with ART failure.

Methods: Data were analysed from a health-facility survey at six hospitals, six large clinics (LHCs) and six small clinics (SCs) in Manicaland, east Zimbabwe (August-September 2017) and a linked medical record review of adults (55.7% women) enrolled on ART at these facilities from July 2015-June 2017. Data on WHO clinical stage, CD4 count, and VL at follow-up appointments were used to identify individuals with detected treatment failure, based on World Health Organisation definitions of clinical, immunological and virological failure. Treatment failure by health-facility type, facility services, and socio-demographic and clinical characteristics were compared in multi-level regression models.

Results: Access to CD4 and VL testing was lowest at smaller health centres. WHO clinical staging (97.2% overall) and CD4 count testing (2.9%) at follow-up visits did not differ by facility type. VL monitoring was rare (1.2%) but higher for patients at hospitals (1.8%) than at LHCs (0.6%) and SCs (0%) (p<0.001).

Treatment failure was 5.6%(71/1279) overall but did not differ by facility type – hospitals: 5.9%(46/782); LHCs: 4.8%(15/343); SCs: 5.8%(9/154) (p=0.7), or by gender (p=0.7). Individuals at WHO clinical stages 3/4 *versus* 1 at ART initiation had 9.3 greater odds of treatment failure (AOR=9.27; 95%CI:3.18-27.0). Individuals with 201+ CD4 cells/mm^3 at ART initiation had 0.19 odds of treatment failure *versus* those with 1-200 CD4 cells/mm^3. Three hypothesised facility-level factors differed by facility type (Table 1) but were not associated with odds of treatment failure.

		Total n (%)	Hospitals n (%)	Large clinics n (%)	Small clinics n (%)	p
	N (%)	18 (100)	6 (33.3)	6 (33.3)	6 (33.3)	
Onsite CD4 count testing		27.8	83.3	0	0	0.002
Total patient/staff ratio	Less than 10 patients per staff member	61.1	100	0	83.3	<0.001
ART adherence counselling available		66.7	100	83.3	16.7	0.009

Table.

Conclusions: Within this cohort, treatment failure did not differ between facility types, however the true detection of failure may be limited by lack of widespread access to laboratory-based monitoring. Further investment is needed to ensure equitable access to laboratory-based monitoring in the era of decentralisation.

PED400

Health systems-level barriers and strategies for improved PrEP delivery for pregnant and postpartum women in Western Kenya

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Background: Pre-exposure prophylaxis (PrEP) is recommended for pregnant and postpartum women at high risk of HIV acquisition within maternal child health (MCH) systems. Identifying health system barriers to PrEP delivery and strategies to overcome barriers could optimize PrEP delivery within MCH systems.

Methods: We recruited health care workers (HCW) with experience delivering PrEP within MCH clinics in two large-scale projects in western Kenya (>25,000 MCH clients offered PrEP at 36 sites). Two surveys (a self-administered and a phone survey) were used to assess barriers to PrEP delivery and strategies to overcome barriers, based on previous qualitative work grounded in the Consolidated Framework for Implementation Research.

Results: Among 101 HCW recruited, 91 completed the electronic survey and 88 the phone survey. Most (54%) were nurses, female (65%), had PrEP training specific to MCH (93%), and 4.3 years (IQR: 2.2, 6.5) providing PrEP.

The strongest reported barriers to PrEP delivery were insufficient number of providers and inadequate training; increased volume of patients and time needed; insufficient physical PrEP services space; and documentation burden.

Less impactful barriers included stockouts of PrEP drugs and documents; multiple implementing partners with competing priorities; increased HIV testing; and clients with challenges (Figure 1A).

Strategies most frequently reported to have been tried and improved delivery included dispensing PrEP in MCH (90%); fast-tracking PrEP clients at MCH (82%), pharmacy (64%) or lab (60%); delivering PrEP education in waiting bays (76%) or other locations (59%); providing communication aids (68%); dedicating space for PrEP (64%); and task-shifting PrEP counseling (55%) and risk assessment (54%) from nurses to HIV testing services providers (Figure 1B).

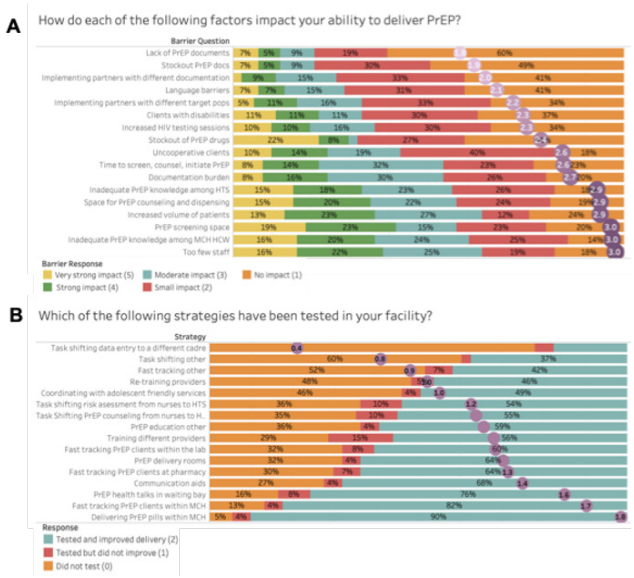

Figure 1A and 1B

Conclusions: Common barriers to service provision—including client-to-provider ratios, space, and documentation—hinder PrEP delivery. Strategies for co-location, fast-tracking, training, and task-shifting are useful for integrating PrEP provision within MCH care.

Methods to improve provider quality, supply and adaptation of services

PED401

Optimal characteristics of Peer Navigators: adapting a peer-based intervention with street-involved youth in Canada and Kenya to increase uptake of HIV prevention, testing and treatment

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Background: We sought to adapt a Peer Navigator (PN) model to increase uptake of HIV prevention, testing and treatment of street-involved youth (SIY) in Canada (Toronto, London, Montreal) and Kenya (Kitale, Eldoret). Here we present findings on the optimal characteristics of the PN model for SIY across and between sites.

Methods: Using an integrated mixed methods approach, eligible participants included SIY aged 16-29 years, in Toronto and Montreal, lesbian, gay, bisexual, trans, queer and two-spirit (LGBTQ2S) SIY; health care providers and community stakeholders. Data collection tools drew from the CATIE (Canada) PN practice guidelines related to: PN role and responsibilities, training, supervision, integration into sites, etc. We conducted 53 interviews, 11 focus groups, and 11 theatre testing workshops where participants provided feedback on the PN intervention. Qualitative data were inductively coded and analyzed using a single codebook. Participants filled out a structured PN checklist to identify optimal 'core' (essential) and 'peripheral' (adaptable, less important) PN characteristics and/or activities. Spearman's rank correlations (r) were used to quantify agreement across sites and participant groups.

Results: Of 39 checklist items, 31(79%) were considered 'core'. These primarily pertained to host organization (supportive self-care environment, 92%; PN training, 87%, mentorship 84%); PN characteristics (commitment, 96%, empathy, 92%, interpersonal skills, 88%); and PN activities (providing HIV education, 86%, making referrals, 85%). There was mixed opinions about asking the PN to declare previous experience with drug use and HIV status, but there was agreement that the PN should have previous experience of street-involvement, and in Toronto/Montreal, identify as LGBTQ2S. Participants across sites described the PN intervention as acceptable, with recommendations for site and host organization-specific adaptations, such as addressing community worker burn-out (Montreal), navigating stigma (Kitale, Eldoret), transportation needs (London) and PN to identify as LGBTQ2S, plus additional identities (racialized) and/or experiences (previous drug use, sex work, etc.) (Toronto).

Conclusions: Our findings indicate high agreement among participant groups across all sites on some optimal PN intervention characteristics, particularly host organization characteristics, the PN themselves, and their activities. However, context-specific adaptations are also necessary to successfully scale-up the PN intervention. This model is applicable in diverse regions and organizational contexts.

PED402

Rapid scale-up of multi-month dispensation of antiretroviral therapy as a COVID-19 mitigation measure, Zambia, 2020

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Background: As a strategy to protect persons living with HIV (PLHIV) from COVID-19 infections by minimizing the number of clinical encounters, the Zambia national HIV program scaled up 6-month multi-month dispensation (6MMD) of antiretroviral therapy (ART). Due to global supply chain disruptions related to the COVID-19 pandemic, however, there was inadequate stock of first-line ART, Tenofovir-Lamivudine-Dolutegravir (TLD), to implement 6MMD among all PLHIV on TLD. As an alternative, there was adequate existing stock of Tenofovir-Lamivudine-Efavirenz (TLE) to provide 6MMD to eligible PLHIV, so patients on TLD were switched to TLE to receive 6MMD. We describe the experience of scaling up 6MMD among PLHIV in Zambia in response to the COVID-19 pandemic and its impact on retention.

Methods: Using de-identified patient-level data from electronic medical records, we analyzed the proportions of PLHIV (>15 years old) on ART who received 6MMD by March 31 2020 compared with September 30 2020, as well as changes to ART regimens and lost-to-follow-up rates (LTFU), defined as the number of patients who are >30 days late to their next scheduled appointment on a given date divided by the sum of lost patients and the number of patients currently on ART.

Results: In March, 376,220 (37.8%) of PLHIV on treatment were receiving 6MMD and by the end of September, 573,614 (56.2%) were receiving 6MMD. Of those on 6MMD at the end of September, 330,315 (57.6%) were on TLE while 158,041 (27.6%) were on TLD, in comparison with 148,948 (39.6%) on TLE and 180,667 (48.0%) on TLD in March. Overall LTFU was 96,310 (9.7%) in March compared with 68,227 (6.7%) in September.

Conclusions: The Zambia national HIV program successfully implemented rapid scale-up of 6MMD as a strategy to protect PLHIV from potential COVID-19 exposures at health facilities. This rapid scale-up was possible despite supply chain disruptions related to the pandemic because of the country's existing stock of TLE. Scale up of 6MMD aligned with an improvement in LTFU rates, supporting its role in improving retention. Now that the country has adequate stock levels of TLD, patients are being transitioned back to TLD.

PED403

Pilot implementation of a screening and linkage intervention to increase PrEP uptake in primary care

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Background: Rapid identification of patients who may be at risk for HIV in primary care settings and the ability to provide brief consultation and prescription or referral for PrEP could help to increase PrEP uptake. The current study aimed to develop and pilot-test a Screening and Linkage Intervention to PrEP (Project SLIP) that could be integrated into the workflow of busy primary care clinics to help facilitate PrEP uptake among at-risk men.

Description: PrEP screening occurred for 12 months in two primary care clinics nested within a large integrated healthcare delivery system in Southern California. An interrupted time series analysis found a increasing pre-intervention trend ($\beta 1$ = 0.04, p = 0.02) before the screener was implemented. After controlling for this pre-intervention trend, there was a significant overall increase in rate of 0.37% ($\beta 2$ = 0.37, p = 0.01) that we observed in the post-intervention period. The referral rate went up to an average of 0.57%, ranging from 0.31% to 0.89% compared to the preceding 12 months.

Lessons learned: When the intervention launched, the PrEP referral rate increased dramatically, then remained high for several months, then slowly regressed over time representing the decay of intervention effects seen in many primary care screening interventions. The use of paper screeners were often overwhelmed by other intake paperwork. Electronic versions of the screenings instrument could help to facilitate routine administration. For example, on an annual basis and could be integrated within a comprehensive sexual health screener for all gender patients. For patients who have not sought office-based care, electronic screenings offered through patient portals could also be used.

Conclusions/Next steps: Brief HIV risk screening in primary care is acceptable, feasible, and shows preliminary effects in increasing PrEP referral rates especially for Black and Hispanic/Latino men. Future efforts could examine the integration of an electronic PrEP screening questionnaire. Project SLIP was the first step in a body of work that seeks to transform sexual health screening in primary care settings from "rare and uncomfortable" to "routine and replicable." As access is scaled up, an additional area for future research is the maintenance or persistence of PrEP use in primary care settings.

PED404

Uptake of a rapid HIV point-of-care diagnostic test with shorter result turnaround to increase the reach of HIV testing services in public sector clinics, South Africa

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Background: Lengthy result turnaround times for HIV rapid diagnostic tests (RDTs) are a bottleneck to increasing the reach of HIV testing services (HTS). This often results in patients declining HTS or HTS-providers reading test results before the recommended time in order to meet daily testing targets. RDTs such as INSTI® HIV-1/HIV-2 point-of-care (INSTI-POC) with a shorter result turnaround time (60 seconds) and high field performance, may address these gaps. We sought to describe the uptake of INSTI-POC by clinic-based HTS-providers in a high HIV prevalence district in South Africa.

Description: From 1 November 2019–29 February 2020, HTS-providers in four selected clinics had the option to conduct HIV screening using INSTI-POC or Abon (standard of care RDT with a 15-minute result turnaround time). Uptake was defined as the proportion HIV tests conducted using INSTI-POC. We also conducted 4 focus group discussions (FGDs) to explore HTS-providers' experiences and perceptions of using INSTI-POC.

Lessons learned: A total of 24,329 HIV tests were conducted across all 4 clinics. Of these 8,330 (34%) were conducted using INSTI-POC. We observed a strongly positive linear trend (p <0.001) in the uptake of INSTI-POC over the evaluation period (Figure 1).

In focus group feedback, INSTI-POC was highly accepted by HTS-providers. They reported that it allowed them to provide faster service and enabled them to meet/even exceed their daily testing targets. Furthermore, HTS providers also mentioned the opportunities created by INSTI-POC to expand service points where HTS could be offered due to fast turnaround times.

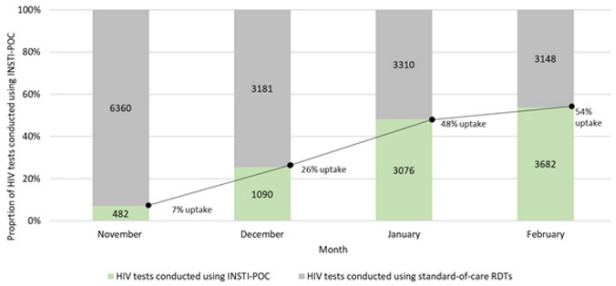

Figure 1

Conclusions/Next steps: Our findings suggest high acceptability of HIV RDTs with faster turnaround times. This suggests several possibilities for increasing HTS reach through gains in productivity of and acceptability with patients. Further work is required to quantify the effectiveness of INSTI-POC in increasing HTS reach for specific target groups and linkage to appropriate HIV prevention and treatment programmes.

PED405

The pharmacy as a link to reaching men with HIV testing services: a case of HIV Self-testing Challenge Fund Project, Kenya

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Background: In 2018, Kenya's National AIDS and STI Control Programme (NASCOP) incorporated HIVST in the national guidelines to increase access to testing among populations with low testing rates such as men. Beginning July 2019, PS Kenya implemented HIV self- testing project in Nairobi and Mombasa regions targeting men through pharmacy distribution. This abstract compares number of men testing using self-test kits purchased from the pharmacies with men who went for conventional HIV Testing services at the health facilities.

Description: PS Kenya project staff recruited 700 registered physical pharmacies in Nairobi and Mombasa. The pharmacies were selected according to potential sales volumes and proximity to hotspots. Merchandising was done to ensure availability and visibility of HIVST kits at each pharmacy. The project also supplied the pharmacies with data collection registers that capture age of the client, gender, type of kit purchased and testing history. The registers were collected at the end of each month and data entry to project's DHIS2 was done.

We reviewed sex-disaggregated data for HIVST and HIV testing data from the Ministry of Health reporting system (DHIS 2) for the period between April 2020 and October 2020. We compared the proportions of men reached with HIVST with that of men reached with conventional testing strategies.

Lessons learned: Of the 22,200 kits sold over the period 15,286 which was 68.9% were purchased by men aged 20 years and above.From MoH DHIS2, over the same period, 783,632 conventional health facility-based HIV tests were conducted, of which 61.8% were from women while 38.2% were from men aged above 20 years. The differences are statistically significant (P<0.05).

Conclusions/Next steps: Our data suggests that men may prefer purchasing test kits from pharmacies as opposed to attending services from conventional HTS approaches. There is need to collect in-depth data to determine preferences of men for HIVST services and linkage strategies.

PED406

FOCUS@GAT: community-based enhanced HIV and HCV screening programs

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Background: GAT supports people most at risk of acquiring HIV infection: trans people and men who have sex with men, people who use injectable drugs (PWUID), and sex workers. The FOCUS@GAT project established interventions to improve testing capacity and linkage to care (LTC) through self-led data collection, 1-minute rapid tests, HIV/HCV RNA point-of-care (POC) stations, automated National Health Service (NHS) referral and enhanced LTC coordination. We aim to describe the impact of RNA stations on HIV/HCV screening program outcomes.

Description: Between August 2019 and December 2020, 18,964 HIV and 10,574 HCV tests were performed at four testing centres and one mobile unit in the Lisbon Metropolitan Area. Two sites were fitted with HIV/HCV RNA POC stations to confirm reactive tests and screen for acute HIV infections (AHI) and HCV reinfections.

Lessons learned: In this period, 234 HIV (1.23%) and 152 HCV (1.44%) reactive antibody tests were found. Among people with a reactive test and no prior knowledge of the infection, 65.77% (123/187) and 57.23% (87/152) accepted onsite confirmation for HIV and HCV, respectively. The remaining were referred to the NHS. Acceptance of confirmation at the community level was higher where RNA POC stations were available. Fifty-one (65.52%) people were positive for HCV and 120 (98.72%) for HIV RNA. Twenty-two (0.12%) people with nonreactive HIV antibody tests were tested for RNA to confirm AHI: three (13.63%) were positive HIV-1 positive. Twenty people were tested for HCV reinfection: seven (35.00%) were positive.

RNA POC stations impact:

- LTC efforts by rapidly differentiating current from resolved HCV infections, avoiding LTC work overload;
- The LTC of people with AHI infection, otherwise undiagnosed with standard testing;
- The disclosure of false-positive results; and,
- Community-based HCV screening program loss to follow-up of people with HCV antibody positive status after a cured/resolved infection, who can now be enrolled in screening for reinfection.

Conclusions/Next steps: RNA stations added value to appropriate and earlier LTC. Since acceptance was higher where RNA POC stations were available, we shifted one station to the centre aimed at PWUID were the uptake was the lowest.

Demand creation for HIV services

PED407

Use of male champions to improve male involvement in HIV testing: the experience of the Malawi EMPOWER activity

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Background: Men living with HIV in Malawi have poor health-seeking behaviors, tend to present at clinics with advanced HIV, and have low viral load suppression rates. Research on men's barriers to HIV services and beneficiary engagement conducted through the USAID-funded Malawi EMPOWER activity, has demonstrated men's preference for male providers and for flexible and confidential service delivery models. EMPOWER's strategy to reach men provides education on HIV prevention behaviors, creates demand for HIV testing services (HTS), ensures that men know their HIV status, and encourages linkage to treatment and care for HIV-positive men. This abstract highlights how EMPOWER contributed to reaching more men with these services.

Methods: EMPOWER reaches priority populations such as estate workers, fisherfolk, and male partners of adolescent girls and young women using targeted one-on-one and small group sessions on risk reduction. To encourage male participation and provide them with services, EMPOWER used trained male champions who are members of these popu-

lations. In addition, EMPOWER's community-based testing approach brings HTS closer to men, at times and locations that are convenient for them. To understand the contribution of this approach, EMPOWER analyzed program data for HTS from April to September 2020

Results: During the period under review (April–September 2020), the total number of men tested increased from 41 in Q3 FY20 to 1,034 in Q4 FY20. In Q4, men accounted for 47% of the quarterly target. In addition, the number of men newly tested HIV-positive increased from 22 in Q3 FY20 to 84 in Q4 FY20, demonstrating an improvement in the targeting of men at high risk of HIV.

Conclusions: Use of male champions and bringing HTS to men is a promising strategy for increasing male participation in HIV prevention and testing services.

PED408

Designing tailored and scalable HIV and contraceptive services for adolescents in Gauteng, South Africa: translating discrete choice experiment results to cost-effectiveness results

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Background: Youth in South Africa are disproportionately affected by STIs, HIV, and unintended pregnancies. Despite this, their utilisation of HIV and contraceptive services remains a challenge and existing approaches fail to adequately address this gap.

Methods: We developed a framework to translate the expected impact of facility-level attributes in increasing HIV/contraceptive service uptake for youth into a cost effectiveness analysis (CEA). We used a discrete choice experiment (DCE, n=805) conducted in Gauteng, South Africa, which found that staff attitude, confidentiality, Wi-Fi, subsidized food, afternoon hours and youth-only services were preferred attributes. Based on this we simulated uptake of services adapted for these preferences. We divided preferences into modifiable attributes that could readily be adapted, and non-modifiable (e.g. staff attitude), and estimated the incremental change in uptake of services using services adapted for preferred attributes. Costs for modifiable preferences were estimated using data from a clinic in South Africa (2019 US$). We determined the incremental cost effectiveness ratio (ICER) of 15 intervention combinations, and report the results of interventions on the cost-effectiveness frontier.

Results: Factors that have the greatest projected impact on uptake are friendly healthcare providers and confidential services, both of which are considered non-modifiable (18.5% 95%CI:13.0-24.0%; 8.4% 95%CI:3.0-14.0% respectively). The remaining (modifiable) factors on their own each resulted in a lower expected uptake (2.3% 95%CI:4.0%-9.00%; 3.0% 95%CI:-4.0%-10.0%; 0.3% 95%CI:-6.0%-7.0%; 0.8% 95%CI:-6.0%-7.0%) for Food, Wi-Fi, Youth only services, and Afternoon services respectively). The order of interventions on the cost-effectiveness frontier are Wi-Fi+youth-only services (ICER US$7 per additional youth accessing services), Wi-Fi+youth-only services+food (ICER US$9), followed by Wi-Fi+youth-only services+extended afternoon hours (ICER US$32) (Table 1).

Conclusions: Combining DCE and costing analyses provides an innovative way to inform decisions on effective ways to utilise resources in the absence of implementation. Modifiable preferences have potential to cost-effectively increase the proportion of youth accessing HIV and contraceptive services.

Package of interventions (in order, incremental)	Total youths at baseline	Total number of youths predicted to access health services compared to baseline	Percent increase in utilization compared baseline	Total monthly expected cost of implementation at one clinic (USD)	ICER (USD per additional youth expected to access services)
Wi-Fi +Youth only services	1808	1971	9%	$1,143	$7
Wi-Fi +Youth only services + subsidized Food		2115	17%	$2,493	$9
Wi-Fi +Youth only services + subsidized Food + Afternoon hours		2224	23%	$6,009	$32

Table 1. Cost-effectiveness of interventions to increase youth uptake of HIV and contraceptive services (those interventions on cost-effectiveness frontier)

Partnerships: Academic-community, public-private

PED409

Extending reach of HIV testing services (HTS) through private-sector outlets: feasibility of offering HIV self-testing (HIVST) at pharmacies and alternative medicine centers (AMC) in Democratic Republic of the Congo (DRC)

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Background: 2019 data show only 56% of PLHIV in the DRC are diagnosed and on antiretroviral treatment (ART), indicating a need for novel models to reach vulnerable populations not currently accessing HTS. PATH, through the USAID-funded Integrated HIV/AIDS Project, tested a public-private model for HIVST at pharmacies and AMCs to extend HTS reach.

Description: Under this model, PATH trained pharmacists and AMC providers to screen clients for HIV risk or signs suggestive of HIV infection, and offer free, directly assisted HIVST to clients who screened positive. They also counseled clients with a reactive self-test result on the need for confirmatory testing, and contacted a project-affiliated community health volunteer to provide an accompanied referral to a public-sector facility for confirmatory testing. PATH supplied HIVST kits to pharmacies/AMCs, and pharmacists/AMC providers were provided $2 for each client confirmed HIV-positive. We piloted this model at 21 private-sector outlets (19 pharmacies; 2 AMCs) across five health zones of Lubumbashi, and used descriptive statistics to analyze HIV testing, referral, and ART initiation data from May through December 2020.

Lessons learned: 172 individuals (median age 34 years; 52% female) were offered HIVST. 97% (98% of males; 96% of females) accepted; all 166 individuals were first-time testers. 34% (57/166) of HIVST clients had a reactive result. 56 out of 57 clients with reactive results were successfully referred to a facility. 71% (40/56) were confirmed HIV-positive, with 100% linkage to ART. Overall HIV prevalence was 24%, with higher prevalence among females (29%) than males (19%). HIV testing yield among pharmacy/AMC clients was higher than the yield observed at routine project-supported HTS outreach during a similar period (24% versus 6.7%), highlighting the model's success in efficiently reaching and linking undiagnosed PLHIV to ART.

Conclusions/Next steps: Our results show the feasibility and acceptability of using a public-private HIVST model to reach and link private-sector clients to public-sector facilities for diagnosis and ART initiation, and its success in identifying hard-to-reach PLHIV. We plan to extend this model to additional private-sector outlets to increase accessibility of HTS services to support DRC's efforts to reach epidemic control.

Community-led initiatives

PED410

Community-based prevention of mother-to-child HIV transmission is perceived as effective and trusted in rural Zambia: qualitative results from the SMACHT project

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Background: While Zambia has made significant progress towards prevention of mother to child transmission (PMTCT) of HIV, gaps remain. Novel differentiated service delivery (DSD) interventions are required to close the gaps in PMTCT as well as testing and linkage to care for HIV-exposed infants (HEIs) along the early infant diagnosis (EID) cascade. We report promising qualitative results from a University of Maryland Baltimore community-based PMTCT program: the Stop Mother And Child HIV Transmission (SMACHT) project.

Description: Project: SMACHT implemented the Community HIV Epidemic Control (CHEC) DSD model in the Southern Province of Zambia from 2015-2020. Under CHEC, SMACHT recruited, trained, deployed and mentored community health workers (CHWs) to conduct community-based PMTCT services. Each CHW was tasked with identifying pregnant and breastfeeding women (PBFW) and ensured they receive antenatal care and HIV testing. The CHWs followed up HIV-infected PBFW to ensure antiretroviral adherence as well as HEI prophylaxis, immunizations, and EID testing.

Study Design: Nine healthcare facilities and corresponding catchment areas spanning three districts were purposively sampled for a qualitative study to examine implementation and perceived feasibility, acceptability and effectiveness of the CHEC model for PMTCT and related services. Methods included in-depth interviews with government and community officials (n=11), program implementers (n=24), and beneficiaries (mothers engaged in PMTCT and/or HEI care) (n=36), as well as focus-group discussions with CHWs and community members (n=14).

Lessons learned: We found facility-based healthcare workers and beneficiaries benefitted from the CHEC model with respect to decongestion of services and increased uptake and retention in HIV care. Community members trusted CHWs to provide confidential HIV-related services; health facility workers observed higher retention in care across HIV treatment cascades; and relations between CHWs and healthcare workers were positive. Both healthcare workers and CHWs perceived increases in the uptake of ANC and facility-based delivery, and retention in care for the HIV exposed infant. Challenges included project sustainability, and shifting guidelines for identifying HIV+ cases.

Conclusions/Next steps: Use of the CHEC model for PMTCT was perceived as effective at increasing community understanding of HIV and influencing reductions in PMTCT. Trusted DSD models like CHEC are needed to achieve elimination of MTCT in Zambia.

PED412

Designing a peer-led comprehensive HIV program for transgender people in Bayelsa State, Nigeria: Early lessons from EpiC Nigeria

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Background: Nigeria has a mixed epidemic—that is, while HIV prevalence among the general population is high, certain groups still carry a far greater burden of HIV compared to the general population. Despite the lack of data, transgender (trans) people are thought to be hugely affected by HIV in West and Central Africa.

However, they face cultural barriers, stigma, and discrimination, preventing them from accessing HIV prevention, testing, treatment, and care services. As a result, some trans people are unknowingly living with HIV or being diagnosed late.

Description: The Meeting Targets and Maintaining Epidemic Control (EpiC) project identified trans people as peer navigators in Bayelsa State to collaborate with stakeholders of men who have sex with men and trans people to identify trans networks and communities. Fifteen peer navigators were recruited and equipped with tools and resources for HIV testing and documentation. They were trained on the provision of targeted HIV services for testing, linkage to antiretroviral therapy and oral pre-exposure prophylaxis (PrEP), and follow-up for trans people and their partners. They were also trained on sexually transmitted infection screening, and referral and linkages to comprehensive HIV clinics and mobile units.

Lessons learned: From January to December 2020, 1,982 trans people were reached with HIV testing services, 317 of whom tested positive (15.9% case-finding rate). A total of 876 HIV-negative trans people were screened for PrEP eligibility, and 355 were initiated on PrEP. Figure 1 shows EpiC's cascade data for this population.

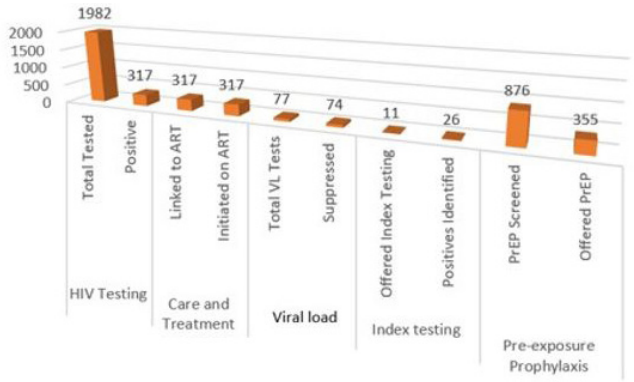

Figure 1.

Conclusions/Next steps: The case-finding rate of 15.9% suggests a high prevalence of HIV among trans people in Bayelsa State. The use of peer navigators for case finding among trans people in Bayelsa State was very effective for accessing trans networks and should be adopted in the design of HIV programs for this population.

Feasibility and acceptability of emerging HIV prevention strategies

PED413

Promotion of mutual disclosure of HIV serostatus among men who have sex with men in China: a social exchange model

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Background: Mutually disclosing HIV serostatus (MDHS) with sexual partners (SPs) have been suggested as a key strategy for men who have sex with men (MSM) to prevent HIV/AIDS. However, still lack of an effective and efficient solution to facilitate the community engagement. Therefore, we introduced a social exchange (SE) model for promoting MDHS among Chinese MSM.

Description: Based on the reciprocity principle from SE theory and the social habit of seeking SPs via social network of MSM, we developed an HIV electronic report exchange tool (HERET) on WeChat (a Chinese social application like WhatsApp), and used HERET to promote MDHS through this largest social network in China. HERET provides online appointment function for MSM to access HIV voluntary counseling and testing (VCT) and HIV electronic report (HER) exchange function for those who have completed testing to MDHS with SPs by exchanging HERs in WeChat. To protect privacy, HERET restricts that HER exchange must be voluntary.

Once a user receives his SP's HER exchange invitation, he could check this SP's serostatus only after returning his own HER. For MSM without HERs, HERET would guide them to make appointments for getting test and HERs.

Lessons learned: SE model has been introduced to Guangzhou, China since September 2018. By the end of 2020, 140 sites have been included in HERET for MSM to access VCT, covered the entire 11 districts of the city. Up to December 2020, 5915 MSM have completed HIV testing through HERET and 4487 (75.86%, 4487/5915) have applied the HERs. 1019 (17.23%, 1019/5915) MSM have invited a total of 2846 SPs to exchange HERs, with a median of 2 (Min: 1, IQR: 7-1, Max: 102). Among, 382 (13.42%, 382/2846) pairs of MSM eventually checked serostatus with each other through exchanging HERs.

Furthermore, 149 MSM have made appointments for testing soon after the failure of checking SPs' HERs since they have no HERs.

Conclusions/Next steps: SE model is a promising solution to promote MDHS. This model can be utilized well in many cities and helps to develop a nationwide network for MSM to communicate HIV serostatus, and consequently reduce infection among Chinese MSM community.

PED414

"We have to learn to cooperate with each other": a qualitative study to explore integration of traditional healers into HIV self-testing and tuberculosis activities in Eswatini

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Background: Traditional healing plays an important role in healthcare in Eswatini and innovative collaborations with traditional healers may enable hard-to-reach men to access HIV and tuberculosis diagnostic services. This study assessed the feasibility and acceptability of traditional healers distributing HIV self-testing (HIVST) kits and sputum collection containers.

Methods: A qualitative study was conducted from September 2019 to February 2020 in Shiselweni region, Eswatini. Eight male traditional healers were trained on HIV and TB including distribution of HIVST kits and sputum collection containers. Attitudes towards the intervention were elicited through in-depth interviews with the eight traditional healers, ten of their clients, five healthcare workers and seven focus group discussions with community members. Interviews and group discussions were conducted in Siswati, audio-recorded, transcribed and translated into English. Data were coded inductively and analysed thematically.

Results: 81 HIVST kits and 24 sputum collection containers were distributed by the healers, with 14% of participants reporting a reactive HIVST result. The distribution of sputum containers did not result in any tuberculosis diagnoses.

Traditional healers perceived themselves as important healthcare providers, and after training, were willing and able to distribute HIV self-test kits and sputum containers to clients. Many saw themselves as peer educators who could address barriers to health-seeking among Swazi men that are influenced by hegemonic masculinities and patriarchal attitudes. Traditional healers were considered to provide consultations that were private, flexible, efficient, and non-judgemental, although some clients and community members expressed concerns over confidentiality. Attitudes among health workers were mixed, with some calling for greater collaboration with traditional healers and others expressing doubts about their potential role in promoting HIV and TB services. Specifically, some did not accept sputum samples from patients collected in this way.

Conclusions: Offering HIVST kits and sputum containers through traditional healers was feasible, leading to high HIV yields, but no TB diagnoses. The intervention was acceptable to the healers' clients, due to the cultural literacy of traditional healers and practical considerations. Scaling-up this approach could bridge HIV testing gaps if traditional healers are well supported, but referral procedures for sputum samples need to be improved to increase TB diagnoses.

PED415

Acceptability of the dapivirine vaginal ring for HIV-1 prevention among women who engaged in transactional sex

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Background: The monthly dapivirine vaginal ring has been found to reduce HIV risk with no safety concerns and acceptable to women. It received a recommendation from the World Health Organization in 2021, and regulatory submissions in sub-Saharan Africa are underway. To inform rollout, we assessed whether opinions of the ring differed among women who had engaged in transactional sex.

Methods: The MTN-020/ASPIRE phase III trial (2012-2015) was conducted among sexually active women aged 18-45 across 15 sites in Malawi, South Africa, Uganda, and Zimbabwe. Women were randomized to use a placebo or active ring and followed monthly for ≥1 year. Audio computer-assisted self-interviews (ACASI) captured history of transactional sex (having received money, goods, gifts, drugs, or shelter in exchange for sex in the past year) at enrollment and acceptability measures at product-use end visit (PUEV). Associations between recent history of transactional sex and acceptability measures were estimated using Poisson regression models with robust standard errors, adjusting for country, arm, and months of follow-up.

Results: There were 162 of 2,629 women enrolled (6%) who had recently engaged in transactional sex. Among these participants, the average age was 26 and 32% were married; 131 (81%) completed ACASI at PUEV. Most indicated the ring was 'usually comfortable' (90%), acceptable to their primary partner (67%), and were 'very likely' (66%) or 'likely' (30%) to use the ring in the future. About one-third minded wearing the ring during sex (36%) and during menses (34%). Women who reported recent transactional sex at enrollment were more likely to mind wearing the ring during menses (Adjusted relative risk [ARR] 1.2, 95% CI: 1.0, 1,4; p=0.04) or during sex (ARR 1.2, 95% CI: 1.0, 1.4; p=0.03) compared to those who had not.

Conclusions: The ring was acceptable to women who had engaged in transactional sex prior to enrollment, with most indicating likely future ring use. While further population-specific research is warranted, some women's acceptability challenges with using the ring during menses and sex may signal the need for exploration of these concerns and differentiated counseling tailored for women engaged in commercial or transactional sex, who are at highest risk for acquiring HIV.

PED416

Clinical outcomes during CUSTOMIZE: a hybrid III implementation-effectiveness study focused on implementation of cabotegravir plus rilpivirine (CAB+RPV) LA in US healthcare settings

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Background: CUSTOMIZE is an implementation-effectiveness study designed to evaluate implementation of cabotegravir+rilpivirine long-acting (CAB+RPV LA) for HIV treatment in diverse US healthcare settings and populations. This abstract reports the key clinical (secondary) endpoints.

Methods: This single-arm study enrolled virologically-suppressed people living with HIV infection to receive monthly CAB+RPV LA at 8 US clinics, representing diverse geography including the Southeastern USA. Adverse events were documented monthly; viral load and lab assessments were collected at Months 1, 2, 4, 6, 9, 12. Clinics recorded total time spent in clinic from patient check-in to departures at Months 1, 5, 11.

Results: 115 participants were enrolled, 109 received at least one CAB+RPV LA injection, and 102 completed Month 12; 6 withdrew prior to any injections. Participants were 87% male, 57% Caucasian, 37% Black, 26% Hispanic/Latinx. Mean age was 38.8 years and mean BMI 28.1. Among those with viral load data at Month 12 (n=102), 100% maintained viral suppression (<50 copies/mL); there were no virologic failures.

Overall, 95% (1076/1140) of injection visits were completed in the appropriate treatment window (+/-) 7 days from the target treatment date. Five participants missed visits due to COVID-19; all received oral therapy to maintain continuous ART.

Majority of adverse events (AEs) were injection site reactions (ISRs). Most ISRs were mild (Grade 1, 78%) or moderate (Grade 2, 18%) and most were reported as pain (69%). Two (2%) participants withdrew due to ISRs. Median total time spent in clinic at Month 1 (first injection visit) was 57 min (IQR: 47-70). Subsequent visits (injection-only visits) were shorter: median duration was 35 min (IQR: 24-48) at Month 5 and 34 min (IQR: 27-44) at Month 11.

Conclusions: In CUSTOMIZE, a study focused on implementation of LA antivirals in a variety of US healthcare settings, CAB+RPV LA was a highly effective HIV treatment in a diverse population. Many patients reported ISRs but few led to discontinuations. The few COVID disruptions were managed with temporary oral therapy, most participants received injections within the treatment window, time spent in clinic decreased over time, and 100% of participants reaching Month 12 maintained viral load suppression.

PED417

A multi-level qualitative analysis of factors influencing community demand for assisted partner services uptake in Western Kenya

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Background: Assisted partner services (APS) is an efficient, effective strategy for diagnosing people with HIV and linking them to care. Its real-world impact, however, relies on participant demand for APS and HIV testing. We explored factors affecting community-level demand for APS within an implementation science study evaluating integration of APS into HIV testing services in Western Kenya.

Description: From May-August 2020, we conducted in-depth phone interviews with APS providers (n=14), male (n=17) and female index clients (n=16) and stakeholders (n=20). Participants were identified using criteria-based purposive sampling and recruited from 8 of 31 study health facilities in Homabay and Kisumu counties.

Interviews assessed awareness, demand for APS, and factors influencing decisions to accept APS. Employing an inductive approach, two qualitative researchers collaboratively identified cross-cutting and diverging themes across participant type.

Lessons learned: Individual desires to remain healthy, live longer, take care of one's family, and engage in HIV care were important motivators of APS demand. Conversely, fear of HIV status disclosure and stigma from partners, peers and family, relationship dissolution, loss of financial support, and intimate partner violence, were seen as barriers. Gender expectations and dynamics influenced demand in multiple ways.

Women, due to the fear of losing financial support, reported that their male partners influenced their APS utilization and ability to make autonomous healthcare decisions.

Men perceived health services as being female-focused, creating less service uptake among them. Societal norms like polygamy were thought to enable men's ability to name multiple sexual partners without fear of being stigmatized; however, women were more likely to experience stigma if they reported more than one partner. Transport costs and opportunity costs of seeking healthcare were healthcare system factors that impacted APS demand.

Conclusions/Next steps: Personal stigma, interpersonal dynamics, and health system factors play important roles in impacting community-level demand for APS in Western Kenya. Stigma awareness and reduction, integrated patient-centered services that include men, and provision of affordable and accessible HIV services, have the potential to increase demand for APS.

PED418

Zero knowledge and high acceptability of long-acting injectable PrEP among adolescents men who have sex with men and transgender women in Northeast Brazil

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Background: Long-acting injectable PrEP (LAI-PrEP) is a promising technology to prevent HIV, but the knowledge and acceptance, particularly among adolescents' key populations (AKP) of men who have sex with men (MSM) and transgender women (TGW) are still scarce. We aimed to analyze the knowledge and acceptability of LAI-PrEP among AKP in Northeast Brazil.

Methods: A qualitative study conducted with 25 AKP aged 15-19 years old, sexually active, and HIV-negative (20 MSM and 5 TGW; 18 oral PrEP users, 7 users of other non- PrEP methods), nested in the PrEP1519 cohort study. Semi-structured interviews (17 face-to-face and 8 on-line) were conducted in the city of Salvador between June 2019-June 2020, classified and analyzed using NVIVO12.

Results: None of the participants had ever heard about LAI-PrEP before taking part of the PrEP1519 study, but acceptability was quite high among MSM as the majority referred a preference for LAI-PrEP compared to daily oral use (overall = 72%; PrEP users = 83% and non-PrEP users = 43%). Convenience and simplicity associated with not having to remember to take a daily pill were emphasized as reasons to prefer LAI-PrEP.

Other reported LAI-PrEP likes were on a positive impact on adherence and continuation and on a reduction in transportation cost to PrEP follow-up visits. In addition, AKP who are "very busy", "with multiple sex partners" and "engaging in commercial sex" considered LAI-PrEP more suitable because of their needs of short wait/visit times and fewer intake.

Reported dislikes were related to the fear of the needle or incorrect injection, while doubts focused on side effects and the efficacy of a new product. Most TGW reported low acceptability as they feel comfortable with the daily habit of PrEP use and someone is worried about the possibility to forget the appointment date of the following injection dose.

Conclusions: Acceptability of LAI-PrEP was high among adolescent MSM. Understanding the acceptability and choices of the forthcoming is key to ensure the development of demand creation strategies culturally appropriate and effective in the process of implementing this technology for AKP in Brazil.

PED419

Comparing the effectiveness of secondary distribution of HIV self-testing to testing card referral in promoting HIV testing among men who have sex with men in China: a quasi-experimental study

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Background: Secondary distribution is one social network-based method whereby individuals (indexes) access multiple HIVST kits and distribute them to their social networks (alters). This quasi-experimental study compared the effectiveness and cost of two social network-based HIV testing strategies (HIVST secondary distribution and HIV testing card referral) in promoting HIV testing among Chinese men who have sex with men (MSM).

Methods: MSM aged 18 years or older were recruited. From May to September 2019, indexes recruited during that period could distribute HIVST kits to their social networks. Indexes recruited from October 2019 to January 2020 could refer HIV testing cards to their social networks for free facility-based test.

Participants could access 1-5 HIVST kits or testing referral cards for distribution. Alters were encouraged to upload a picture of their test results and complete an online survey. Participants who completed the survey received $3 for incentive.

Results: Overall,106 indexes were recruited in the HIVST arm with mean age of 27 (SD=7.33) and 102 in the testing card arm were recruited with mean age of 28.7 (SD=6.74). At the one-month follow-up, 92 indexes in the HIVST arm self-reported having distributed self-test kits to 179 unique alters, and 62 in the testing card arm to 26 unique alters.

Additionally, 69/92 (75%) in the HIVST arm distributed any test to friends or sexual partners compared to 18/62 (29%) in the testing card arm, a risk difference of 46% (95% CI 31%, 61%). Indexes in the HIVST arm motivated 1.95 (SD=1.90) tests in average, compared to 0.42 (SD=0.78) in the testing card arm, with a risk difference of 1.53 (95% CI 1.09, 1.96).

Subgroup analysis suggested that indexes in the HIVST arm who self-identified as gay (p = 0.007) or previously tested for HIV (p = 0.02) are more likely to distribute. The HIVST arm had a higher total cost and higher case identification. The ICER between the two groups was USD$13563.

Conclusions: Secondary distribution of HIVST was more powerful in promoting social network-based HIV testing among Chinese MSM, although more cost-effective ways for implementation that takes into account the costs of HIVST, promotion, and personnel should be developed.

Operational challenges in implementing HIV services

PED421

Access to maternal health and prevention of mother-to-child HIV transmission services during the COVID-19 era in sub-Saharan Africa

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Background: In response to the COVID-19 pandemic, governments restricted travel and implemented modifications in service delivery during April-June 2020, while individuals changed behaviors to reduce risks. Impacts of these changes on essential health services such as maternal health and prevention of mother-to-child HIV transmission (PMTCT) services are not well-understood. We examined data from health facilities (HF) across 7 countries in sub-Saharan Africa (SSA) to assess trends in services.

Methods: We analyzed aggregate data reported quarterly from 467 HF in 7 countries between October 2019-September 2020 (88 HF in Burundi; 74 in Cameroon;192 in Democratic Republic of Congo; 36 in Eswatini; 1 in Kenya; 58 in Mozambique; and 18 in South Sudan).

For each country and quarter we calculated the number of pregnant women initiating care at antenatal clinics (ANC); number and proportion with HIV status determined and, for women living with HIV (WLHIV), number receiving antiretroviral therapy (ART) (Figure 1a-h).

Figure 1a-h. Number of pregnant women initiating care at ANC, proportion with HIV determined, and proportion of WLHIV receiving ART, by country and overall, by quarter (Q1: Oct-Dec 2019; Q2: Jan-Mar 2020; Q3: Apr-Jun 2020; Q4 Jul-Sep 2020)

Results: Overall 370,570 pregnant women initiated ANC services during the period, including 91,167 during October-December 2019 (Q1); 93,165 during January-March 2020 (Q2); 91,084 during April-June 2020 (Q3); and 95,154 during July-September 2020 (Q4).

Moderate declines in ANC attendance between Q2 and Q3 were observed in several countries, including Eswatini (Q2: 2063; Q3: 1822), Kenya (Q2: 642; Q3: 427), and South Sudan (Q2: 8846; Q3: 7817). High proportions of patients

had HIV status determined, including 94% in Q1, 97% in Q2, 98% in Q3, and 99% in Q4. ART for WLHIV was near-universal, with 98% of these patients in Q1 and Q2, 99% of in Q3, and nearly 100% in Q4 receiving ART.

Conclusions: A moderate decline in ANC attendance was observed during April-June 2020; coverage of HIV services remained high. With a resurgence of cases of COVID-19 in SSA, monitoring the impact on maternal health and PMTCT services is critical.

PED422

Understanding HIV and health care utilization among men in Gauteng, South Africa

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Background: Utilisation of HIV and health services amongst marginalised populations is critical to South Africa, achieving UNAIDS 95-95-95 targets. Studies show that men are underrepresented in health services, in particular HIV services. In this study, we describe health and HIV service utilization in a sample of men accessed outside of healthcare facilities.

Methods: A survey was conducted between October-November 2020. Men (≥18 years) were recruited from homeless shelters, parks, taxi ranks, factories and outside business parks in Johannesburg, South Africa. Descriptive analysis (using STATA 15) was used to characterize these men to understand their access and utilization of healthcare services.

Results: A total of 150 men participated, 103 (69%) were unemployed. The majority 121 (84%) reported using public clinics, 9(6%) used private healthcare services, 8(5%) hospitals, and 7 (5%) traditional health practitioners or avoided healthcare facilities. Whilst just over 60% of participants utilized healthcare services at least once in the last 12 months, 46 (38%) had not sought health services despite 26 (56%) reporting needing healthcare. Reasons for not accessing care included distance to the facility and cost. Long queues and poor staff attitudes were also reported (30% and 17% respectively) as barriers to accessing care.

	Category	Accessed care at least once in last 12 months (n=75)	Not accessed care in last 12 months (n=46)	Total (n=150)
Age	18-45 years	64(85%)	40(87%)	124(83%)
	46+	11(15%)	6(13%)	26(17%)
Employment status	Student/retired	4(5%)	0	4(3%)
	Formal sector	6(8%)	0	7(5%)
	Informal sector/ piece work/self-employed	15(20%)	16(35%)	36(24%)
	Unemployed	50(67%)	30(65%)	103(68%)
Residence status	Citizen/visa	62(83%)	34(74%)	121(81%)
	Migrant	12(16%)	11(24%)	26 (17%)

Table 1. Healthcare access by age, employment and residence status

Almost all participants 140(93%) reported testing for HIV at least once, the majority 91 (65%) tested within 12 months with the remainder testing more than a year ago. There were 75 (50%) participants who reported testing for COVID-19 and 121 (80%) reported they could access care if ill from COVID.

Conclusions: While a majority of the population had accessed healthcare services, over half of those who had not accessed care reported they had needed health services. Health facility issues such as poor staff attitudes and long queues remain a barrier to achieving this. Addressing these issues and maximising opportunities to engage men in healthcare is key to ensuring men are not underrepresented.

PED423

Impact of COVID-19 on Elton John AIDS Foundation projects for key populations in Eastern Europe and Central Asia: adaptive strategies and lessons learned

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Background: In 2020, the Elton John AIDS Foundation (EJAF) supported service-delivery projects for key populations (KPs) across nine Eastern Europe and Central Asia (EECA) countries. The COVID-19 pandemic posed significant risks to implementers' ability to maintain HIV prevention and care services for KPs, while presenting new economic, health and social challenges for project beneficiaries.

Description: To sustain supported interventions and adapt to new KP needs, EJAF, EECA's largest HIV philanthropic funder (FCAA,2020), worked with each implementing partner to reallocate resources and released additional funds for COVID-19 mitigation activities where most needed. EJAF's 'Lighthouse' projects in Russia's three largest cities (Moscow, St. Petersburg, Novosibirsk), which support NGO-led HIV service delivery for KPs in partnership with government HIV clinics from 2018-2021, showed that with effective re-programming, service coverage could be maintained and even increased. In March-November 2020, 'Lighthouses' provided outreach, testing, and linkage services to 25,310 KPs and their partners, 26% more than in the equivalent period in 2019.

Implementers across EECA adopted the following successful strategies:

1) COVID-19 personal protective equipment (PPE) to enable safe access to HIV services and enable mobility for most vulnerable KPs;

2) Increased gender-sensitive material support, including food, shelter and hygiene services, to respond to economic crisis for vulnerable KPs;

3) Innovative modalities, such as home-based HIV testing and on-line outreach;

4) Mobile ART dispensing to vulnerable PLHIV to ensure adherence.

Lessons learned: 1) Pre-COVID-19 investments in digital innovation paid off by allowing services to continue;

2) Amid COVID-19, KPs need basic life support to maintain demand for HIV services;

3) PPE enabled clients to maintain mobility in their communities, particularly where PPE is required but unaffordable;

4) Integrating COVID-19 and HIV prevention services allowed getting 'two birds with one stone', e.g. delivering masks alongside condoms;

5) COVID-19 has enabled some HIV-service improvement (e.g. home-based models), allowing projects to reach new KP sub-groups;

6) NGOs demonstrated their value-add and received pubic recognition from government partners amid restrictive civil society environment.

Conclusions/Next steps: Despite challenges, implementing partners' strategic creativity enabled effective continuation and in some cases improvement of community-led HIV services. Implementing partners will continue best practices that improve accessibility and quality of HIV services beyond the COVID-19 pandemic.

Uptake of HIV testing

PED424

Understanding the pathways leading to socioeconomic inequalities in HIV testing uptake among women in 4 sub-Saharan African countries: a mediation analysis

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Background: Despite large scale-up in HIV testing over the past years in sub-Saharan Africa, important socioeconomic inequalities persist. Understanding the different pathways between socioeconomic position and HIV testing could help design programs aimed at reducing inequalities.

Methods: We used cross-sectional data collected among women from recent Demographic and Health Surveys conducted in Côte d'Ivoire, Mali, Ethiopia and Kenya (2011-2018). Using a potential outcomes framework, different mediation models based on the product method were applied to explore pathways linking indicators of socioeconomic position (SEP, measured by education or wealth) and recent (<12 months) HIV testing uptake via proxy variables related to HIV testing demand or offer. Multivariable modified Poisson models were used to estimate natural direct and indirect effects, while accounting for exposure-mediator interaction when present.

Results: We analyzed data from 67,341 women aged 15-49 years. Both SEP indicators were significantly associated with HIV testing in all countries. These associations decreased for both SEP indicators after adjusting for some mediators (partial mediation) depending on the country: HIV-related knowledge (Côte d'Ivoire and Kenya), positive attitudes towards people living with HIV (Côte d'Ivoire and Mali), distance to facility (Ethiopia and Kenya), difficulty getting money for advice/treatment (Côte d'Ivoire, Ethiopia and Kenya) and difficulty getting permission to see a doctor (Ethiopia and Kenya).

The indirect effects of each mediator differed for each country and SEP indicator. The proportion mediated tended to be higher for demand-related than for offer-related mediators. Indeed, it was estimated at 2%-11% (education) and -2%-14% (wealth) for HIV-related knowledge, and at 6%-10% (education) and 1%-15% (wealth) for positive attitudes towards PLHIV, while for the three offer-related proxy variables it was always below 2%, with non-significant association with HIV testing in 10 of 24 models explored. Similar trends were found when repeating analyses on men, with higher proportions mediated by the demand-related proxy variables.

Conclusions: Our findings suggest that socioeconomic inequalities in HIV testing may be mediated by demand- more than offer-side characteristics. Overall, the lack of an identified strong, single mediator illustrates that inequalities may not be addressed by solely acting upon a single factor but must be tackled upstream.

PED426

Determinants of recent HIVST uptake among Jiangsu MSM: a cross-sectional survey

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Background: China adopted HIV self-testing (HIVST) to expand HIV testing among hard-to-reach key populations that may otherwise not test due to factors like stigma and discrimination. To help inform HIVST upscale plans, our study evaluated the recent use of HIVST among Chinese men who have sex with men (MSM) in Jiangsu province

Methods: We conducted an online survey from March and April 2020. Data on socio-demographic characteristics, HIV testing history, and attitudes towards HIVST were collected. Men biologically born males, 16 years and above, ever had anal sex with other men in the last 6 months, and ever tested for HIV were eligible for inclusion. Differences between participants who had ever self-tested and those who had never self-tested were evaluated using Pearson's chi-square test. Logistic regression was used to investigate associations between socio-demographic, sexual history, and HIVST experience between two subgroups. P-value < 0.05 was statistically significant.

Results: Of the total 692 eligible participants surveyed, 69.5% (481) were aged between 18-40 years, and 67.5% (467) self-identified as homosexuals. HIVST uptake was barely above average as only 65.9% (456) had ever self-tested. 16.6% (71/467) of self-testers and 14.4% (31/236) of non-self-testers were living with HIV (PLWH). 76.1% (54/71) of PLWH used HIVST for their first-ever HIV test and obtained reactive results. Sexual orientation disclosure to others (AOR=10.96, 95% CI 6.65-18.05) was associated with having ever self-tested. Additionally, having used HIVST for the first HIV test (AOR=1.97, 95% CI: 1.20-3.23) was associated with recent HIVST. HIVST being more private (AOR=1.53, 95% CI: 0.93-2.52) and not needing to go to a health facility (AOR=1.61, 95% CI: 1.17-2.22) were also factors associated with recent HIVST. Regardless of cited disadvantages, 84.3% (199) of never self-tested participants were likely to use HIVST if recommended by a healthcare provider or sexual partner.

Conclusions: HIVST uptake among Jiangsu MSM is still less than optimal and needs to be promoted. MSM who visit healthcare facilities should be encouraged to help in distributing HIVST kits to their sexual partners and peers. Moreover, healthcare providers should provide more information and recommend the use of HIVST to their key population clients.

PED427

Secondary data analysis investigating the effect of gender-based violence interventions on experience of violence and uptake of HIV testing among adolescent girls and young women, in KwaZulu-Natal, South Africa

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Background: Gender-based violence (GBV) against women is profound and widespread in South Africa, disproportionately affecting adolescent girls and young women (AGYW). Women with a history of violence have poorer health outcomes and are likely to acquire human immunodeficiency virus (HIV). Effective approaches to target GBV in the HIV context such as Stepping Stones and Vhutshilo 1 & 2 are in place, specifically designed to reduce GBV and consequently improve HIV and sexual health outcomes. This study explores if exposure to these aforementioned gender norms and violence prevention-related interventions reduces GBV and increases uptake of HIV testing services by AGYW aged 13-22 years in KwaZulu-Natal, South Africa.

Methods: A secondary data analysis was performed on data from a closed, longitudinal and randomly selected cohort of 3,010 AGYW, stratified by age (13-17 and 18-22 years) from the health and demographic surveillance system (HDSS) sampling frame in uMkhanyakude, KwaZulu-Natal, between 2017 and 2019. GBV intervention exposure, HIV testing, history of violence and sexual risk behaviours, among other factors were explored via baseline descriptive analysis. Logistic regression explored association between exposure to GBV interventions and experience of violence and use of HIV testing, by adjusting for relevant confounders.

Results: Univariate and multivariable models for association between exposure to GBV intervention and experience of violence were statistically insignificant (p= 0.260 and p= 0.670, respectively). However, univariate and adjusted logistic regression analysis indicate a significant increase in odds in testing for HIV among AGYW exposed to the GBV interventions, by 71% (OR: 1.71, 95% CI: 1.50-1.95, p<0.0001) compared to non-participants.

Conclusions: Findings suggest no significant difference among AGYW exposed to the intervention when exploring their experience of violence, compared to unexposed, which contradicts the theory. Significant results are seen when exploring AGYW's exposure to GBV interventions and use of HIV testing.

Although random sampling was used to reduce selection bias, possibilities for alternative bias such as social desirability bias, measurement bias and lack of causality push for further longitudinal studies to be conducted, with appropriate analysis, including time-to-event analysis, to be undertaken. Additional investigations should include rigorous evaluation of GBV interventions' effect on multiple HIV-related outcomes in KwaZulu-Natal.

PED428

Index testing as a cornerstone of HIV case identification: experiences from Tanzania

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Background: The UNAIDS benchmark for HIV testing is that 95% of people living with HIV know their HIV status by 2030. The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), through the USAID Boresha Afya North/Central Zone Project, implements index testing as one of core modalities of HIV case identification through HIV Testing Services (HTS).

Description: From October 2019 to September 2020, EGPAF supported index testing through implementing a package of four main interventions in 328 facilities:

(i) HTS to index contacts beyond work hours and weekends,

(ii) HTS at community points,

(iii) integrating intimate partner violence (IPV) risk assessment and mitigation, and

(iv) hands-on mentorship through peer champions and use of index contacts follow-up diaries, which shifts the burden of HTS from clients to service providers.

Outcome data of HIV case identification through index testing was extracted from annual program report and analyzed quantitatively using MS-Excel. Total index contacts (sexual partners and biological children) reached for HTS increased by 95% from 9,087 in October-December 2019 to 17,715 by July-September 2020, while cases identified increased by 144% from 1,184 to 2,893 within the same period. Yield among sexual partners was maintained between 20% and 22% from October-December 2019 to July-September 2020; while among biological children, yield was maintained between 4% and 6% from October-December 2019 to July-September 2020. By July-September 2020, index testing contributed to 46% of total positive cases identified as compared to 30% in October-December 2019.

Lessons learned: Fidelity of index testing improved after implementing direct site level support through supporting a package of services. Appropriate IPV risk assessment, active follow-up of appointments for testing index contacts, use of dedicated service providers and champions increased likelihood of reaching more index contacts and improved the quality of care.

Conclusions/Next steps: Expansion of the use of dedicated service providers and champions may further scale-up uptake of index testing and improve contribution of index testing to overall HIV case identification. Strengthening an enabling environment for service providers to provide index testing beyond work hours and weekends to capture those likely to be missed in usual business hours will be important.

PED429

Reaching males living with HIV though scale-up of index testing services: 8 countries in sub-Saharan Africa

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Background: As part of a strategy to improve HIV case finding, programs have increasingly prioritized HIV index testing services. This shift is envisioned to improve testing access for males living with HIV.

We examined index testing data from health facilities (HF) across 8 countries in sub-Saharan Africa to assess results among male and female clients.

Methods: We analyzed quarterly, aggregate data reported for adults and children between October 2019-September 2020 by 779 HF supported by ICAP at Columbia University through the US President's Emergency Plan for AIDS Relief.

This included 84 HF in Burundi, 52 in Côte d'Ivoire, 196 in Democratic Republic of Congo (DR Congo), 36 in Eswatini, 19 in Ethiopia, 1 in Kenya, 20 in South Sudan, and 371 in Zambia.

Results: Overall, 68,330 clients of HIV services were offered index testing, 61% (41,553) of whom were female (Table 1).

A total of 62,833 (92%) index cases accepted the services; they named an average of 2.1 contacts (132,308), a small majority of whom were male (68,551; 52%). Slightly more male (51,585, 75% of male contacts) than female (49,856, 78% of female contacts) contacts were reached and had their HIV status documented; among those eligible for testing, a slightly higher proportion of female (19%) than male (16%) contacts tested HIV+.

Across countries, one HIV-positive female contact was found for every 9.1 index cases, and one HIV-positive male contact was found for every 10.2 index cases. Wide differences in these measures were observed across countries.

Conclusions: While female clients represented a substantial majority of index cases, a majority of contacts named were male.

However, most contacts testing HIV+ were female, and results varied substantially by country. Further evidence is needed on index testing strategies for reaching men living with HIV.

PED430

Co-creation of a tailored U=U (undetectable=untransmittable) message to increase HIV testing in men in Western Cape, South Africa

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Background: Taking daily ART eliminates sufficient virus so that HIV is undetectable via viral load (VL) testing within 24 weeks. HIV-positive individuals with an undetectable VL cannot transmit HIV to sexual partners or through giving birth, this message is commonly referred to as U=U (undetectable equals untransmittable).

Since South African men have poorer HIV outcomes than women, we used interactive human centred design co-creation workshops to ask men to create a relatable U=U message aimed at increasing HIV testing and ART uptake in men from high HIV burden communities in Cape Town, South Africa.

Methods: Two facilitators explained the U=U message to men (n =39) attending the workshop and asked them how to effectively communicate the message.

Participants designed messages in the local language, isiXhosa, to assuage fears of testing HIV positive explaining that ART enables people living with HIV to live normal lives and to be "untransmittable" to their sexual partners.

Results: Participants emphasized three main insights in developing the U=U message:

1) "Introduce" the benefits of the antiretroviral pill,

2) positively redefine the man for whom the pill is intended, and

3) reframe the benefits of ART to be simple and straightforward for men to understand.

Country	Cases offered index testing (#, %F, %M)			Contacts identified (#, %F, %M)			% contacts with documented status (% of F, % of M)		% contacts known HIV+ (% of F, % of M)		Contacts with documented status newly tested HIV+ (F:#, % pos; M:#, % pos)				# cases to find 1 HIV+ F or M contact (F, M)	
Burundi	4553	*55%*	*45%*	9115	*54%*	*46%*	96%	94%	4%	3%	660	*14%*	506	*13%*	6.9	9.0
Cote d'Ivoire	7166	*63%*	*37%*	11809	*45%*	*55%*	89%	90%	3%	3%	664	*14%*	409	*7%*	10.8	17.5
DR Congo	13534	*58%*	*42%*	17326	*52%*	*48%*	86%	90%	2%	1%	1924	*25%*	2251	*30%*	7.0	6.0
Eswatini	2690	*65%*	*35%*	4715	*43%*	*57%*	59%	51%	47%	35%	180	*28%*	189	*21%*	14.9	14.2
Ethiopia	1083	*62%*	*38%*	2137	*44%*	*56%*	60%	59%	9%	19%	36	*7%*	58	*10%*	30.1	18.7
Kenya	2670	*62%*	*38%*	4482	*47%*	*53%*	87%	88%	28%	33%	189	*14%*	148	*10%*	14.1	18.0
South Sudan	4394	*62%*	*38%*	7855	*51%*	*49%*	43%	41%	4%	4%	239	*15%*	212	*14%*	18.4	20.7
Zambia	32240	*61%*	*39%*	74869	*47%*	*53%*	77%	72%	29%	32%	3627	*19%*	2930	*15%*	8.9	11.0
Total	68330	*61%*	*39%*	132308	*48%*	*52%*	*78%*	*75%*	*19%*	*21%*	7519	*19%*	6703	*16%*	9.1	10.2

PED429 Table 1. Index cases and contacts, by sex, October 2019-September 2020

In addition, men discussed fear around testing HIV+ and that this may change their lifestyle in terms of health, girlfriends/wives and partying/alcohol consumption. Men created a message to emphasise
1) "you cannot spread the virus (HIV) to the other person"
2) and "(the pill) keeps on killing the virus so I can live a normal life for the rest of my life."

Conclusions: Men who participated in the workshops co-created a U=U message to flip the HIV cascade to focus on addressing fears related to testing HIV positive and being on ART instead of simply promoting HIV testing. The participants emphasized introducing the positive effects of ART, positively redefining the men for whom the pill is intended, and keeping the message simple, focusing on normalizing having HIV through targeted U=U messages. Programs promoting testing, treatment, and viral suppression may benefit from co-creating tailored messaging with beneficiaries to improve the uptake of HIV services.

PED431

Improving HIV assisted partner services by eliciting additional partners after the initial encounter

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Background: The World Health Organization recommends assisted partner services (APS) to identify, test, and link to HIV care the sexual partners of persons newly diagnosed with HIV (index clients). Most APS programs elicit partners at the time of HIV diagnosis of index clients. We evaluated whether eliciting partners from index clients after the initial visit would identify additional sexual partners and improve APS outcomes.

Methods: Female index clients were offered APS at 31 health facilities in Kisumu and Homabay counties in western Kenya August 2019-March 2020. Indexes named male sexual partners both at HIV diagnosis and during routine HIV clinic visits over 14 months with counselors and clinicians. All partners were contacted and offered HIV testing. We compared characteristics of partners named during initial encounters with those named afterwards and determined if elicitation after the initial encounter was associated with new HIV diagnosis using multivariable Poisson regression.

Results: Overall, 3,429 male sexual partners were elicited from 872 index clients. At the indexes' initial visit, 2,166 (63%) partners were elicited and 1,760 (81%) were enrolled. After the initial visit, 1,263 (37%) partners were elicited and 959 (76%) enrolled; 237 (24%) were elicited by 3 months, an additional 225 (23%) by 6 months, and 497 (52%) after 6 months.
Partners elicited after the initial encounter were more likely to be above 34 years (69% vs 52%), in monogamous marriages (82% vs 75%) and engaged in high-risk sexual behaviors such as inconsistent/no condom use and multiple sexual partnerships (53% vs 41%) compared to partners elicited at the initial encounter (p<.001 for all).
Of 2,009 partners tested, 87 (6%) of those elicited at the initial visit were HIV-positive compared to 173 (26%) among those elicited later. Partners elicited after the initial visit were 4 times as likely to be newly diagnosed with HIV as those elicited initially (adjusted relative risk [aRR] 3.82, 95% CI: 2.94 – 4.98).

Conclusions: Eliciting partners for APS up to 14 months after HIV diagnosis increases new HIV diagnoses among partners and expands the types of partners reached. APS programs and HIV clinics should consider systematically eliciting additional partners during follow-up.

PED432

No one is left behind: community-based HIV services for key population members with hearing impairment

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Background: To scale up HIV services among transgender people and other high-risk key populations (KPs), Service Workers in Group Foundation (SWING) working in partnership with the USAID- and PEPFAR-funded EpiC project led by FHI 360, engaged with various popular opinion transgender leaders from all walks of life including transgender women with hearing impairment starting in October 2019.

Description: SWING started engaging with hearing-impaired transgender leaders through a national beauty pageant called Miss Deaf Queen Thailand and the Deaf Rainbow Club of Thailand. Deaf Rainbow Club members are interested in KP health services, including HIV services and hormone-level monitoring, but have difficulty accessing these services through formal health care sector providers. Therefore, SWING customized its community health centers to facilitate services for clients with hearing challenges. First, SWING trained its staff on working with hearing-impaired clients and partnered with Thai Communications Relay Service Centre to provide relay translation via mobile phones. Next, SWING hired a staff member with hearing impairment to help facilitate clinic services and to assist in production of health communications materials for those with hearing challenges.

Lessons learned: In October 1, 2019 - December 20, 2020, SWING provided HIV testing to 40 hearing-impaired KP clients, including 19 men who have sex with men (MSM), 13 transgender women (TGW), three male sex workers (MSWs), and five female sex workers (FSWs), none of whom had ever previously been tested. Among these, seven MSM (37%), two TGWs (15%), and three MSWs (100%) tested positive. All HIV-positive clients were assisted to successfully initiate antiretroviral treatment. While the total number of hearing-impaired clients tested was low, the case-finding rate was much higher compared to other KP clients tested during the same period (30% versus 7%), excluding FSWs for whom no positive cases were detected among either group.

Conclusions/Next steps: Key population members with disabilities such as hearing impairment experience vulnerability that may contribute to increased risk; at the same time, they face challenges accessing health care services at multiple levels relating both to KP status and disability. It is crucial for HIV programs to conduct more targeted interventions to ensure these groups are able to access appropriate HIV services.

PED433

Assisted partner services is effective at HIV case-finding among people who inject drugs in Kenya

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Background: People who inject drugs (PWID) are at increased risk for both HIV and hepatitis C (HCV). Assisted partner services (APS), while safe and efficient for identifying and testing partners of people living with HIV (PLHIV), has not been used extensively among PWID and has rarely been used to identify partners with HCV. We determined whether we could use APS to find, test for HIV and HCV, and link to care the injecting and sexual partners of HIV-positive PWID in Kenya.

Methods: We recruited index participants (indexes), defined as PLHIV who injected drugs in the previous year, through needle and syringe programs in Nairobi, Mombasa, and Kilifi. Indexes provided contact information for partners from the previous 3 years and peer educators attempted to contact all partners by phone or community tracing. Health providers notified partners of potential exposure and offered HIV and HCV counseling and testing. APS efficacy was determined by calculating the number of indexes needed to interview (NNTI) to find a:

1) new HIV case;
2) PLHIV not on treatment; and,
3) HCV-positive partner.

Results: To date, 670 indexes have enrolled and named 2,202 partners. Of named partners, 1,975 (90%) have been traced and enrolled, of whom 392 (20%) were HIV-positive. Among HIV-positive partners, the majority (82%) reported being on treatment, 58 (15%) were unaware of their status, and 13 (3%) were aware but not on treatment. NNTI was 11.6 per newly HIV-diagnosed partner, and 9.4 per PLHIV not on treatment (including newly diagnosed). HCV antibody was found in 128 (19%) indexes and 249 (13%) partners. Among HCV seropositive participants, 84 (28%) knew their status, and 42 (11%) had been treated. NNTI to find an HCV-positive partner was 2.7.

Conclusions: APS is an effective strategy for finding and testing partners of PWID for both HIV and HCV. 20% of enrolled partners were HIV-positive, of which nearly 20% were unaware of their status or not on treatment. 13% of partners were HCV seropositive. Guided by ethical protocols, APS can be used to promote HIV and HCV testing and engagement in care among PWID in Kenya.

PED434

Factors associated with uptake of HIV self-testing among adolescents' men who have sex with men and transgender women enrolled in the PrEP1519 cohort study in Brazil

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Background: HIV screening in healthcare facilities face several obstacles when offered to adolescents' key population, including a lack of confidentiality, stigma, and discrimination. Thus, HIV self-testing (HIVST) is recommended as an alternative choice to increase early HIV diagnosis among adolescent's key population of men who have sex with men and transgender women (AKP). We aimed to investigate the factors associated with uptake of HIVST among AKP in Brazil.

Methods: Data from the first PrEP demonstration cohort study among sexually active AKP aged 15-19 years old ongoing in Brazil (PrEP1519). Eligible participants were enrolled between March 2019- December 2020 in three large Brazilian capital cities (Salvador, Belo Horizonte and Sao Paulo). PrEP1519 team offered HIVST to all participants (899) throughout the follow-up at PrEP clinics or at online PrEP1519 platforms. A socio-behavioral questionnaire was applied and multivariate analyses were performed using logistic regression with adjusted odds ratio (aOR) and 95% confidence intervals (95%CI).

Results: The uptake of HIVST among the 899 AKP was 46.4%. Out of those, most were 18-19 years old (79.5%), MSM (92.6%), identified as a homosexual (71.4%), black or mixed-race (67.9%), and attended high school (63.6%). Factors associated with HIVST uptake were black or mixed-race (aOR=1.38, 95%CI=1.01-1.90), receptive anal intercourse with a casual partner (aOR=1.38, 95%CI=1.03-1.84), and experienced sexual violence (aOR=1.65, 95%CI=1.19-2.28).

Conclusions: Despite a moderate proportion of HIVST uptake among the AKP, the odds of uptake were higher among those who are in a context of social and individual vulnerability. Early HIV diagnosis should be expanded to this population group and HIVST most likely will contribute to the expansion especially among black AKP and those at higher risk of HIV infection. Finally, we recommend that an HIVST should be part of the HIV combination prevention program in the Brazilian National Health System.

PED435

HIV testing in jails: comparing strategies to maximize engagement in HIV treatment and prevention

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Background: HIV testing is not standard in U.S. jails despite 15% of entrants having undiagnosed HIV infection. Previous studies show that it can be cost-saving. Maximizing the yield and speed of HIV testing in detention facilities could promote rapid entry/re-entry into care. The D.C. Department of Corrections (DC DOC) offers opt-out HIV testing at entry and transitioned from rapid point-of-care (POC) testing to laboratory-based antigen/antibody (Ag/Ab) testing in September 2019, providing an opportunity to study optimal jail HIV testing strategies.
Methods: In this retrospective cohort study, we used aggregate historical data to compare two study periods: rapid POC testing (January 2019 to August 2019) and laboratory-based Ag/Ab testing (October 2019 to January 2020). We calculated the rates of testing and result received per month across each time period and conducted interrupted time series (ITS) analyses to assess the difference between each phase.
Results: During period one, 4,012 rapid POC HIV tests were performed among 14,143 entrants for a testing rate of 28.4%. All entrants received their HIV test results, whether positive, negative, or indeterminate, due to the rapid testing strategy. During period two, 3,191 Ag/Ab tests were performed among 9,365 entrants for a testing rate of 34.2%. The predicted probability of accepting an HIV test increased significantly after the transition to Ag/Ab testing (IRR: 23.2%, 95% CI: 2.5% to 48.0%), but the likelihood of receipt of test results decreased (IRR: -14.8%, 95% CI: -19.4% to 10.1%).
Conclusions: We demonstrate that rapid POC testing greatly enhanced the ability for persons to receive test results. Given tremendous, quick churn in jails, the type of test performed is important. Utilizing both rapid POC and laboratory-based Ag/Ab testing might maximize test uptake, receipt of test results, detection of infection among all PLWH, and implementation of prevention interventions for those who test negative.

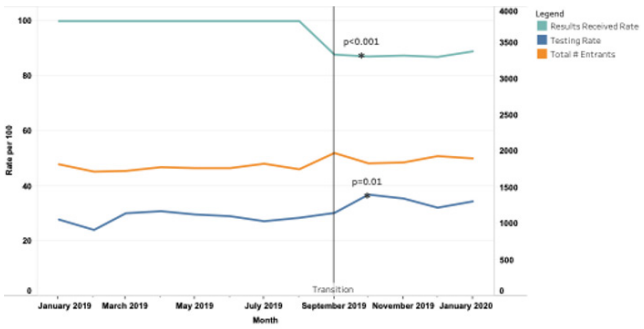

Figure 1. Total number of entrants and rate of HIV testing, and results received, Washington D.C. Department of Corrections Jail, 2019-2020.

Update of HIV prevention

PED436

Socioeconomic inequalities in the access to HIV prevention and care services in sub-Saharan Africa

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Background: Despite HIV prevention is playing a key role in controlling HIV epidemic in sub-Saharan Africa (SSA), socio-economic inequalities are reported as serious obstacle to reach prevention program targets. Measuring these inequalities over a continuum of HIV primary and secondary prevention indicators and over a large set of countries is needed to monitor them and inform potential interventions.
Methods: We used data from Demographic and Health Surveys conducted in 18 SSA countries between 2010 and 2018. We defined seven HIV-related indicators aimed at capturing access to and uptake of HIV prevention and care services among adult participants. Country-specific wealth-related inequalities were measured using the Relative Index of Inequalities (RII) and were then averaged across countries using random-effects meta-analyses. We compared the levels of inequalities between Western-Central versus Southern-Eastern African countries using the Wilcoxon rank-sum test.
Results: The sample consisted of 358,591 adult participants (66% women). Despite the variability in inequalities between countries and indicators, the meta-analysis reported significant average levels of inequalities for 6 out of 7 analysed HIV-related indicators. For instance, the richest participants were five times more likely than the poorest to report condom use at last sexual intercourse (RII=5.02 [95% confidence interval: 2.79-9.05]). The richest participants were about twice more likely than the poorest to have good HIV-related knowledge (RII=2.45 [1.91-3.14]), to have a positive attitude towards people living with HIV (RII=1.99 [1.57-2.53]), to report having accessed prevention of mother-to-child transmission services (women only, RII=1.70 [1.20-2.43]), to report being medically circumcised (men only, RII=2.08 [1.38-3.15]), and to report recent uptake of HIV testing (RII=2.43 [1.47-4.04]). We observed no significant relative inequalities in the report of unique sexual partner in the past year (RII=0.99 [0.98-1.00]). Overall, inequalities tended to be larger in Western-Central versus Southern-Eastern African countries. Results were quite consistent in a sex-stratified analysis or when measuring absolute, instead of relative, inequalities.
Conclusions: Despite efforts to scale-up HIV-prevention programs, socioeconomic inequalities remain substantial over the continuum of HIV primary and secondary prevention in several SSA countries. Further efforts are needed to address inequalities in the design, monitoring and evaluation of HIV-prevention programs.

Adherence to HIV treatment

PED437

Effectiveness of an enhanced patient care (EPC) intervention on viral suppression among patients living with HIV in Kenya

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Background: Effective patient-centered interventions are needed to promote patient engagement in and adherence to HIV care. We assessed the impact of a patient-centered intervention referred to as Enhanced Patient Care (EPC) on viral suppression among patients living with HIV in Kenya.

Methods: This pilot randomized control trial was conducted in two rural HIV clinics within the Academic Model Providing Access to Health care (AMPATH). The EPC intervention incorporated continuity of clinician-patient relationship, enhanced treatment dialogue and improved patients' clinic appointment scheduling. Provider-patient communication (PPC) training was offered to all clinicians in the intervention site.

Study eligibility included: being on first line antiretroviral regimen and virally unsuppressed (≥400 copies HIV RNA/ml). We targeted 360 virally unsuppressed patients:

1) 240 in the intervention site with 120 randomly assigned to Arm A (PPC training + EPC) and 120 to Arm B (PPC training + standard of care),

2) 120 in the control site (Arm C).

Our primary outcome was viral suppression (<400 copies HIV RNA/ml) at 6 months, and our secondary outcome was appointment adherence defined as having had a clinical appointment within seven days of a scheduled clinic date. Our analyses applied difference in difference (DID) and chi-square to compare proportions at baseline and endline.

Results: A total of 328 (91.1%) were enrolled: 110 (92%) Arm A, 110 (92%) Arm B, 108 (90%) Arm C. Mean age of participants was 48.2 years (SD: 12.05). The majority were females (55.8%), married/coupling (60.4%), and had least a primary level of education (82%). Compared to Arm C, there was an increase in PPC scores in Arm A (DID 0.227; 95% confidence interval [CI], 0.052-0.403) and Arm B (DID 0.209; CI, 0.031-0.387).

There were significant differences (p=<0.001) across the three study arms in terms of viral suppression: Arm A 81(84.4%), Arm B 87(83.7%), Arm C 67(64.4%). The intervention had no significant impact (p=0.341) on patient appointment adherence: Arm A 104(98%), Arm B 97(95.1%), Arm C 99(94.3%).

Conclusions: PPC training may have had the greatest impact on patient viral suppression. Efforts to ensure providers receive adequate training is fundamental to achieve desired patient outcomes. More rigorous studies are however needed.

PED438

An assessment of multi-month dispensing of antiretroviral therapy for children and adolescents across 10 African countries

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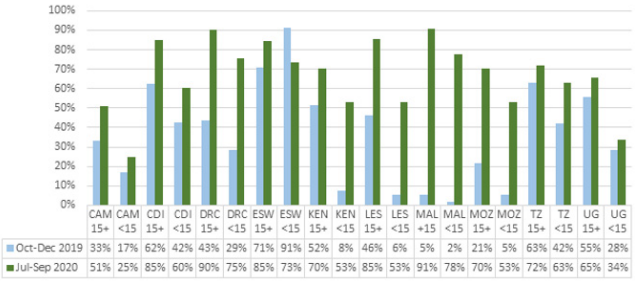
Background: Multi-month dispensation (MMD) allows people living with HIV (PLHIV), including children and adolescents ≤15years (CALHIV), to obtain treatment for longer periods, reducing frequency of facility visits and patient volume. Informed by national policies, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) supports implementation of MMD for both CALHIV and PLHIV. In light of the COVID-19 pandemic and subsequent response, transitioning patients to MMD became an important strategy to ensure clients remain on ART.

Methods: We analyzed routinely reported PEPFAR-program data from October 2019-September 2020 from 10 countries in EGPAF-supported regions (Cameroon, Cote d'Ivoire, Democratic Republic of Congo, Eswatini, Kenya, Lesotho, Malawi, Mozambique, Tanzania, Uganda). MMD regimens were defined to include 3-5 months and >6 months dispensation. The proportion of PLHIV currently on treatment receiving MMD was calculated by taking the total reported number of PLHIV currently on treatment for each 3-month period and dividing by the number of PLHIV on an MMD regimen. Data was disaggregated by age (≤15 and >15 years) and country.

Results: The proportion of clients on MMD increased across countries from October2019 to September2020 for both PLHIV and CALHIV populations. Malawi and Mozambique experienced the highest increase of CALHIV clients on MMD over the 12-months, with proportions increasing from 2% (n=232) to 91% (n=10,854) and 5% (n=734) to 53% (n=6,120) respectively. The proportion of CALHIV on >6 month MMD across countries increased from 10.6% to 14.6% by September2020. This proportion for PLHIV (>15 years) increased more steeply from 10.2% to 28.7% over the same period.



	CAM 15+	CAM <15	CDI 15+	CDI <15	DRC 15+	DRC <15	ESW 15+	ESW <15	KEN 15+	KEN <15	LES 15+	LES <15	MAL +15	MAL <15	MOZ 15+	MOZ <15	TZ 15+	TZ <15	UG 15+	UG <15
Oct-Dec 2019	33%	17%	62%	42%	43%	29%	71%	91%	52%	8%	46%	6%	5%	2%	21%	5%	63%	42%	55%	28%
Jul-Sep 2020	51%	25%	85%	60%	90%	75%	85%	73%	70%	53%	85%	53%	91%	78%	70%	53%	72%	63%	65%	34%

Figure. Estimated percentage of clients currently on treatment on MMD regimen by country and age group

Conclusions: The estimated proportion of CALHIV on MMD was lower compared to adults across countries. There was increased momentum of transitioning adults to MMD compared to CALHIV over time. There was an increasing trend of transitioning clients to >6 month MMD. The changing policy landscape could have contributed to this increase.

PED439

Improving viral load suppression rates among HIV positive children and adolescents through directly observed treatment swallowing (DOTS): a case control evaluation in Fortportal region in Uganda

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Background: Children and adolescents living with HIV (caLHIV) have challenges in achieving and sustaining suppressed viral loads. Literature about the effect of directly observed swallowing (DOTS) of anti-retroviral therapy (ART) in these categories is limited.
We describe viral load outcomes of children who were observed swallowing their HIV medicines daily compared to standard of care in Fortportal region, Uganda.
Methods: Virally unsuppressed children and adolescents within the July-Sept 2019 quarter within Kabarole and Bunyangabu districts (considered as cases) were enrolled on the home-based DOTS program starting March till June 2020 (3 months). Facilities that contributed 80% of the unsuppressed caLHIV were included in the program.
Expert clients supporting their fellow clients in care within the respective health facilities were identified to support each of the children and adolescents. Each expert client was facilitated with a transport fee of 0.9 USD (3000 UGX) per day for the 3 months period.
Secondary data of other virally non-suppressed caLHIV who were on facility-based Intensified Adherence Counselling (IAC) from within and around the evaluation sites were abstracted to form the control group. We compared the odds of being suppressed after DOTS or IAC in both groups (DOTS vs IAC).
Results: A total of 88 and 104 virally unsuppressed Children and Adolescents Living with HIV (CLHIV) formed cases and controls respectively and of these 87 cases and 94 controls were used in the final analysis (ignoring lost, transfer outs and those still on IAC). Majority (56%, 102/181) were female, with a mean age of 11years (SD=4.1). Mean log CD4 count before DOTS or IAC was 8.71 (SD=1.78) and 8.62 (SD=1.78) for controls and cases respectively. CLHIV who received daily community DOTS were two times more likely to re-suppress compared to CLHIV that received the conventional facility DOTS [OR: 2.43, 95% CI: 1.28-4.60, p=0.006].
Conclusions: Daily observance of swallowing HIV medications in children and adolescents was feasible and led to better viral re-suppression. We recommend a large-scale evaluation with modified home visits by the expert clients to assess the effect and cost effectiveness of this intervention at program level.

PED440

Improving viral suppression among children and adolescents on antiretroviral therapy in Nampula province, Mozambique

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Background: Early access to optimized antiretroviral therapy (ART) regimens for children living with HIV (CLHIV) is essential to reducing morbidity and mortality. In August 2019, the pediatric ART optimization policy was implemented, including transition of children who weighed >20kg to dolutegravir (DTG)-based regimens and children <20kg with previous exposure to prevention to child transmission interventions (PMTCT) to boosted lopinavir (LPV/r)-based regimens. National stock challenges delayed the implementation of transition to LPV/r-based regimens for children <20kg regardless of their PMTCT exposure, until November 2020. In October 2019, Nampula province, in northern Mozambique, had only 37% of CLHIV who achieved viral suppression (VS). We assessed VS among children and adolescents after implementation of the pediatric ART optimization.
Description: ICAP supports the Nampula Provincial Health Services and 59 health facilities (HFs) to strengthen stock management and transition of CLHIV to optimized regimens using targeted tools and intensive monitoring. From October 2019 to December 2020, ICAP monitored ARV stocks at HF-level weekly and stock and consumption at provincial-level monthly. HF teams monitored transition of CLHIV to optimized regimens daily, flagging patient files prior to clinical consultation, and weekly, tracking the trends. Monthly reviews of longitudinal high viral load registers enabled identification of CLHIV with no clinical follow-up, fast-tracking patients to optimized regimens or second-line.
In addition, ICAP developed a flipchart for use during clinical consultations and by peer educators and mentor mothers at waiting areas and during home visits with practical demonstrations to guide caregivers on provision of LPV/r formulations.
Lessons learned: There was a 111% increase in optimized regimens among CLHIV in Nampula between October 2019 (918/2010) and December 2020 (2819/2925). Between October 2019 and December 2020, VS increased 36% to 44% among CLHIV 1-4 years, 41% to 62% among 5-9 years, and 45% to 71% among 10-14 years.
Conclusions/Next steps: Increased access to optimized regimens was associated with increased VS among all age groups. Despite these improvements, limited availability of LPV/r granules in country has impacted VS in young children. Further efforts are necessary to enhance uptake of optimized regimens among CLHIV including adequate provision of LPV/r granules for younger CLHIV.

PED441

Relationship of depression with ART adherence and HIV treatment outcomes amongst women living with HIV in India

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Background: Depression among women living with HIV (WLHIV) has been linked to worse health outcomes and poorer antiretroviral therapy (ART) adherence globally, however little data exists for WLHIV in India. The present study was conducted in a large care and support program for PLHIV (Vihaan) to assess the association of depressive symptoms with ART adherence and HIV treatment outcomes among Indian WLHIV.

Methods: A cross-sectional descriptive survey was undertaken in 2020. WLHIV, aged 18-45, who had undergone CD4 and HIV viral load testing within the past 1 month were sampled (N=302) from eight of Vihaan's care and support centres and ART centres from four states of India. Information on depression (using Patient Health Questionnaire (PHQ-9)), anxiety (General Anxiety Disorder-7), socioeconomic characteristics, and food security, and ART adherence (self-report) was collected telephonically. Treatment outcomes of viral load and CD4 counts were extracted from Vihaan databases and linked to survey data. Descriptive and inferential statistic tests were used to analyze the data.

Results: Overall, depressive[VP1] symptoms was found in 10% of the women. Majority (86.7%) of the women with depression experienced food insecurity (*p<0.01*) [VP2] and 43.3% had lack of food daily *(p<0.001)*. Increasing depression scores were significantly associated with increasing anxiety (*p<0.001*), food insecurity (*p<0.001*) and detectable viral load (*p<0.05*). Current ART use was lower (56.7%) in WLHIV with depression *(p<0.001)*. Poorer ART adherence was associated with increasing depression and increasing food insecurity (all *p<0.001*).

Conclusions: Among WLHIV in India, depression was associated with poorer ART adherence, increased HIV viral load, and food insecurity. There is a need to incorporate mental health services and schemes to improve food security as integral components of HIV care programs in India.

PED442

Clinical and psychosocial determinants of adherence: results from the MaxART clustered randomized stepped wedge trial of early access to ART

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Background: Early Access to ART for All (EAAA), or equivalently, the "Treat All" policy, has been widely adopted across sub-Saharan Africa. The MaxART trial was implemented to determine the impact of EAAA versus the then-standard-of-care (SoC) on retention and viral suppression in Eswatini, with results reflecting strong support of EAAA scale-up. However, with an increased number of people eligible for ART without a corresponding expansion of the health care workforce, and in light of social factors that arise in a resource-limited country where HIV is highly stigmatized, ART provision may be negatively affected. This study assesses the impact of EAAA, as well as other clinical and psychosocial factors, on clinic visit adherence.

Methods: MaxART was conducted between 2014 and 2017 in 14 government-managed health facilities, with one pair transitioning from SoC to EAAA at each 4-month interval. Clinical and social science survey data were linked to assess the joint effect of clinical and psychosocial determinants on visit adherence. Adherence was defined as attending a visit on or before the scheduled appointment date. Generalized estimating equations, accounting for clustering at the facility and participant level, were used to assess the repeated measure of adherence throughout follow-up. SoC participants were censored at clinic transition to avoid survivor bias and ensure causal interpretations of the findings.

Results: The study included 1273 visits across 202 participants, with an adherence rate of 73%. In the multivariate-adjusted model, EAAA had no impact on visit adherence (OR=1.05, 95% CI=0.91-1.20). Factors that increased adherence included higher baseline viral loads (OR=1.15, 95% CI=1.07-1.23), having felt pressured to start ART by health care providers (OR=1.15, 95% CI=1.02-1.30), being in a relationship (OR=1.04, 95% CI=0.01-1.06), and living with people who know about their treatment (OR=1.07, 95% CI=1.00-1.15). Factors that decreased adherence included being TB-positive at baseline (OR=0.60, 95% CI=0.21-0.86), having longer transport times to health facilities (OR=0.93, 95% CI=0.97-1.00), and feeling better after starting ART (OR=0.92, 95% CI=0.88-0.98).

Conclusions: EAAA implementation had no effect on visit adherence. Attention should be paid to the factors that decrease visit adherence in countries with similar HIV epidemics and health systems when implementing EAAA.

PED443

High viral suppression among clients with high viral load after implementing multifaceted interventions in a clinic setting in Eswatini

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Background: In January to December 2019, at Bulandzeni clinic 18/47 (38.3%) clients with high VL were not recorded in high VL register, and 15/29 (51.7%) recorded in the register were not managed according to Ministry of Health guidelines.
Description: From January to June 2020, the clinic implemented several strategies to improve management of clients with high VL. A VL focal person was appointed to list clients without VL results two to four weeks after drawing a sample, obtain VL results from the laboratory, and record all clients with VL>1000 copies/mL in the VL register. A minimum of three stepped up adherence counseling (SUAC) sessions one month apart were provided to clients with high VL. Counselling was provided by a team comprised of an ART nurse and by health facility-based and community-based expert clients. Cases of clients with high VL were also discussed during multi-disciplinary team (MDT) meetings held every two weeks to develop client-specific interventions. For clients with a persistent high VL after SUAC, an ART doctor from a nearby hospital and EGPAF Senior Clinical Advisors were consulted on possible switching of ART.
Lessons learned: The health facility traced and recorded all VL results for the 47 clients; 43/47 (91%) were receiving first-line ART regimens and 4/47(9%) were on second-line. 6/47 (13%) were children 0-19 years. All clients received SUAC and 42/47(89%) completed all sessions. After SUAC 39/47(83%) of the clients had suppressed VL on subsequent testing; 38/39 (97%) were on first-line ART and 1/39 (3%) on second-line. Among those who were on first-line, 27/38 (71%) suppressed their VL to <1000 copies/mL following SUAC and 11/38 (29%) suppressed following switching to a second-line regimen. All 6 (100%) children 0-19 years suppressed VL after SUAC with 1 suppressing after switching to second-line. Among the 8/47 (17%) clients without a suppressed VL outcome; 3 remained unsuppressed, but active in care, 1 was transferred to a health facility closer to their home before completing SUAC, 2 died and 2 were lost to follow-up.
Conclusions/Next steps: Effective tracking of results and tailored short-term counselling can result in high suppression rates among clients with high VL.

Retention in HIV services

PED444

Exploring the impacts of COVID-19 on engagement in care among postpartum women living with HIV in Durban, South Africa

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Background: COVID-19 and efforts to manage widespread infection may compromise engagement in HIV care, especially in low-resource settings. Given that postpartum women are already at heightened risk of HIV care attrition, it is important to assess whether the pandemic has further impacted access to HIV care appointments, medications, and infant care services in this population.
Methods: Publicly available questions about COVID-related experiences disseminated by social scientists in the early stages of the pandemic were added to a longitudinal cohort study assessing predictors of postpartum attrition from HIV care. Participants (N = 266) responded to these questions when completing a study visit (6, 12, 18, or 24 months postpartum) between June 1, 2020 and Nov 30, 2020. We assessed history of COVID-19 testing and concerns about contracting the virus. We also calculated the percentages of women who had trouble (1) making or keeping their HIV care appointments, (2) procuring their HIV medications, (3) procuring contraception, and (4) accessing immunization services for their infants.
Results: 253 (95.1%) women reported taking a COVID-19 test, and 2 (0.7%) received a positive result. Among participants who were not diagnosed, 70% (n = 183) were extremely concerned about contracting the virus. 8.2% (n = 22) of the sample reported challenges making/keeping HIV care appointments, 4.9% (n = 13) reported difficulties accessing HIV medications, 7.5% (n = 20) reported problems securing contraception, and 5.2% (n = 14) indicated challenges accessing infant immunization services. Overall, 20.7% (n = 55) reported at least one of the challenges described above; common reasons for these challenges included reduced transportation options, limited availability of non-COVID services, contraceptive stock-outs, lack of financial resources, fear of being stopped by police, and HIV stigma.
Conclusions: Over 95% of the women in this sample were tested for COVID-19, and about one in five participants reported challenges accessing care, medications, or services. Given the dynamic nature of the pandemic and the identification of a new, more transmissible strain of the virus in South Africa at the end of 2020, ongoing assessment of pandemic-related barriers among postpartum women and other vulnerable populations is needed to avoid care disruptions.

PED445

Improved retention to HIV care and viral suppression among PLHIV through community home based care in Vihiga County, Kenya

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Background: Treatment Care and Support for People Living with HIV (PLHIVs) main focus is to enable achievement of 95% retention into HIV care and 95% viral suppression for those on HIV treatment [1].

Vihiga County's viral load suppression is at 93% which is still below the Kenya Strategic Framework II target of 95% [2].

The county has a retention rate of 81% for patients on HIV care and treatment. Priority groups that contribute significantly to reduced retention and viral suppression include adolescents, men; TB/HIV co infected patients and the newly diagnosed clients. OGRA Foundation, under the Global Fund for HIV, has implemented community home based care intervention in Vihiga County to improve retention and viral suppression.

[1] Kenya AIDS Strategic Framework II 2020/21-2024/25

[2] Kenya HIV Estimates report, 2018

Description: The project identified 6307 (33% male and 67% female) PLHIV receiving care in Vihiga County including defaulters, newly diagnosed clients, HIV/TB co infected patients, pregnant & lactating mothers as well as adolescents and men.

The clients were linked to the respective community health volunteers (CHVs) who had been trained on community home based care. The CHVs conduct monthly home visits where they provided counseling & psychosocial support on treatment adherence, positive living, address stigma & discrimination as well as providing community differentiated care for stable clients.

They maintained bidirectional referral and linkages with the health facilities including referral for index client testing. Each CHV is assigned at most 20 clients whom they retain under their follow up for 12 months and thereafter visit quarterly.

Lessons learned: Out of the 6307 PLHIV under the home based care program in January 2020, a total of 6295 (99%) were retained in care over 12 months. This was higher than the average retention in the county of 81% over the same period. 96% of the clients under the program achieved viral suppression compared to 93% average for the county.

Conclusions/Next steps: Community home based care has an important role in improving retention to HIV care and viral suppression for those on HIV treatment. Line listing priority clients is key in reaching the most needy PLHIVs.

PED446

Examining structural barriers to optimal HIV care engagement: is neighborhood of residence a risk factor for HIV patient attrition?

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Background: Persons living with HIV (PLWH) can be assigned to one of three healthcare utilization classes: "Adherent," "Non-adherent," and "Sick", based on a prior latent class analysis. Relationships between socioeconomic indicators, latent class membership, and the dynamics of movement between these classes remain to be explored

Methods: A three-latent class model was previously derived based on healthcare utilization indicators (emergency department visits, clinic attendance, hospital admissions, and HIV viral suppression) of PLWH who presented at least once for HIV care at Duke between 2009-2013.

Social Deprivation Index (SDI) scores, an aggregate score of seven socioeconomic factors, were assigned to each patient based on residence address. Logistic regression was used to assess the association of patient-level covariates (age, sex, race, and SDI score) with class membership. Latent transition analysis was used to examine associations between these covariates and movement between classes over time.

Results: In our cohort(N=2019), results indicate that relative to being in the "adherent" class: young patients (age<40) were more likely to be in the "non-adherent"(OR 2.35, 95% CI 1.70-3.27) class. Female patients were more likely to be in the "non-adherent" or "sick classes. Whites were less likely to be in the "non-adherent" or "sick" classes. Patients in the top decile of SDI scores (worst neighborhood conditions) were less likely to be in the "non-adherent"(OR 0.23, 95% CI 0.08-0.64) class and more likely to be in the "sick"(OR 2.07, 95% CI 1.32-3.23) class. Patients in the top decile of SDI were more likely than others to transition out of the "adherent" class to either the "non-adherent" or "sick" classes, and less likely to transition out of the "sick" class.

Conclusions: Living in adverse socioeconomic conditions and age<40 years were associated with membership in the "non-adherent" class of healthcare utilization, a class previously associated with falling out of HIV care. Furthermore, patients living in disadvantaged neighborhoods were more likely to transition into the "sick" class and less likely to transition out of this class.

Understanding the association of these patient-level determinants with class membership is important to design targeted interventions to prevent disengagement from HIV care and improve clinical outcomes.

PED447

Community-based ART refilling centers as a strategy to prevent LFUs: learnings from the Care and Support Centres (CSC) in India

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Background: Since the start of free Anti-Retroviral Treatment (ART) in Government Anti-Retroviral Therapy Centers (ARTC), preventing Lost to follow up (LFUs) for treatment has been an important activity to improve quality services to PLHIV. Due to various reasons such as timings of the ARTCs, a long distance from home, long queue in ART, etc has lead to increased LFUs. Several strategies have tried to decrease the LFUs including the delivery of medicine through CSCs. The present work brings the learnings from community/CSC based ART refilling.

Description: National Care Support and Treatment (CST) Program, Vihaan, PLHIV Community lead CSCs are established for providing holistic care and support to improve the quality of life and decrease the mortality of PLHIV registered with ARTCs in India. These centers provide gender-sensitive, discrimination-free, convenient timings. Etc.

Currently, 310 CSCs serving 1.4M PLHIV registered with 575 ARTC. ARTC clients LFU reasons study shown 15.60%- inconvenient time, 5% distance, 2.30% long queue, 12.80% fear of status disclosure, stigma and discrimination, etc. Since April 2019, as a model, to decongest ARTC & to improve the accessibility, NACO started decentralizing the ART refilling through CSCs.

Being a community lead model, without stigma client visits the CSC at a preferred time to refill the ART that effectively decreased the LFU and increased the ART adherence. Currently, 1951 PLHIV receives services of refilling from 26 CSC in 5 states.

Lessons learned: The models showed improved access and decreased LFU to 1% in the model CSC-ARTCs when compared to the national average of 13% LFU. The community lead model facilitated enabling environment avoiding stigma and discrimination to fearless access to medication. The decentralized refilling model decreased the load of stable clients at ARTC, thereby increased the quality time to be catered to the newly initiated and poor adherence clients by the providers at the ARTCs.

Conclusions/Next steps: Based on the learning and outputs, NACO is going to expand the Community based ART refiling to all the CSCs, other CBOs, in the Vihaan phase 4 implementation.

PED448

Addressing disengagement from HIV healthcare services in Khayelitsha, South Africa, through Médecins Sans Frontières' *Welcome Service* approach: comprehensive clinical and patient-centered care

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Background: Many people living with HIV experience competing psychological and socioeconomic challenges that impact their ability to remain on antiretroviral therapy (ART) lifelong, magnified by disorganized clinic systems, stigmatizing attitudes towards 'difficult' patients and delays in clinical management. Recognising the need to tackle these challenges, Médecins Sans Frontières and the Western Cape Department of Health developed a differentiated service to support long-term ART engagement by creating a more streamlined and client-centered approach to care.

Description: The *Welcome Service,* implemented at a primary healthcare clinic Khayelitsha, a low-income area in South Africa with a high HIV prevalence, focused support on patients returning after *disengagement* (interrupted ART or missed appointments). Clinic services were reorganised and training conducted to (1) reduce delays in ART re-initiation and unsuppressed VL management; (2) re-organise triage to streamline services; (3) improve counseling with additional tools to manage barriers to engagement; and (4) address negative healthcare worker (HCW) attitudes and authoritarian behaviours.

Lessons learned: Re-organising triage prevented returning patients from waiting longer to be seen than other patients and flagged acutely unwell patients requiring urgent care. Training provided HCWs with knowledge and tools to manage 545 disengaged patients (July 2018-October 2019) through focused identification of client-specific challenges. However, high staff turnover set back gains, highlighting the difficulty with sustaining a programme long-term. This reflected in modest retention at 5-12 months (60%) and poor one-year VL completion (49%) and suppression (51% of complete, <50 copies/ml). A reluctance to change clinical practice with local guideline updates was noted, largely due to staff motivation and buy-in. Addressing HCW's stigmatizing attitudes proved challenging and required constant re-engagement. A parallel programme (*Risk of Treatment Failure*), supporting clients with detectable VLs, complicated *Welcome Service* rollout. Recognising that both programmes supported clients having difficulty with ART, the two were merged to provide one service for 'struggling' patients.

Conclusions/Next steps: Modest retention and VL suppression were seen amongst this group, where poorer outcomes may be expected than amongst stable clients on ART, highlighting the need to continue developing scalable strategies to tackle disengagement. As we continue rolling out this intervention, adaptation to clinic needs is essential to long-term success and sustainability.

PED449

Long-term patterns of postpartum engagement in HIV care among women living with HIV in Cape Town, South Africa

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Background: Postpartum women living with HIV (WLHIV) are vulnerable to loss from care. Few data exist on long-term engagement patterns in this population.

Methods: The MCH-ART study enrolled WLHIV entering antenatal care in Gugulethu, South Africa 2013-2014. Routine electronic medical records through June 2019 (minimum four years postpartum) were used to determine ART interruptions (no evidence of ART visit, ART dispensing, CD4 or HIV viral load test) and return to care (RTC) in 6-month (m) windows from delivery (0) to 48m. Unique, linked folder numbers accounted for movement between clinics across the Western Cape. Generalised estimating equation (GEE) models examined predictors of being in versus out of care in all windows.

Results: Among 1296 women included (83% of 1554 MCH-ART participants), 57% initiated ART at enrolment. At 6-12m, 37% (n=475) had interrupted ART, increasing to 44% (n=576) at 18-24m. Thereafter the proportion out of care stabilised and 5-7% of women RTC or had new interruptions in each window (Figure). In GEE models (9072 observations), women who initiated ART in pregnancy were less likely to be in care than women previously on ART (aOR 0.91 95% CI 0.87-0.95). Compared to women who had remained in care in the previous 6m, women who RTC (aOR 0.94 95% CI 0.91-0.98), had a new interruption (aOR 0.71 95% CI 0.69-0.73), or remained out of care (aOR 0.68 95% CI 0.67-0.70) in the previous 6m had increased odds of being out of care in the subsequent window.

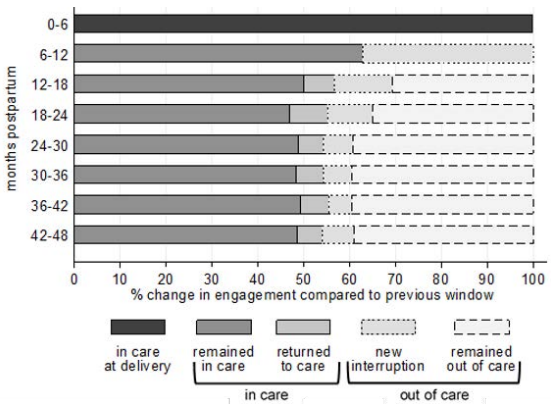

Figure.

Conclusions: Most interruptions occurred in the first 24m postpartum and a small but consistent proportion of women continued to cycle in and out of care in the study period. Previous interruption was an important predictor of being out of care, even among women who RTC in between. Interventions are urgently needed to support sustained engagement and re-engagement in HIV care postpartum.

PED450

Outcomes of multi-month dispensing on continuation for pre-exposure prophylaxis: findings from a longitudinal surveillance study in Kenya

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Background: Since the release of WHO recommendations in 2015, countries globally are progressively scaling up oral PrEP, as exemplified by the increasing number of new PrEP initiations. However, the majority of new PrEP clients discontinue their PrEP use within the first three months, with frequent clinic visits for PrEP refills documented as a barrier. We examined the impact of multi-month dispensing (MMD) on PrEP continuation through Jilinde, a PrEP scale-up project in Kenya.

Methods: Using a longitudinal surveillance design, four purposively-selected PrEP delivery sites implemented MMD to eligible PrEP clients during their routine revisits using an opt-in approach. Two and three-months' PrEP supply were offered during the first and second clinical revisit, respectively. Clients opting out were provided monthly refills according to the standard of care. Dispensing data routinely collected by PrEP providers were used to compute continuation rates. A PrEP refill within 97 and 187 days of scheduled return at 3- and 6-months post-start served as a proxy for continued PrEP use at Month-3 and Month-6, respectively. Bivariate and multivariate logistic regression analyses were used to identify independent predictors of continuation.

Results: Between February and December 2019, 714 clients initiated PrEP; 168 (24%) opted for MMD and 546 (76%) for monthly refills. Continuation was higher at Month-3 and -6 for MMD vs. monthly refills (75% vs 50%, and 20% vs. 12%), respectively. Receiving MMD was associated with significantly higher odds for PrEP continuation at Month-3 (aOR: 2.17; 95%CI: 1.41, 3.34; p<0.001) but not Month-6 (aOR: 0.84; 95%CI: 0.50, 1.40; p=0.507). PrEP continuation at Month-3 was associated with being married (aOR: 1.53; 95%CI: 1.08, 2.16; p=0.018), enrolment through outreach (aOR: 2.60; 95%CI: 1.65, 4.09; p<0.001) and through peer networks (aOR: 2.92; 95%CI: 1.97, 4.32; p<0.001). Similarly, continuation at Month-6 was associated with being married (aOR: 2.58; 95%CI: 1.62, 4.10; p<0.001), enrolment through outreach (aOR: 13.11; 95%CI: 5.39-31.87; p<0.001), and through peer networks (aOR: 10.30; 95%CI: 4.19, 25.31; p<0.001).

Conclusions: These findings suggest that MMD is associated with higher PrEP continuation, but was complemented by social support networks and delivery of services within the proximity of beneficiaries. These areas need further investigation through controlled studies.

PED451

Scaling up multi-month dispensation (MMD) of antiretroviral therapy in response to COVID-19 in Zambia

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Background: In Zambia, scale up of differentiated service delivery (DSD) models have helped the country achieve the second of the UNAIDS 90-90-90 targets. However, following Zambia's first reported COVID-19 case in March 2020, COVID-19 has threatened recent gains in antiretroviral therapy (ART) scale up. To maintain ART services for PLHIV during the COVID-19 pandemic, we scaled up Multi-Month Dispensation (MMD) of ART for ≥3 months (3MMD) for newly diagnosed PLHIV and up to 6 months (6MMD) for stable PLHIV in care.

We hypothesized that MMD uptake would increase during COVID-19, and that treatment interruption would decrease for those who did, versus did not, receive 6MMD.

Description: We used an interrupted time series design and Poisson regression modeling to evaluate our hypothesis before and after March 2020 using routine data from care recipients in 82 health facilities in Lusaka Province and 24 in Western Province. To scale MMD programmatically, we introduced infection prevention measures and called patients to come to clinic or have a home delivery to receive 3MMD (for new patients) or 6MMD (for stable patients). We defined "uptake" as the proportion of patients who received ≥3 months of MMD at each monthly window between January, 2018-July, 2020 and "treatment interruption" as any late ART distribution made 28 days or later from the scheduled pharmacy appointment.

Lessons learned: We reviewed 1,283,726 records from 191,246 patients ranging in age from 15—65 years (median= 35.4, IQR = 28.0_42.9), with 63.0% being female. After March 2020, 6MMD increased 18% (RR=1.18; 95% CI: 1.11, 1.26; p<0.001). After adjusting for confounding by seasonality, the effect remained statistically significant (RR=1.19; 95%CI:1.10, 1.28; p<0.001). Patients who did not receive 6MMD had 3.9 times the odds of experiencing a treatment interruption than patients who did receive 6MMD (OR=3.9; 95%CI: 3.78, 4.11; p<0.001).

Conclusions/Next steps: To improve treatment access during COVID-19, we scaled up 6MMD, resulting in increased uptake of this DSD model over a 5-month period, which resulted in fewer treatment interruptions for PLHIV. These results show that rapid deployment of DSD models like 6MMD can help maintain essential HIV services during emergencies such as the COVID-19 pandemic.

PED452

Policy changes in Honduras to ensure access to treatment in the context of COVID-19 and two hurricanes

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Background: In Honduras, the COVID-19 pandemic combined with damage from two hurricanes that struck the country in November 2020 led to unprecedented disruptions of the country's health system and reduced capacity to address HIV/AIDs.

Prior to the pandemic, health care for people living with HIV/AIDS (PLWHA) was exclusively face-to-face, and dependent on PLWHA visiting a limited number of health facilities. The country lacked mechanisms to allow for health services at the community level.

Governmental policies implemented in response to the pandemic, including suspension of public transport and a national curfew, meant many PLWHA could not travel to health facilities to receive their ARV treatment, increasing by 30% the percentage of cases lost to follow-up. Additionally, COVID-19 restrictions had a damaging effect on living conditions of PLWHA, with an estimated 84.3% reporting difficulties obtaining food.

Responding to these crises, the Ministry of Health implemented several measures to ensure access to care for PLWHA.

Description: Key policy changes included:

Coordination between municipalities, government agencies, and civil society organizations, including organizations with existing connections to key populations (particularly LGBTI organizations) for the delivery of ARVs. Between March and December 2020, ARV deliveries were made to 4,184 people.

Follow-up via telephone and social media to monitor health status and coordinate service delivery. 1,094 people received follow-up by telephone, and 3,636 people by social media.

Delivery of food rations to prioritized groups, including older adults living with HIV, with 568 bags of food rations delivered to families of PLWHA.

Lessons learned: Multi-sectoral coordination is essential for implementing contingency plans to maintain care in the context of large-scale disasters.

The implementation of care models including ARV home delivery, appointment spacing, and involvement of community actors, made it possible to bring services directly to PLWHA during the pandemic. As a result of these interventions, there was a demonstrated increase in people restarting ARV treatment (102% in the second semester of 2020 as compared to the first semester).

Conclusions/Next steps: It is important to develop and implement an immediate response protocol for HIV care to use in major crises. Actors in the HIV sector should be included when planning responses to such scenarios.

PED453

Using community-led monitoring to hold national governments' & PEPFAR HIV programmes accountable to the needs of people living with HIV for quality, accessible health services

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Background: With just 10 years to UNAIDS' global target of "95-95-95", persistent accessibility and quality of HIV treatment and prevention services challenges must be corrected. Service delivery quality indicators like retention, viral load suppression, and advanced HIV disease show many countries are failing to strengthen weak HIV service cascades. Community-led monitoring (CLM) is an innovative response to this crisis. People living with HIV (PLHIV) and other communities directly impacted by poor quality services routinely collect and analyze evidence from sites and patients directly and identify root causes of poor outcomes (e.g. rude treatment by staff). CLM trains, supports, equips, and pays members of directly affected communities to carry out routine, ongoing monitoring of the quality and accessibility of HIV treatment and prevention services and uses those data to highlight performance problems, generate solutions, and hold decision-makers accountable to fix them.

Description: CLM is a continuous cycle: communities 1) gather evidence on the state of HIV and health services, 2) analyze data, 3) generate solutions, 4) engage duty bearers to adopt solutions and 5) advocate for change if solutions are not adopted. Differentiating CLM is the use of evidence-based advocacy: evidence is used by PLHIV, key populations, and other direct users of HIV services to hold national governments, PEPFAR, and the Global Fund accountable.

Lessons learned: Ritshidze (Tshivenda for "Saving our Lives") was built to address South Africa's persistent HIV retention crisis. Ritshidze monitors more than 400 sites in 27 districts across 8 provinces, focused on the poorest performing clinics representing >50% of people on treatment. Data generated is used to hold duty-bearers accountable including health department officials at all levels, and PEPFAR. Ritshidze training, monitoring, and advocacy materials are being used and adapted in developing CLM programmes in several countries.

Conclusions/Next steps: Systemic challenges undermine access to quality services for PLHIV, as shown by variable country progress in treatment retention and viral load suppression. Ritshidze's model of independent CLM shows promise as an innovative approach to holding the duty-bearers accountable to the priorities of the communities of service users, using community-generated evidence and advocacy based on that evidence.

Indicators of quality of care

PED455

Comparative analysis of unannounced standardised patient surveys and regular exit surveys in assessing quality of HIV care in Zambia

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Background: Mounting evidence suggests that sub-optimal patient experiences in HIV care (e.g., unfriendly interactions with health care workers [HCW], long wait times, lost laboratory results) contribute to disengagement from care. Surveys of exiting patients, however, are susceptible to information and social desirability biases. Standardised patients (SPs, "mystery-clients") may represent a more valid method for measuring poor patient experiences and represent a widely usable approach to improving systems.

Methods: In 12 government-operated HIV clinics in Lusaka, Zambia, we assessed patient experience among both patients exiting care who had no previous exposure to the instrument and SPs who underwent a single training session on the survey contents. The instrument contained 11 items on patient experience (e.g., waiting times, communication, respectful providers). HCWs were blinded to whether patients had received training. We compared trained and untrained responses of 11 binary measures (Fig1.) using mixed-effect Poisson regression, adjusting for age and sex and reported differences in the presence of each item.

Results: Among 1176 participants receiving antiretroviral therapy who participated in the exit surveys, 920 were untrained (56% female, median age 40 (IQR:33-47)) and 256 were trained SPs (58% female, median age 37.5 (IQR:31-47)). Trained SPs reported overall more critical assessments of experience (Fig 1.).

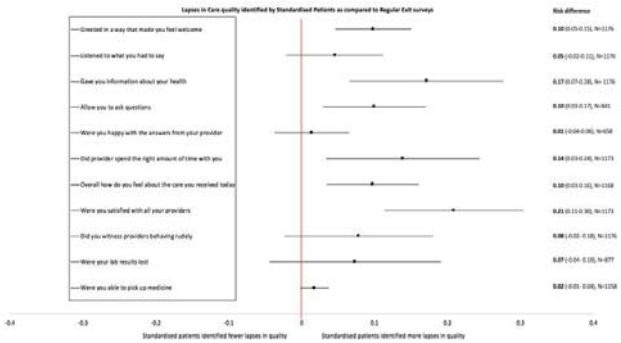

Fig 1. Forest plot comparing responses from Standardised patients relative to Regular exit surveys on 11 measures of clinic experience. Regular exit survey responses are the reference and indicated by the red line at 0. Adjusted for age, sex and modelled allowing for random effects at the facility

For example, SPs reported increased prevalence of patients feeling unwelcome by providers (risk difference [RD]: 0.1 [95% CI:0.05-0.15]) and of not being allowed to ask questions (RD: 0.1 [95% CI:0.03-0.17]).

Conclusions: Patients who received a brief training provided more critical appraisal of care either because they were more alert to the items solicited or felt empowered to be more critical. We trained actual patients rather than true "mystery clients" who are often drawn from outside of the true patient population, thereby making reproducibility in routine settings more feasible. Trained SPs represent an important method for assessing quality of care received in HIV settings.

Use of e-health/m-health

PED456

Can digital HIV self-testing (HIVST) be the next paradigm for self-testing? A systematic review of global evidence

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Background: In line with UNAIDS targets to end HIV by 2030 and WHO HIV self-testing (HIVST) recommendations, HIVST deployment and integration in health services is an emerging priority. Digital HIVST is defined as use of digital interventions (e.g., website-based, social media, mobile HIVST applications (apps), text messaging, digital vending machines) to improve the efficiency and impact of HIVST. Following COCHRANE methodology, we conducted a systematic review to inform policy recommendations and close the knowledge gap.

Methods: We searched all literature on PubMed and Embase for the period February 1, 2010 to December 1, 2020. We assessed all outcomes (i.e., uptake, acceptability, HIVST, kit return rate, linkages to care, etc.) across at-risk populations. Data were narratively synthesized as heterogeneity of interventions and diversity of outcomes precluded a meta-analysis.

Results: Of 39 studies reviewed, 28% (11/39) were RCTs and 72% (28/39) were observational studies. About 49% of studies (19/39) evaluated websites (e.g., study websites, videos, chatbots), followed by social media (31%, 12/39), text messaging (10%, 4/39), apps (5%, 2/39), and vending machines (5%, 2/39). A significant proportion of HIVST users (range: 30%-51%) were first-time HIV testers. High uptake (up to 95%) was reported for websites and apps. Acceptability, defined as willingness to use digital HIVST, was high (77%-97%). HIVST kit return rates (54%-94%) increased with text messaging reminders/prompts. Most importantly, linkage to care was high (53%-100%). Linkages to care were initiated for HIV positive and negative self-testers.

Conclusions: In the context of the current COVID-19 pandemic, digital HIVST is a timely and convenient strategy for hard-to-reach and at-risk populations. Mobile apps and website-based counselling were effective in reaching populations in diverse settings. Digital HIVST reported successes in increasing uptake, acceptability, participant preference, kit return rates, and in linking participants to care. The overall evidence suggests that digital HIVST is well poised to become the new paradigm for HIVST.

PED457

Participants' perceptions on a nurse-led IVR system for ART adherence support in Kampala, Uganda

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Background: In 2016, the Ministry of Health guidelines for prevention and treatment of HIV, advised use of phone calls and text messages to support ART adherence, in Uganda. We aimed to explore participants' perceptions towards involvement and usage of a Nurse-led interactive voice response (IVR) tool 'Call for Life Lite'(CFL), implementation project.
The IVR provides monthly clinic appointment reminders, weekly pill reminders, health messages, adherence calls and self-reported symptom option through a toll-free telephone number.
Methods: This qualitative study, approved by School of Medicine Ethics Committee, was nested in a nurse-led IVR implementation project at a Health Facility in Kampala. In 2019 we recruited PLHIV who had been on IVR for 12 months, conducted four Focus Group Discussions (FGD) (N=28). Six months later we followed-up with in depth interviews (N=10). The interviews were audio recorded, transcribed verbatim, NVivo software used for coding. A thematic content approach was used for analysis.
Results: There were 19 women in FGDs and 6 in IDIs stratified by duration on ART (<2 years; > 2 years) and age group (15-24 years; 25 and above). We found: taking ART is a challenge due to forgetting to take drugs, stigma, missing facility appointments and losing hope. Most were comfortable using the tool with reported benefits of IVR including; remembering to take drugs and attending appointments on time, widened health knowledge and receiving professional advice on symptoms. Most patients liked the privacy through use of the secret pin, the uniqueness and friendly voice-tone.
Almost all PLHIV reported not differentiating services offered by doctors and nurses on the system. There were mixed feelings on how to sustain the system with many willing to pay between 0.05 USD and 2.7 USD per month for CFL.
Conclusions: Among the factors that promoted adherence, the friendly welcome note *"Hello friend"* during the call coupled with the soft kind voice had a lasting impact of encouragement on participants who view it as a sign of care and comfort. Notably, emphasis should be put on a financially inclusive sustainability management plan to accommodate all patients.

PED458

Pivoting the use of e-Health & mHealth: assessing impact of peer via phone eservice delivery interventions on adherence, retention in care, viral load uptake and final infant outcomes during COVID-19

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Background: While the COVID-19 pandemic spread globally in early 2020, potentially catastrophic impacts on health for those living with HIV served by already overburdened health systems were predicted. mothers2mothers (m2m) supports 10 African countries and to curb the effects of the pandemic, we rapidly pivoted to develop and deliver an electronic service (eService).
Methods: m2m developed an eService platform, a component of which, termed Peer via Phone (PvP) refers to support provided telephonically. PvP was designed through the DHIS2 mobile tracker capture application, where m2m Peer Mentors were equipped with smartphones to perform guided, scripted, and free flow calls to clients. m2m has thus far rolled out PvP in nine of ten countries in which we operate (Angola, Ghana, Kenya, Lesotho, Malawi, Mozambique, South Africa, Uganda, and Zambia), and implemented in 31 provinces, 54 districts, and 293 health facilities. This comprises 94% of m2m health facilities. DHIS2 data from all countries were analysed looking at key indicators including infant final test uptake, ART pick-up and adherence to treatment support, viral load testing, and uptake of eServices by clients with phone access. A timeline snapshot of our data looking at the average performance before (Jan-Mar 2020), and during COVID-19 (Apr-Dec 2020) in all 9 countries was analysed.
Results: Analysis indicated that for infant final test result uptake, m2m achieved & maintained a 97% result; for ART pick-up and adherence to treatment support, 83% of HIV+ women picked up their ART according to schedule pre-COVID and 85% after COVID, with an average adherence scoring of 97% throughout the observation period; for viral load testing, m2m ensured that 60% of our clients had a VL test pre-COVID and 65% during the pandemic, and finally uptake of the PvP eServices by clients with phones increased from 93% to 100% by the end of the observation period.
Conclusions: Through strong relationships with key stakeholders, m2m was able to pivot timeously to ensure continued support during the pandemic. Established peer mentor-client relationships facilitated high uptake of the PvP service and early data confirms the continued achievement of key health outcomes for mothers and infants in m2m programs.

Adaptations of HIV treatment services during COVID-19

PED459

Outreach points fill HIV service gaps while health facilities were closed in Harare, Zimbabwe, August-December 2020

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Background: COVID-19 related travel and other restrictions, compounded by a health-worker strike in Harare, Zimbabwe, reduced access to antiretroviral therapy (ART) refills and other critical HIV services. In July 2020, 27 of 43 Harare facilities, serving 54,605 (50%) patients on ART, closed. We describe the results of a community outreach program to provide ART and other HIV services while reducing COVID-19 exposure to health workers and clients.

Description: ZimPAAC provides human resources and technical assistance to the Zimbabwe Ministry of Health and Child Care (MOHCC) to support HIV services in 43 Harare facilities. Starting in August 2020, with input from PLHIV-association members, we identified 23 community sites, primarily open spaces, community halls and schools as outreach locations. ART patients were notified of the outreaches by phone calls, text messages and through PLHIV organisations.

Outreach points were staffed by nurses, primary counsellors, and data-entry assistants. Sites adhered to COVID-19 prevention measures and provided services outdoors. Based on number of clients on ART, outreach points operated 1-3 days per week. Program outputs were captured from MOHCC registers.

Lessons learned: From 17 August to 18 December 2020, 29,330 ART clients (64% women) were seen at 406 outreach sessions (mean 72 clients/session; range 5-170).

Of the clients supplied, 95% were registered at the host facility. In line with increasing multi-month dispensing, 15,679/29,330 (53%) of clients received 3-5 months of medicines and 10,376/29,330 (35%) received 6 months.

Of clients eligible 3,741 (99.6%) received TB preventive treatment and 8,656 (99.9%) had viral load testing. Among clients issued viral load results, 335/3,357 (10%) had high viral load and all received adherence counselling.

Of 302 HIV tests done, 15% were confirmatory for reactive HIVST, 88 (30%) were positive and all were initiated on ART. Prophylactic medicines were supplied to 642 HIV exposed infants and 77 samples collected for early infant diagnosis.

Conclusions/Next steps: Community-based outreach can be an effective approach for providing HIV services while reducing COVID-19 risk, even in urban settings. Engaging PLHIV in selection of sites can optimize utilization. Communication through mobile phones is an important mechanism for informing PLHIV of the availability of outreach services.

PED460

Impact of COVID-19 on the HIV care continuum in the United Kingdom

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Background: The UK is often considered a model for differentiated service delivery, with UNAIDS 90:90:90 targets exceeded since 2018. The success of the care continuum can be attributed to collaborations between the National Health Service, public health bodies and a whole-system approach for service provision which includes civil society and social care.

Our study aims to describe how the HIV care continuum and service delivery models have been affected by COVID-19.

Methods: This study integrates evidence from community involvement, grey literature, a survey of people living with HIV (n=236) and interviews with healthcare workers, charities and peer-led community-based groups (n=14). The evidence is assessed in relation to the HIV care continuum and changes in service delivery.

Results: COVID-19 has reframed the HIV care continuum. Firstly, reduced HIV testing resulted in fewer diagnoses, and those newly diagnosed were unable to benefit from peer support during lockdown.

Secondly, the shift to remote HIV clinics and support groups has renewed concerns over privacy, confidentiality, and digital exclusion. Linkage, engagement, and retention in care were affected by the fear of acquiring COVID-19; some clients disengaged whereas others re-engaged with care.

Well-functioning service models were disrupted by redeployment of staff, and regular monitoring of viral suppression was interrupted. Postal deliveries of ART increased but concerns were voiced about poorer adherence among vulnerable groups.

Finally, health-related quality of life has been challenged by widespread financial and food insecurity, social isolation, loneliness, and the exacerbation of other health issues including mental health. Nevertheless, multi-agency partnerships have attempted to address inequalities through rapid, innovative solutions that support people living with HIV, including the most vulnerable.

Conclusions: HIV services in the UK have adapted to the situation caused by COVID-19 through collaborative efforts in and between the public sector, charitable and community-based organisations.

However, COVID-19 has undoubtedly affected all aspects of the HIV care continuum, the magnitude of which can only currently be estimated. Adaptations to HIV services have accelerated previously proposed and actual changes, some of which will likely be retained in the future.

PED461

Circumventing COVID-19 challenges while expanding access to HIV services: lessons from the Nigeria Antiretroviral Therapy (ART) Surge, February–September 2020

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Background: To reach UNAIDS 90-90-90 targets, CDC-Nigeria initiated an Antiretroviral Therapy (ART) Surge in 2019 to find and link 350,000 people living with HIV/AIDS (PLHIV) to treatment. COVID-19 threatened to interrupt Surge progress. To overcome this disruption, CDC-Nigeria quickly adapted Surge strategies during February–September 2020.

Description: Nigeria reported its first COVID-19 case in February, and by April, Surge strategies to expand HIV services while mitigating COVID-19 transmission were developed, disseminated, and implemented. Strategies included community case-finding using personal protective equipment, expansion of community-based index testing, immediate community-based linkage to ART via starter-packs (first ART dispensation), expansion of starter-packs from 14 days to 3 months, "touchless" ART distribution through community drop-offs, and broadened access to multi-month dispensing (MMD) (3–6 months ART) among PLHIV established in care prior to the reporting week. Weekly data reporting through an Excel-based dashboard facilitated program monitoring.

Lessons learned: During April–September 2020, the number of PLHIV initiated on ART per week increased from 2,077 to 5,329 (Figure 1). The percentage of newly-identified PLHIV initiating ART with 3-month MMD increased from 63% to 98%. The percentage of on-time ART refills improved from 88% to 98%. The percentage of PLHIV established in care on less than 3-month MMD declined from 22% to 4%. HIV service delivery best practices included virtual provision of tracking and tracing activities for client retention, ART adherence counseling, and COVID-19 mitigation messaging.

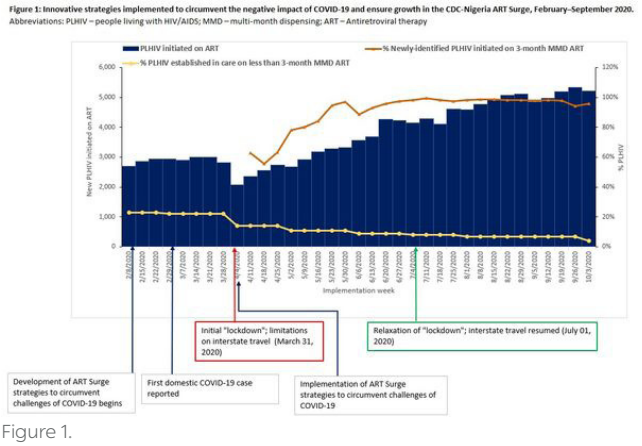

Figure 1.

Conclusions/Next steps: A rapid and flexible HIV program response, guided by principles of keeping PLHIV and staff safe while ensuring delivery of lifesaving ART, was critical in overcoming COVID-19-related disruptions to the ART Surge. Next steps are to analyze retention and viral load suppression among PLHIV initiating or continuing ART via community-based MMD to demonstrate that these innovations facilitate favorable clinical outcomes. This response could be adapted to mitigate disruptions to other Nigerian public health programs.

PED462

Improving retention of HIV clients in treatment in the era of COVID-19: lessons from a mid-volume facility in North-Central Nigeria

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Background: Following the first reported case of COVID-19 in February 2020, movement restrictions were imposed by the government between March and May 2020 to curb its spread. As a result, the number of HIV clients Lost to Follow-up (LTFU) surged due to restricted access to treatment. To address this, continuous quality improvement intervention was implemented by a cross-functional team.

Description: Nyanya General Hospital, in Abuja, Nigeria had 1,112 active clients receiving ART at the facility as of 31st March 2020. Utilizing the electronic Nigerian Medical Records System (NMRS) generated client line-list between April and July 2020, those who became LTFU peaked at 230 in May with a median value of 77. Following root-cause analysis, six tests of change were implemented in four PDSA cycles. These were: home/community pharmacy refills & improved documentation, scale-up of community tracking/services, weekly line-list of clients with clinic appointments and missed appointments, and mid-week performance review supported by an online interactive dashboard, the AchieveR app.

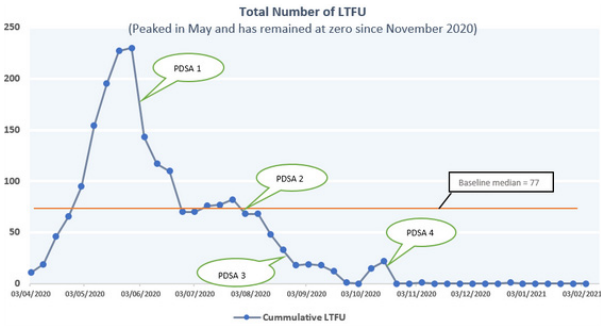

Figure. Total number of LTFU
(peaked in May and has remained at zero since November 2020)

Figure. Trends in weekly number of inactive clients
(lowest in September 2020 with less than 3 new inactives weekly)

Lessons learned: Clients LTFU reduced to zero by November 2020 till now with proxy retention of 112% while new inactive patients (dead, transfer out, and stopped) have remained at less than 3 per week. Clients active on treatment have also increased to 1,513 by February 2021.

Conclusions/Next steps: Quality improvement approaches demonstrated remarkable success despite the COVID-19 challenge. The AchieveR app allowed for easy monitoring of progress, the adaptation of strategies as needed, and support sustainability of the successes recorded. Project Scale-up to other facilities and expansion to include viral load and TB cascades is planned.

PED463

CAB+RPV LA implementation outcomes and acceptability of monthly clinic visits improved during COVID-19 pandemic across US healthcare clinics (CUSTOMIZE: hybrid III implementation-effectiveness study)

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Background: COVID-19 has disrupted healthcare service delivery globally. CUSTOMIZE was a 12-month implementation science study evaluating monthly provider-administered cabotegravir+rilpivirine long-acting (CAB+RPV LA), started before and continued during the COVID pandemic. This analysis summarizes COVID-19 impact on CAB+RPV LA implementation outcomes.

Methods: Implementation outcomes from staff and patients were descriptively compared at Months 4 (M4) (~Nov-Dec 2019, pre-COVID) and 12 (M12) (~Oct 2020, during COVID). 19 patients (19%) had COVID-impacted visits (missed/rescheduled visit, quarantine, clinic closure, etc) related to the pandemic vs. 82 (81%) without COVID-impacted visits.

Results: All implementation outcomes scores among staff and patients improved during COVID (M12) vs pre-COVID (Table). At M4, staff were most concerned about awareness of missed injection visits (45.8%), which decreased to 21.7% at M12. At M12, more staff disagreed that the following were barriers to LA implementation: patient failing LA due to missed doses/injection appointments (78.3% vs. M4: 41.6%), management of other care needs (73.9% vs. 41.6%), and patient transitioning from oral to injectable treatment (91.3% vs. 79.1%). Five patients received temporary OT to cover impacted injection visits. All five restarted LA; no viral failures occurred. No COVID-impacted patients withdrew from the study. Overall patient acceptability of monthly clinic visits slightly improved during COVID (M12: 87.2% vs. M4: 83.3%). At M12, COVID-impacted patients were more likely than non-COVID-impacted patients to indicate that monthly clinic visits were extremely/very acceptable (94.7% vs. 85.5%); to be positive/extremely positive about receiving CAB+RPV LA (100% vs. 97.6%); and to prefer LA over daily oral tablets (94.7% vs. 91.6%).

Conclusions: During the pandemic, CAB+RPV LA remained highly acceptable and appropriate to staff and patients. Some patients were given OT for missed injection visits and maintained uninterrupted ART; all patients restarted LA with no virologic failures. Acceptability of coming to clinic monthly and preference for LA ART remained extremely high during the COVID pandemic.

	All Staff Agreed/Completely Agreed % [Range] (Mean Score)		Physicians Agreed/Completely Agreed % [Range] (Mean Score)		Nurses/Injectors Agreed/Completely Agreed % [range] (Mean Score)		Administrators Agreed/Completely Agreed % [range] (Mean Score)		All Patients Agreed/Completely Agreed % [range] (Mean Score)		COVID-Impacted Patients Agreed/Completely Agreed % [range] (Mean Score)	
	M4 N=24	M12 N=23	M4 N=8	M12 N=8	M4 N=8	M12 N=8	M4 N=8	M12 N=7	M4 N=105	M12 N=102	M12 N=19 Impacted	M12 N=82 Non-Impacted
Acceptability of Intervention Measure (AIM)	91.6% [83.3-95.8] (4.39)	95.6% [95.6-95.6] (4.45)	96.9% [87.5-100] (4.47)	100% [100-100] (4.5)	90.6% [75-100] (4.44)	90.6% [87.5-100] (4.44)	87.5% [75-100] (4.25)	96.5% [85.8-100] (4.39)	94.0% [91.5-97.1] 4.61	97.5% [96.1-100] 4.78	97.5% [94.7-100] 4.78	97.6% [96.4-100] 4.78
Intervention Appropriateness Measure (IAM)	94.8% [91.7-95.8] (4.45)	100% [100-100] (4.61)	93.8% [87.5-100] (4.44)	100% [100-100] (4.63)	100% [100-100] (4.50)	100% [100-100] (4.50)	90.6% [87.5-87.5] (4.41)	100% [100-100] (4.71)	95.3% [94.3-97.2] 4.60	96.3% [95.1-98] 4.78	96.3% [90-100] 4.64	95.0% [94.1-96.5] 4.78
Feasibility of Intervention Measure (FIM)	84.4% [79.2-87.5] (4.32)	94.5% [91.3-95.6] (4.46)	84.4% [75-87.5] (4.31)	96.9% [87.5-100] (4.41)	84.4% [75-87.5] (4.34)	100% [100-100] (4.53)	84.4% [75-87.5] (4.31)	85.7% [87.5-87.5] (4.46)	n/a	n/a	n/a	n/a

AIM, IAM, FIM utilized a 5-point Likert Scale (1-5): 1=Completely Disagree to 5=Completely Agree; Mean score based on Likert scale. % = Mean% participants who Agreed or Completely agreed with each of 4 statements. %Ranges provided. Patients were not administered the FIM.

Table. Acceptability, appropriateness and feasibility of CAB+RPV LA implementation scores for healthcare staff and patients pre-COVID and during COVID, M12 patients COVID-impacted, non-COVID impacted

PED464

Expansion of multi-month dispensing of HIV antiretroviral medication in sub-Saharan Africa in the COVID-19 era

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Background: In response to the COVID-19 pandemic, many ministries of health moved quickly to avoid interruption of HIV treatment and decompress health facilities (HF) by expanding multi-month dispensing (MMD) of antiretroviral therapy (ART). In sub-Saharan Africa (SSA), countries leveraged their previous experience with differentiated service delivery to deliver MMD at HF and in the community. We reviewed MMD data across 7 countries in SSA to assess changes during the first wave of COVID-19.

Methods: We examined aggregate data collected and reported quarterly between October 2019-September 2020 by 1084 HF supported by ICAP at Columbia University through the US President's Emergency Plan for AIDS Relief. This included 40 HF in Eswatini, 19 in Ethiopia, 59 in Mozambique, 547 in Zambia, 74 in Cameroon, 146 in Côte d'Ivoire, and 199 in Democratic Republic of Congo (DR Congo). Numbers and percent of recipients of care (ROC) receiving <3, 3-5, and 6+ months of ART were calculated for countries, by quarter (Figure 1).

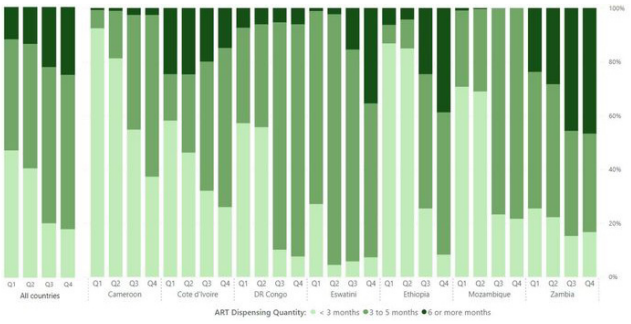

Figure 1. Antiretroviral therapy dispensing quantity, by country and quarter, October 2019 - September 2020

Results: Across the 7 countries, 434,665 ROC received ART during the first quarter (Q1) of the period; this increased to 498,005 by the final quarter (Q4). Overall, provision of 3-5 months of ART (3-5MMD) increased from

41.2% of ROC in Q1 to 55.3% in Q4 and provision of 6+ months of ARV (6-MMD) increased from 12.6% in Q1 to 27.4% in Q4. MMD increased in all countries. Large increases in 3-5MMD were observed in Cameroon (Q1:6.8%, Q4:60.2%), Côte d'Ivoire (Q1:17.2%, Q4:59.1%), DR Congo (Q1:35.5%, Q4:86.3%), Ethiopia (Q1:6.9%, Q4:52.9%), and Mozambique (Q1:28.4%, Q4:78.4%). Increases in 6-MMD were observed in Eswatini (Q1:1.2%, Q4:35.5%), Ethiopia (Q1:6.3%, Q4:38.8%), and Zambia (Q1:23.8%, Q4:46.7%), while Côte d'Ivoire reduced 6-MMD distribution (Q1:24.6%, Q4:14.9%).

Conclusions: MMD for ART increased substantially across all countries. Impacts on ROC satisfaction and outcomes such as retention and viral suppression should be assessed.

PED465

Implementation of service delivery changes to maintain access to HIV pre-exposure prophylaxis and mitigate COVID-19 in Kenya

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Background: HIV pre-exposure prophylaxis (PrEP)—a key prevention strategy for at-risk populations—is being scaled up for HIV serodiscordant couples throughout Kenya. The COVID-19 pandemic posed new challenges to PrEP roll-out. We conducted a qualitative study of PrEP providers to understand whether and how clinics adjusted PrEP delivery practices in response to the COVID-19 pandemic.

Methods: Since 2017, the Partners Scale-Up Project has integrated PrEP into 25 HIV clinics in Central and Western Kenya. We conducted qualitative interviews with 40 clinic personnel, purposively sampled by region, PrEP delivery role, and clinic size. We interviewed personnel once during the first wave of the pandemic (May – Aug 2020) and again after some decline in COVID-19 rates (Nov – Jan 2021). We analyzed data using an inductive memo-writing and diagramming approach and summarized data by themes along the PrEP delivery cascade.

Results: Our sample included 27 clinical officers, 5 nurses, 4 data specialists, and 4 counselors from Central (N=20) and Western (N=20) Kenya. About half (N=19) were female, with a median age of 32 (IQR: 29-34) and 2.3 years of experience delivering PrEP (IQR: 2-3). All participants reported changes in PrEP demand creation and delivery during the COVID-19 pandemic (Table 1). Commonly reported changes included dispensing longer refills, intensifying phone-based client engagement, and collaborating with other HIV clinics to ensure that clients with prolonged stays in other regions could continue to access PrEP. Some clinics also adopted practices to streamline visits, such as within clinical-room PrEP dispensing, pre-packing PrEP, and task-shifting. Most providers liked these changes and hoped they would continue after the pandemic subsides.

Conclusions: COVID-19 served as a catalyst to service delivery innovations in Kenya. HIV clinics successfully and rapidly adapted their PrEP demand creation, refill, and retention strategies to continue to reach HIV serodiscordant couples during the COVID-19 pandemic. These modified implementation strategies highlight opportunities to streamline PrEP delivery and engage hard-to-reach populations during subsequent waves of COVID-19 and post-pandemic.

Themes related to PrEP delivery cascade	Practice prior to COVID-19 pandemic	Changes during the COVID-19 pandemic
Clinic infrastructure, staffing	Most clinics offered PrEP services in the HIV care and treatment area, with PrEP delivered primarily by ART providers	Two clinics became COVID-19 isolation centers and relocated PrEP delivery to other areas of clinic; some temporarily lowered staffing levels to decongest the clinic
PrEP demand creation	Health talks in waiting bays; community outreach activities; contact tracing	Most activities suspended or scaled back; intensified phone-based contact tracing of individuals newly diagnosed with HIV and partner notification services; increased screening at other clinic departments
PrEP initiation	Most clinics dispensed 1-month refills to new initiators and required they return for HIV testing at Month One	Some clinics switched to dispensing 3-month refills to new initiators and request they return for HIV testing at Month One
PrEP refill visits	Most clinics dispensed 1-month refills to continuing clients	Most switched to dispensing 3-month refills to continuing clients with good adherence; many have temporarily transferred the care of clients (e.g., clients on lockdown in another region) to other clinics or received such transfer clients; a few started dispensing PrEP within the clinical room, pre-packing PrEP, and/or task-shifting so that clients see fewer providers (e.g., clinics have the same clinician, rather than two separate providers, do both the adherence counseling and clinical review)
PrEP retention	Some clinics did appointment reminders and followed up with no-shows by phone	Most clinics have adopted or intensified appointment reminders and follow-up calls for no-shows

Table 1. Summary of key changes to PrEP delivery during the COVID-19 pandemic in Kenya

PED466

Early impact of COVID-19 containment measures on HIV service delivery and utilization in Uganda

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Background: Uganda, like many other developing countries, has faced challenges in sustaining essential health services during the COVID-19 pandemic. On March 21, 2020, the Government of Uganda implemented a national lockdown to mitigate COVID-19 spread. The lockdown included banning public gatherings and use of private and public vehicles as well as closing schools and non-essential businesses. In addition to creating social and economic consequences, the lockdown created barriers for HIV service delivery and utilisation.

We evaluated the impact of COVID-19 containment measures on key HIV prevention and treatment services including HIV testing services (HTS), safe male circumcision (SMC) and antiretroviral treatment (ART) during the early phases of the national lockdown.

Methods: We examined service delivery and utilization data during April–June 2019 and April–June 2020 using national level aggregate data obtained from the District Health Information System (DHIS2). We compared the following metrics from the two time periods:

(i) number of people receiving HTS,
(ii) number of males receiving SMC services and
(iii) number of HIV-infected people enrolled to receive ART.
Results: The number of people receiving HTS declined from 1,622,194 to 882,208 during April–June 2019 to April–June 2020, a reduction of 45.6%. The number of males receiving SMC services dropped by 70.0%, from 194,373 to 58,338, and the number of HIV-infected people who initiated ART declined by 32.3% from 45,873 to 31,065.
Conclusions: HIV service delivery and utilization declined during the national COVID-19 lockdown. The impact on HIV services should be monitored closely to provide essential HIV services to the most vulnerable populations. Alternative and innovative approaches to maintain essential health care services should be explored and evaluated to address these challenges.
Disclaimer: The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

PED467

Maintaining HIV services in the context of COVID-19 pandemic in Nampula province, Mozambique

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Background: After the first COVID-19 case in Mozambique, the government instituted a State of Emergency between April–September 2020. To reduce exposure for people living with HIV (PLHIV), the Ministry of Health modified service delivery guidance, interrupting community activities, revising patient flow within health facilities (HFs), and simplifying criteria for differentiated service delivery (DSD). ICAP supported the Nampula Provincial Health Services to ensure continuation of HIV service delivery at 59 supported HFs.
Description: Since April 2020, ICAP implemented a package of interventions to increase COVID-19 knowledge, reduce transmission, and ensure continuous essential care for PLHIV, including: development/dissemination of COVID-19 prevention radio spots; prevention talks by lay staff in HF waiting areas; infection prevention measures; phone-based outreach to index patients inviting contacts for HIV testing; one-stop models for HIV services; phone-based adherence counseling using targeted scripts; daily review of patient files to identify and transition eligible patients to three-month drug distribution (3MDD).
In June 2020, ICAP launched community-based HIV service delivery using mobile clinics and brigades based at 12 HFs, expanding to 16 HFs and 5 key population hotspots in September 2020. ICAP and HF teams reviewed HIV cascade data by subpopulation weekly to identify/address gaps.
Lessons learned: Monthly HF attendance decreased by 37% between March (430,435) and September (270,547) as COVID-19 cases increased. The number of PLHIV on treatment in Nampula continued to increase, however, from 83,847 (Q2, January–March) pre-pandemic to 90,094 (Q3, April–June) at the start of the pandemic and 99,048 (Q4, July–September) later on. Patients in DSD models increased 101% Q3-Q4 (46,676 to 93,630), with 3MDD increasing 155% (24,648 to 62,931).
Despite declines in testing and linkage indicators in Nampula between Q2-Q3, indicators improved by Q4. HIV testing decreased 8% from Q2 (131,228) to Q3 (120,749) but increased 13% by Q4 (136,104). Positive tests increased 22% between Q2-Q3 (7,141 to 8,739). Individuals newly initiating ART decreased 12% from Q2-Q3 (8,228 to 7,239) but increased 21% in Q4 (8,777).
Conclusions/Next steps: Innovative approaches to service delivery, including phone-based outreach, expansion of multi-month distribution and community-based service delivery, were key to maintaining PLHIV in care and continuing service provision throughout the COVID-19 pandemic.

PED468

Interactive voice response system (ARTmitra) - a lifeline to prevent treatment interruption during COVID-19 in Mumbai, India

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Background: In March 2020, India announced a nationwide lockdown due to the COVID-19 pandemic. People living with HIV (PLHIV) were at risk for treatment interruption. As the lockdown continued, the Mumbai District AIDS Control Society (MDACS) generated a list of 7,480 PLHIV due for a monthly refill. Over a period of 10 days, 14 program assistants, made phone calls and nearly 53% of clients were unreachable raising concern for impending ART interruption. To ensure treatment continuity, MDACS, I-TECH and AVGEN developed a new interactive voice response system (IVRS) ARTMitra" (*Mitra* meaning friend), to guide PLHIV to services based on their location during lockdown; distribute ART based on patient location; identify and operationalize new decentralized ART refill sites; ensure real-time stock update and reduce the burden of making phone calls.
Methods: PLHIV who missed appointments received an SMS in vernacular from ARTMitra IVRS with a helpline number. The IVRS prompted PLHIV to respond on the availability of ART; current location and ability to reach the nearest ART center. Depending on the responses recorded in the IVRS, Program Assistants called PLHIV for further guidance and referral to the nearest ART refill site. The webform captured data at refill sites and allowed for real-time updates.
Results: During April - July 2020 SMS notifications went out to over 13000 PLHIV and 1506 used IVRS and 1,314 (87%) collected ART**.** Based on the patient location data, an additional 13 decentralized dispensation sites were established. These sites led to the support of an additional 1,660 PLHIV who did not initially call the helpline mitigating a potential increase in treatment interruption. Due to the automated voice system, time spent by staff on making phone calls decreased by 57% allowing them to prioritize other critical duties. The webform was critical to move stocks around to keep centers replete.
Conclusions: Implementation of the ARTMitra platform averted a potential crisis of treatment interruption by optimizing technology to ensure treatment continuity during the pandemic. The user-friendly mobile web forms facilitated dispensation of the right and uninterrupted supply of ARV at the decentralized sites.

PED469

Implementation of multi-month dispensing to improve retention in care among PLHIV in a community pharmacy ART model (CPART) during the COVID-19 pandemic: experience from Benue State, Nigeria

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Background: The COVID-19 Pandemic negatively impacted access to quality HIV care and antiretroviral therapy (ART) among people living with HIV (PLHIV) in sub-Saharan Africa including Nigeria. Therefore to ensure ARV drug delivery during the COVID-19 lock-down and reduce missed appointment and overcrowding in ART clinics, we implemented a 3-6 multi-month drug dispensing (MMD) and CPART model of service delivery for PLHIV.

The objective of this study is to determine the retention rate and associated factors among PLHIV receiving 3-6 multi-month ART refill via community-based ART pharmacy outlets in Benue State, Nigeria.

Methods: This is a retrospective cohort study of routinely collected data in community-based pharmacy outlets for HIV positive clients in Benue State. Clients were recruited into the study between December 2019 and May 2020 and these were followed up till December 2020. Data were extracted from the electronic medical record of the hub-ART facilities. Both ART naïve and experienced clients were recruited into the study regardless of their clinical status and stability. Variables of interest were sociodemographic, viral load, WHO stage, TB status and treatment outcomes. Data were presented using summary statistics and frequency tables while associated factors were examined using chi-square at p-value of 0.5%.

Results: Two hundred and ten (210) PLHIV from 5 comprehensive health facilities were devolved to community pharmacy outlets in this study. Mean age of participants was 45years (SD-8.9) in the CPART model and 65% of them were female. 27.6% (58), 40.5% (85), 0.5% (1) and 31.4% (66) of clients were initiated on 3, 4, 5 and 6 months ARV supply respectively. All clients (100%) were retained in care and 1 (0.5%) was transferred out at the median follow-up time of 6 months on ART. One client (0.5%) died during the study period at 10 months on ART. Viral load eligible clients had 99.5% (207/208) viral load suppression rate.

Conclusions: Devolvement of PLHIV into CPART model regardless of clients' clinical status and/or DSD eligibility criteria are feasible without negatively impacting on clients' outcomes. We recommend further studies to explore long-term outcomes of 3-6 months MMD in the setting of community-based ART pharmacy models and emergency situations.

PED470

Provision of multi-month dispensing (MMD) of ARV in the time of COVID-19 in Cote d'Ivoire

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Background: Since 2017, Cote d'Ivoire (CDI) rolled out multi-month dispensing (MMD) of ART with provision of a 90-day supply of ART to patients meeting stability criteria. Due to COVID-19, national health authorities instructed facilities to expand provision of MMD to all patients. We describe the characteristics of patients enrolled on MMD as part of pandemic mitigation efforts.

Methods: From June to November 2020, we reviewed the records of HIV-positive patients active in care at 29 health facilities across CDI. We abstracted variables such as age, date of ART initiation, date and result of most recent viral load and date of MMD initiation. Patients were classified according to national guidelines as "stable," "not stable," or "not classified. We performed descriptive analysis for frequencies and logistic regression models to explore factors associated with transition to MMD, related to stability status and period when participant started MMD (pre and during COVID-19).

Results: Records from 41,525 patients were reviewed. The mean age was 43 years and 73% (30,387) were female. Of the patients transitioned to MMD prior to the COVID-19 pandemic, 74% were classified as stable at the time of data collection. In contrast, of patients transitioned to MMD during COVID-19, only 19% were classified as stable (Figure). Compared to those transitioned prior to COVID-19, those transitioned during the pandemic were also significantly younger (37 years vs. 40 years) and more recently initiated on ART (1 year vs 6 years on ART).

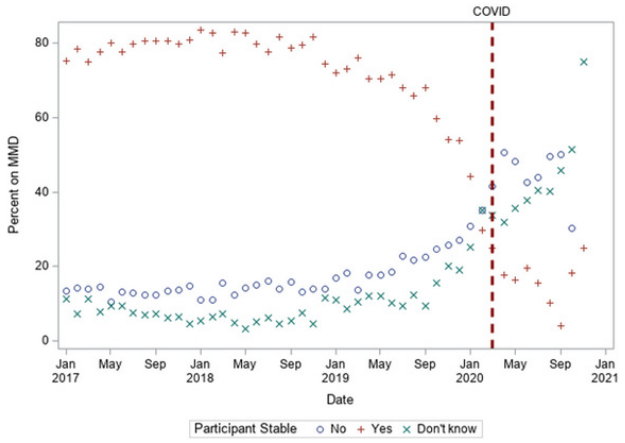

Figure: Timing of transition to MMD by stability

Conclusions: MMD of ARV was done for a large proportion of HIV infected patients during COVID-19 period. This include many unclassified and not stable patients who are more likely to be unsuppressed yet were receiving MMD due to national COVID-19 mitigation efforts. It will be critical for programs to carefully monitor them to better address their needs.

PED471

The impact of COVID-19 on access to HIV prevention services among people who inject drugs

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Background: The COVID-19 pandemic has necessitated a range of restrictive orders as well as programmatic changes within healthcare and other supportive systems in the United States and globally. These measures may be associated with disruptions in healthcare services, including for opioid-dependent people who inject drugs (PWID) who are at increased risk for HIV acquisition.
This study aims to assess the impact of COVID-19 pandemic on access to and utilization of various HIV prevention services among PWID with opioid use disorder (OUD).
Methods: We interviewed 110 PWID enrolled in medication for opioid use disorder (MOUD) treatment (e.g., methadone) between May-October, 2020 to identify if this sample experienced changed in access to the following services due to the COVID-19 pandemic:
a) HIV or sexually transmitted infection (STI) testing,
b) pre-exposure prophylaxis (PrEP) services,
c) HIV counselor or doctor appointments, and,
d) clean injection equipment.
Results: A majority of the sample, 95 (86.4%), reported that the onset of COVID-19 had not changed their access to HIV testing. Similarly, 90 participants (81.8%) reported that the onset of COVID-19 had not changed their access to STI testing.
Almost half of the sample, 48 (41.8%) participants reported that getting an appointment with a doctor decreased after the onset of COVID-19. Participants reported that access to a lab or blood testing (22.7%), access to injection equipment (11.8%), and sessions with a case manager or counselor (20%) decreased.
One-fourth of the 32 participants who were taking PrEP before the onset of COVID-19 reported that they had trouble getting their PrEP prescription due to COVID-19, and 15.6% reported that they had difficulty getting the PrEP prescription filled at their pharmacy. Out of the entire sample, 20% reported that they stopped using PrEP since the COVID-19 pandemic began.
Conclusions: Our results indicate that most participants did not report reduced access to HIV or STI testing, blood testing or injection equipment due to COVID-19. Contrarily, difficulties in obtaining appointments with HIV counselors or doctors and limited access to PrEP were presented. Innovative strategies are needed to reduce the adverse effects of COVID-19 on HIV prevention among PWID.

PED472

'Lockdown is a good thing, but there should be more access to health': HIV and SRH service delivery experiences of South African adolescents and healthcare workers during COVID-19

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Background: The advent of COVID-19 has created unprecedented health system challenges, especially in contexts of high inequality and high HIV burden. The impact of health system disruptions may be particularly pronounced for adolescents and young people (AYP), including those living with HIV or needing sexual and reproductive health (SRH) services. Their voices, and those of their healthcare workers, are crucial to the design and delivery of effective health sector responses but are often not heard. This research reports on experiences of South African AYP accessing HIV and SRH services, and their healthcare workers.
Methods: Two rounds of in-depth, semi-structured telephone interviews were conducted with AYP (ages 15-23) in the Eastern Cape and Western Cape provinces in April (n=13) and September-October (n=27). Following this, nine rounds of weekly online participatory activities were held with the same group (n=41). Most participants were HIV-positive or living in AIDS-affected households in a mixture of urban, rural and peri-urban areas
In parallel, in-depth, semi-structured telephonic interviews were conducted with 13 healthcare workers from public health facilities delivering services to AYP living with HIV in a mixed urban-rural district of the Eastern Cape.
Results: Adolescent participants suggested that a focus on COVID-19 resulted in their other health needs, including access to HIV and SRH services not being met, while healthcare workers reported a decrease in adolescent attendance at health facilities.
Adolescent participants reported that their challenges accessing HIV/SRH services included: (1) fear of contracting COVID-19; (2) longer health-facility wait times; (3) getting yelled at by healthcare workers; and (4) discomfort and perceived stigma from queuing outside health facilities. Healthcare workers reported the following challenges providing services to AYP: (1) staff shortages and clinic closures which contributed to high levels of stress; and (2) feelings of guilt that they were not providing a "good enough" service due fear of acquiring or transmitting COVID-19. They strongly suggested that dedicated equipment and infrastructure for AYP are needed.
Conclusions: The disruptions to HIV/SRH service access for AYP reported here speak to the importance of continued, integrated HIV and SRH service delivery and care for AYP and continued and sustained psychosocial support for healthcare workers.

PED473

Assessing outcomes of multi-month dispensing on viral suppression among treatment naive clients in Northern Nigeria

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Background: In 2016, the World Health Organization (WHO) recommended multi-month dispensing (MMD) to improve treatment adherence for virally suppressed (VL<1000 copies/ml) ART patients as part of differentiated service delivery models. Many high HIV burden countries including Nigeria adopted these recommendations and have been in the process of scaling up MMD to eligible clients. In 2020, early COVID-19 lockdowns and reluctance of patients to visit health facilities for fear of contracting COVID-19 led many countries to expand MMD recommendations to treatment-naïve clients. The USAID-funded Strategic HIV/AIDS Response Program Task Order 3 (SHARP TO3), which supports HIV care and treatment services in six states in Northern Nigeria, subsequently expanded MMD to treatment-naive clients. We assess 6-month viral suppression among treatment-naive clients on MMD and share lessons learned from implementation of MMD in northern Nigeria.

Methods: We conducted a retrospective analysis of viral load outcomes for all treatment-naïve clients on MMD from March-July 2020 in 94 facilities in six states in northern Nigeria. Data for the analyses were obtained from the Lafiya Management Information System (LAMIS), a USAID-funded electronic medical record system used in public health facilities across Nigeria. Univariate and bivariate statistics were generated using SPSS® Statistics V26.

Results: A total of 3779 clients (M38%, F62%) were initiated on ART. 49% (1848) of newly initiated clients were placed on MMD 3 (three months) while 22% (816) were on MMD 6 (6 months). 29% (1115) of clients were not on MMD because they lived close to an ART pickup point. 6-month viral load results were received for 45% (1203) of clients (M35%, adult F65%) on MMD. The majority (90%) of treatment naïve clients on MMD were virally suppressed at 6 months. Viral suppression was highest among female adults (90%) followed by male adults (88%) and children <15 (81%).

Conclusions: Our data show that most treatment-naïve clients placed on MMD can achieve viral suppression. We recommend an intensive remote case management approach to improve viral suppression among children on MMD. Scaling up MMD among treatment-naïve clients is feasible and should be considered in settings similar to Northern Nigeria.

PED474

Impact of virtual follow-up and six-month dispensing on viral suppression and loss to follow-up (LTFU) during COVID-19 in the Democratic Republic of the Congo (DRC)

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Background: In the DRC, COVID-19 related restrictions and fear decreased access to and use of facility-based HIV services. To maintain access to antiretroviral treatment (ART), the Integrated HIV/AIDS Project in Haut-Katanga (IHAP-HK) rapidly pivoted to six-month dispensing and intensified enrollment in adapted differentiated service delivery models, including community-based ART distribution points (PoDi+). Our analysis aims to measure the impact of adaptations to our PoDi+ model on clients' viral suppression and LTFU.

Methods: IHAP-HK established the PoDi+ model in 2016, under which ART refills, adherence counseling, and nutritional and TB screenings are provided at a community site. During COVID-19, IHAP-HK adapted the model to integrate appointment reminders; institute monthly virtual adherence and health checks between appointments; and shift eligible clients from three- to six-month ART dispensing.

We analyzed programmatic data across three PoDi+ sites from inception through December 2020, using last VL and LTFU rates to assess the impact of COVID-related PoDi+ adaptations on LTFU and viral suppression (<1000 copies/mL) before and during COVID-19. We used descriptive statistics to describe population characteristics, and multivariate logistic regression to assess the association between viral suppression and the pre-COVID-19 (through February 2020) and during COVID-19 (March—December 2020) periods, controlling for sex, age at ART initiation, and months on ART.

Results: A total of 2,370 clients (69% female; 21% of clients enrolled after March 2020) were included in the overall analysis. 45 clients were LFTU during the analysis period, with a greater LTFU rate before COVID-19 (0.77/100 person-years [PY]) than during COVID 19 (0.2/100 PY; IRR = 3.15 95% CI: 1.59–6.22).

Of the 1,379 clients with a current VL count, viral suppression was greater among clients who had their last VL result during COVID-19 (676/752; 95% suppression) than those before COVID-19 (596/627; 90% suppression) (OR = 7.63 95% CI: 4.12–14.12).

Conclusions: IHAP-HK's adapted PoDi+ model yielded higher viral suppression and reduced LTFU among PoDi+ clients, highlighting its success in minimizing COVID-19's impact on treatment outcomes. Scaling and sustaining these client-focused adaptations are critical for promoting long-term treatment access and viral suppression to enable achievement of epidemic control targets.

PED475

Successful scale-up of optimal antiretroviral regimens and improvement in viral suppression for children and adolescents living with HIV amidst COVID-19 pandemic in Kenya

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Background: Emergence of COVID-19 in mid-March of 2020 posed unprecedented challenges to provision of services to children and adolescents aged 0-19 years living with HIV (CALHIV) in Kenya. There were several adaptations including: reduced clinic visits, virtual adherence support and re-alignment of clinic appointments with treatment monitoring. The country rolled out phase 2 of CALHIV transition from Efavirenz-based (EFV) regimens to Dolutegravir-based (DTG) antiretroviral therapy (ART) in May of 2020. We report progress in optimization and viral suppression among CALHIV before COVID-19 and 9 months into the pandemic.

Methods: We analyzed data from 1037 sites with electronic medical records in the national HIV data warehouse from 41 counties. We defined baseline period as January to March 2020 and end line as September to December 2020. Outcome variables of interest were number of children transitioned to DTG-based ART, children receiving ≥3-month clinic ap-

pointments, viral load testing coverage (VLC) and viral load suppression (VLS). We compared outcome measures at baseline and end line and tested for significance using chi-square tests

Results: Of the 58,395 CALHIV, 47,384 (81.1%) were eligible for optimization to DTG based ART . Median age was 13 years (interquartile range 9-16) years and 52.0% were female. Proportion of CALHIV on DTG-based ART increased from 29.9% at baseline to 65.3% (p<0.0001). At end line, DTG uptake was higher among older age groups: 50.3%, 67.5% and 69.3% for ages 5-9, 10-14 and 15- 19 years, respectively (p<0.0001). There was no difference in DTG uptake by sex: 65.0% in females and 65.5% in males, p=0.236. Proportion of CALHIV on ≥3-month clinic appointments increased from 33.4% at baseline to 46.0% (p<0.0001). VLC increased from 88.2% to 89.6% (p<0.0001) and VLS from 82.8% to 88.2% (p<0.0001) from baseline to end line. At end line, VLS varied by regimen in patients on DTG (92.1%) efavirenz (80.2%), nevirapine (87.1%) and other regimens (79.3%).

Conclusions: Kenya achieved significant progress in ARV optimization and improvement in VLS following implementation of COVID 19 adaptation interventions. Results confirm that with a combination of measures it is possible to improve performance and sustain CALHIV program gains amidst the pandemic.

Integration of HIV services with TB programmes

PED476

Tuberculosis Preventive Therapy (TPT) focal point strategy and its impact on TPT cascade in Nampula Province

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Background: Tuberculosis (TB) preventive therapy (TPT) is an evidence-based strategy to reduce morbidity and mortality among people living with HIV (PLHIV). In Mozambique, TPT has been recommended for PLHIV since 2007; however, uptake has been limited. In 2019, 67% of new ART patients initiated TPT nationally (Ministry of Health). In Nampula, in the same period, only 41% of new ART patients initiated TPT. ICAP supports the Provincial Health Services and 59 health facilities (HFs) in Nampula to implement TB/HIV collaborative activities.

Description: In June 2020, ICAP implemented a TPT focal point (TPT FP) strategy to improve TPT uptake and completion, allocating cough officers and lay counselors at 17 high volume HFs to improve TB case identification and TPT initiation and completion. ICAP developed training and support materials and monitoring and evaluation tools and designed patient and information flow. Cough officers conducted daily TB screenings in waiting areas of maternal and child health and HIV services, fast-tracking presumptive TB cases for diagnosis and identifying and referring all eligible TPT patients. The TPT FPs used a "TB Prevention and Treatment Cascade Longitudinal Register" to monitor patients from initiation through completion and to conduct outreach to patients missing appointments as necessary. ICAP HF teams reviewed data weekly with HF management to identify gaps and to adjust the strategy as needed. We reviewed retrospective data from pre (May 2020) and post (September 2020) strategy implementation to assess TPT initiation improvements.

Lessons learned: There was an 84% (from 1,363 to 2,512) increase in the number of patients initiating TPT in the 17 HFs comparing pre and post implementation data form the 17 HF, compared with a 23% increase observed in 42 HFs with the standard of care in the same period. With intensive monitoring and notable engagement of HF staff, five of the 17 HFs had improved performance, with an increase of 263% (from 363 to 1318) during the same period.

Conclusions/Next steps: Targeted interventions, including dedicated human resources and close monitoring, are essential to address gaps within the TPT cascade. ICAP will continue to closely monitor and address gaps and to expand this strategy to all supported HFs in Nampula.

PED477

Enhanced early TB diagnosis through integrated sputum sample courier with HIV programs in six provinces in Zambia

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Background: The Ministry of Health (MoH) has made it policy that the Xpert MTB/Rif® rapid diagnostic tool is the primary TB test in Zambia, however the country has limited numbers of Xpert platforms, with 274 machines catering for, leaving a gap of access to testing services for the majority of the population. Specimen courier system implementation was fragmented by disease or program and was poorly funded without partner support but the project implemented integration of service provision.

Description: USAID Eradicate TB project (ETB) partnered with the MoH and the HIV program to provide an efficient integrated sputum and viral load (VL)sample transportation service utilizing the existing HIV program motorbike transportation system. With project support, the intra-district courier system for rapid diagnosis of TB for 48 Xpert MTB/Rif® testing sites, referred to as "hubs," supporting 187 peripheral facilities in 19 districts was integrated with the VL courier system. The samples are triple packaged by laboratory staff and maintained at 2-8°C using ice packs. ETB enabled, transporting specimens 3- 5 times per week. The motorbike riders are trained in the required biosafety measures.

Lessons learned: A total of 40,920 sputum samples were couriered between October 2019 to September 2020; 40,542 (99%) were successfully tested with results transmitted back to the referring facilities. Laboratories recorded a 1% rejection rate due to no sample in sputum containers . The courier service also takes back hard copies of results to referring facilities within 24-48 hours enabling early treatment initiation.

Conclusions/Next steps: Integration of essential services across different vertical programs provides an opportunity for enhanced access to cost effective, efficient, rapid TB diagnosis and treatment to improve outcomes. Based on this successful experience, the ETB supported MOH to formulate guidelines for integrated courier for nationwide scale up.

PED478

TB/HIV one-stop clinic reduces nonmedical cost of staying in care at Makululu Urban clinic and Kabwe Women, Newborn & Children's Hospital (KWNCH) in Kabwe District, Zambia

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Background: TB and HIV services integration has not been optimized in many resource-limited settings in Zambia, creating additional costs for TB/HIV co-infected clients who require an average of 4 appointments for each condition in 6 months. At Makululu Urban clinic and Kabwe Women Newborn and Children's Hospital (KWNCH), USAID Eradicate TB (ETB) implemented One-Stop TB/HIV Clinic to reduce non-medical costs, improve patient's adherence and outcomes of the TB/HIV clients.

Description: Front line Health Care Workers (HCWs) and Community Based Volunteers (CBVs) from ART and TB clinics received onsite orientation on the formation and objectives of One-Stop TB/HIV clinic in March 2020 followed by monthly mentorship by District health supervisors on TB and HIV treatment and management according to Ministry of Health (MOH) guidelines.

TB-HIV coinfected patient case records were stored at the TB clinic during the duration of TB treatment and returned to ART clinic upon completion of TB treatment. Routine screening and recording for TB among PLHIV and HIV testing among TB clients were intensified.

Lessons learned: A total of 112 TB/HIV co-infected patients were enrolled from March 2020 to December 2020 at Makululu Urban clinic and KWNCH. Of these, 17% completed TB treatment, 9% died and 74% are still on treatment. All the enrolled clients received integrated services for laboratory, clinical and pharmacy. The number of appointments halved after integration during the 6 months of TB treatment and a proportional 50% decrease in the transport costs, and time spent by patients at the facility.

The period between ART initiation and TB diagnosis among coinfected reduced from three days to one day. Testing of HIV among TB clients and screening for TB among PLHIV improved from 88% to 99%, and adherence levels improved from 90% to 100%.

Conclusions/Next steps: One-Stop TB/HIV clinic intervention of integrating TB/HIV services reduced TB's catastrophic economic burden by halving non-medical costs (transport and time) of staying in care for TB/HIV coinfected patients. It also improved TB/HIV appointment adherence and TB treatment outcomes.

PED479

Contextualizing and optimizing novel strategies to improve the latent TB cascade of care: insights from PLHIV, health care providers and program managers in 3 cities in Brazil

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Background: Tuberculosis (TB) causes 1 in 3 deaths among people living with HIV (PLHIV). Diagnosing and treating latent tuberculosis infection (LTBI) is critical to reducing TB mortality. Blood-based screening tests (e.g. QuantiFERON-TB Gold Plus (QFT+), Qiagen) and the shortened TB preventive therapy (TPT) regimen, once-weekly isoniazid-rifapentine (3HP), hold significant promise to improve the LTBI cascade. We aimed to understand the context, barriers and solutions to optimizing QFT+ and 3HP among PLHIV in Brazil.

Methods: We conducted 110 in-depth interviews with PLHIV (n=40), their health care providers (HCP) (n=40) and program managers (PM) (N=30) across 3 cities in Brazil: Rio de Janeiro, Sao Paulo and Manaus. Interviews were audio-recorded and transcribed. Thematic analysis was conducted and synthesized across population groups and cities.

Results: LTBI screening and treatment practices among HCP were highly dependent on individual perceptions of whether they were critical and likely to improve TB outcomes. Many HCP lacked a strong understanding of LTBI and perceived the current TPT regimen as complicated. HCP reported that their LTBI screening and treatment practices were further constrained by clinic-level challenges such as staff shortages and turnover.

While PLHIV generally expressed willingness to consider any test or treatment that their doctors recommended, they indicated that HCP rarely discussed LTBI and TPT with them, and that they had to balance testing and treatment requests with structural constraints of their daily lives related to jobs, time off, food insecurity, stigma and caring for families and others. QFT+ and 3HP were viewed by all study participants as positive tools which could significantly improve the LTBI cascade by avoiding the complexities of TB skin tests and longer LTBI treatment courses.

However, neither of these innovations were without their own challenges. HCP, in particular, relayed that QFT+ test ordering forms and results notifications processes, as well as patient-provider communication strategies to engage and retain PLHIV in TPT, were currently confusing, time consuming and unstandardized.

Conclusions: Multi-level interventions that increase understanding of LTBI and TPT among HCP, improve patient-provider communication, and streamline clinic-level processes related to introducing QFT+ and 3HP are needed to optimize their use and impact among PLHIV.

PED480

Finding the missing cases: Integrating lay-provider HIV testing services (HTS) for people with presumptive tuberculosis (TB) during household TB screening campaigns in the Democratic Republic of the Congo (DRC)

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Background: Missing cases fuel the dual HIV and TB epidemics in the DRC. 2019 DRC data show only 56% of PLHIV are diagnosed and on antiretroviral therapy, and only 68% of people with TB know their HIV status. New approaches are needed to reach undiagnosed PLHIV who are outside the reach of the current healthcare system. PATH, through the USAID-funded Integrated HIV/AIDS Project, integrated lay-provider HTS services into a household TB screening campaign to improve HIV case-finding.

Description: Under this model, National TB Program community health volunteers conducted household TB screening in geographies with poor healthcare coverage. PATH trained these volunteers to offer directly assisted HIV self-testing (HIVST) to individuals who screened with presumptive TB, with accompanied referrals to project-supported health facilities for those with reactive HIVST results for confirmatory diagnosis and treatment initiation. Samples were collected from people with presumptive TB and sent to facilities with GeneXpert for confirmatory diagnosis.

We tested this strategy during two campaigns (14 days each in July and August/September 2020) in 41 health areas across 5 health zones of Haut-Katanga province, using descriptive statistics for analysis.

Lessons learned: 1,660 people with presumptive TB were offered HIVST (57% female; 81% between 20 and 49 years of age). 51% (843) accepted HIVST (all first-time testers). 29% (243) received a reactive HIVST result, among whom, 97% (236) were confirmed HIV-positive. Overall HIV prevalence was 28%, with a higher prevalence among females (31%) than males (25%).

Among those with presumptive TB, 8% (127/1,660) were diagnosed with TB; TB was more frequent among those between 15 and 44 years. Overall TB/HIV co-infection rate was 2% (17/843). The overall HIV testing yield was higher than the project's average yield during the same period (28% versus 5.9%), indicating this strategy's success in identifying undiagnosed PLHIV who were first-time testers.

Conclusions/Next steps: These results show the feasibility and acceptability of using lay providers to offer HIVST, and this strategy's success in diagnosing hard-to-reach PLHIV. PATH will replicate this model in other geographies to increase access to and uptake of HIV and TB services among hard-to-reach populations in support of epidemic control in the DRC.

Integration of HIV services with non-communicable disease programmes

PED481

Piloting an integrated HIV/non-communicable disease (NCD) peer support programme in Cape Town

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Background: The burgeoning NCD burden in South Africa accounted for 51% of deaths in 2016, with diabetes and hypertension among the most common conditions seen at primary health care facilities. In the Western Cape, hypertension and diabetes prevalence is estimated at 37% and 11% respectively. Research has found a significant unmet need for care, and for those treated, 48% do not meet the threshold for control. In response, mothers2mothers (m2m) developed a pilot intervention using its peer-based model, to provide integrated HIV/NCD care, aiming to improve health outcomes in enrolled clients.

Description: m2m employed and trained 20 Mentor Mothers (MMs) to deliver facility and community-based integrated care for HIV/NCDs, to adults with uncontrolled diabetes and/or hypertension, served at two high-volume facilities in Khayelitsha, Western Cape. Clients are educated about their condition, and supported to attend appointments, adhere to medication and make lifestyle changes through regular goal-setting, by women from their communities facing similar health challenges. Blood pressure is monitored monthly, and HbA1c quarterly. Over 900 clients are enrolled in this ongoing programme, of which 636 are participating in research to assess impact.

Lessons learned: Seventy-nine clients have been enrolled for six months or more, of these sixty-four (81%) have thus far completed follow up at six months. Forty (93%), 3 (46%), and 12 (86%) of those with hypertension, diabetes and both conditions respectively, showed improvements in biomarkers. Early assessment of acceptability provided insights into challenges and best practices. Clients conveyed the value of interactions with MMs and their increased motivation as they experienced health improvements, however requested more group support. MMs noted reluctance from some clients to join the programme due to m2m's association with HIV support and resulting stigma. The challenge of instituting healthy eating when resources are particularly compromised during the COVID-19 pandemic were noted by all.

Conclusions/Next steps: Enrolled clients will continue to be supported and follow up data collected. Virtual support groups are being established for additional support for clients. A community awareness campaign regarding m2m's HIV/NCD programme is planned; and partnerships with organizations who can teach clients to grow their own food will be explored.

HIV services for migrant and mobile populations

PED484

The potential for integration of HIV testing with family planning, violence screening, education, and employment services: cross-sectional survey findings with an urban refugee adolescent and youth cohort in Kampala, Uganda

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Background: Urban refugee adolescents and youth are understudied in HIV prevention research. However, refugee youth disproportionately experience sexual and gender-based violence and poverty-both established structural drivers of HIV. Scant research has examined factors associated with HIV testing among urban refugee youth. This study aimed to examine socio-demographic and sexual and reproductive health (SRH) factors associated with lifetime HIV testing among urban refugee adolescents and youth aged 16-24 in Kampala, Uganda.

Methods: We include baseline data from an ongoing cohort study with a peer-recruited sample of urban refugee youth aged 16-24 in Kampala living in informal settlements. We conducted descriptive statistics, chi-square tests, and logistic regression to examine demographic (age, gender, education, employment) and SRH (relationship status, having children, violence exposure) factors associated with lifetime HIV testing. We then conducted multivariable logistic regression analyses to assess settlement, gender, demographic, and SRH factors associated with lifetime HIV testing.

Results: Participants (n=450; mean age: 20.4, standard deviation: 2.4) were largely from the Democratic Republic of Congo (70.9%) and had lived in Uganda between 1 and 5 years (53.3%). Less than half reported lifetime HIV testing (43.4%). In multivariable analyses, lifetime HIV testing odds were higher among: youth with secondary school education or higher (aOR: 2.24, 95%CI: 1.24-4.07, p=0.001), employed vs. unemployed youth (aOR: 1.77, 95%CI: 1.02-3.06) or students (aOR: 0.62, 95%CI: 0.36-1.07), youth with children (aOR: 2.28, 95%CI: 1.03-5.05, p=0.04), and youth reporting physical violence exposure (aOR: 2.57, 95%CI: 1.10-6.01, p=0.03).

Conclusions: HIV testing uptake among urban refugee youth in Kampala falls far short of the 95-95-95 UNAIDS targets for an AIDS Free Generation by 2030, with less than half ever testing for HIV. HIV testing is higher among parenting refugee youth, signalling the successful integration of HIV testing with prenatal care. It also highlights the potential to integrate HIV testing into family planning services for urban refugee youth to concurrently address HIV and unplanned pregnancy needs. Findings indicate that HIV testing could involve screening for violence exposure to link urban refugee youth with trauma-informed care. Finally, structural interventions could provide integrated services that address educational and employment needs among urban refugee youth alongside HIV testing services.

Integration of prevention interventions with care/treatment

PED485

Mediators of healthcare utilization among heterosexual African, Caribbean and Black (ACB) men: implications for HIV diagnosis and treatment

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Background: Heterosexual contact is the second most common means of HIV transmission, but little is known about the systemic and structural factors that disempower heterosexual ACB men from accessing healthcare services and early HIV diagnosis and care. we examined the correlates of utilization versus non-utilization of healthcare services, and its implications on HIV diagnosis and treatment.

Methods: Drawing from the quantitative data from a larger weSpeak research program (2015 – current), we analysed the correlates of healthcare utilization among heterosexual ACB men living in Ottawa (n=210) and Windsor (n=156). Hierarchical binary logistic regression modelling was used because it controls for confounding factors, city of residence and self-rated health status at the year in consideration.

Results: Significant numbers of the ACB men in Ottawa (n= 63, 48.09%) and Windsor (n = 33, 58.33%) used the services of a family doctor or a nurse practitioner only once over the last year prior to the survey. Precisely, 29.79% (n=56) in of the men in Ottawa and 24.14% (n=35) in Windsor did not use healthcare services in the last year preceding the survey. Heterosexual ACB men in age groups; 20 -29 years (OR = .13, p < .01, 95% CI = .03/.53) and 30 -39years (OR =.13, p < .01, CI = .03/.54) had lower odds of utilizing healthcare services.

In contrast, heterosexual ACB men with high scores on the following attributes; resilience (OR = 1.04, p < .05, 95% CI = 1.00/1.08), HIV knowledge (OR = 1.08, p < .05, 1.01/1.16) and HIV testing behaviour (OR = 1.83, p < .05, 95% CI = 1.01/3.30) were more likely to use healthcare services.

Conclusions: Heterosexual ACB men aged 20-29 and 30-39 years, are often most vulnerable to HIV and need targeted interventions to increase HIV diagnosis and care. Promoting resilience, increasing public awareness of the modes of HIV transmission and prevention; and fostering positive attitudes towards HIV testing will invariably increase healthcare service utilization including early HIV diagnosis and treatment of any new cases among these young men, heterosexual ACB men and their community.

PED486

Interventions to enhance uptake of PrEP for high-risk populations in Nampula Province, Mozambique

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Background: Mozambique has a generalized HIV epidemic, with 13.2% overall prevalence among adults aged 15-49 and 15.4% among women. Pre-exposure prophylaxis (PrEP) is an evidence-based HIV combination prevention intervention. Recognizing its importance for epidemic control, the Mozambique Ministry of Health (MOH) initiated PrEP implementation in select provinces in 2018.

However, limited demand creation for PrEP impacted uptake, with only 3,504 individuals enrolled in PrEP services by September 2018. By January 2019, the MOH expanded PrEP to Nampula province, targeting female sex workers (FSW), men who have sex with men (MSM), serodiscordant couples, and adolescent girls and young women (AGYW).

Description: In January 2019, ICAP began to support the Nampula Provincial Health Directorate (DPS) and health facilities (HF) in its implementation of PrEP through targeted training, tools, job aids, and communication materials. ICAP redesigned patient flow to ensure demand creation at entry points and client referrals to points of service offering PrEP. In May 2020, ICAP implemented a PrEP champions strategy, using experienced PrEP clients with strong adherence to support demand creation, patient navigation, phone reminders, and outreach. ICAP supported the DPS to expand PrEP services to additional HF—16 in 2019, 34 in 2020, and 59 in 2021—and integrated PrEP service delivery into community ART distribution strategies in 16 communities in July 2020. Lastly, ICAP strengthened capacity of community partners to reinforce PrEP literacy and demand creation among subpopulations through development and dissemination of radio spots in local languages.

Lessons learned: There was a 251% increase in clients enrolling in PrEP between the Quarter 1 (October-December 2019; n=643) and Quarter 4 (July-September 2020; n=2,256). Of the 5,729 clients enrolled in PrEP in Nampula between October 2019 and September 2020, 3,578 (61%) were serodiscordant couples, 1,045 (20%) AGYW, 632 (11%) breastfeeding and pregnant women at high risk, 283 (5%) FSW, and 191 (3%) MSM.

Conclusions/Next steps: Targeted demand creation and literacy strategies coupled with use of PrEP champions and expansion of PrEP services are an effective strategy to increase uptake. However, continued efforts are necessary, particularly for vulnerable populations. ICAP will expand the use of PrEP champions to venues where AGYW and key populations congregate.

PED487

Poor COVID-19 vaccination uptake in a cohort of Clinically Extremely Vulnerable (CEV) people living with HIV: a sign of the challenge ahead?

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Background: HIV related factors may cause people living with HIV (PLWH) to be clinically extremely vulnerable (CEV) to SARS-CoV-2 (COVID-19), warranting priority access to vaccination. We reviewed the uptake of COVID-19 vaccination within a cohort of CEV PLWH to determine factors associated with vaccine hesitancy to help guide future vaccination strategies.

Methods: PLWH attending a large inner-city centre considered CEV due to HIV related factors were identified from electronic clinical records based upon the following criteria:

- CD4 < 50 cells/mm^3
- CD4 50-200 cells/mm^3 with additional risk factors
- Opportunistic infection within 6 months

CEV patients were contacted by the hospital vaccination team and offered COVID-19 vaccination in line with the UK Government vaccination programme. Demographic data and responses were collected to identify factors associated with vaccine uptake.

Results: 119 patients were identified as CEV: 22 (18%) having a CD4 <50 cells/mm^3, 87 (73%) CD4 50-200 cells/mm^3 with additional risk factors and a further 10 (8%) having an opportunistic infection within 6 months. 65 (55%) were male, 32 (27%) were white, and 79 (66%) were of non-white ethnicity. The median age was 48.

Overall, only 23 (19%) were successfully booked or had already received vaccination. 65 (55%) were uncontactable by telephone. Of the 54 contacted by the vaccination team, 13 (24%) accepted vaccination, 10 (19%) had already booked or undergone vaccination elsewhere, 16 (30%) declined and 15 (28%) were considering vaccination but did not book, 3 of whom requested further information. Of the 31 who declined to book vaccination, 14 (45%) were male and 26 (84%) were of non-white ethnicity.

Conclusions: Uptake of COVID-19 vaccination in our cohort of CEV PLWH was poor, particularly in those of non-white ethnicity, with over half being uncontactable and with only 43% of contactable patients accepting, or having already received vaccination.

PLWH considered most vulnerable to COVID-19 represent a difficult to reach group and clinics need to take an individualised approach over standard vaccination invitation.

Further work is required to explore reasons for vaccine hesitancy in this population, including involvement of community and voluntary sector organisations to address reasons for reluctance and encourage maximum uptake of vaccination.

PED488

Finding out myself: using community-based HIV self-testing to reach underserved men and women in Botswana, 2020

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Background: Currently in Botswana, 92% of all people living with HIV (PLHIV) are aware of their HIV status, 89% are on antiretroviral therapy (ART), and 95% are virally suppressed. Despite excellent progress made toward reaching the first of UNAIDS' 95-95-95 goals (that's 95% of PLHIV know their status), gaps remain with more women tested than men. Since January 2020, the USAID-funded, FHI 360-led Accelerating Progress in Communities (APC 2.0) project rolled out HIV self-testing (HIVST) to reach underserved populations, particularly men.

We present the outcomes of community-based rollout of HIVST in five districts of Botswana.

Methods: APC 2.0 reached clients in construction sites, taxi ranks, public drinking spots, and football fields where men mostly congregate. Trained health care workers used an HTS screening tool that determines eligibility for HIVST based on risk factors. All contacts of index cases and identified high risk men were offered HIVST. We extracted and analyzed APC 2.0 HIVST project data for the period April 1 to December 15, 2020. Data were analyzed using SPSS Version 21.

Results: A total of 1,135 clients were issued HIVST kits, and 753 (66%) were men. Of these men, 90% (679/753) were issued HIVST kits based on screening tool results, while rest 10% (74/753) were contacts of index clients. In total, 191 (16.8%) of 1,135 clients who tested had a reactive result. Females were more likely than males to have a reactive test: reactivity rate =23.2% versus 13.7%, p<0.001. More males in the older age-groups above 25% were reached compared to females, though the latter had a higher reactivity rate (Table 1).

Age-group	Number of HIVST kits distributed	Number reactive	Reactivity rate
Females			
<15	7	0	0.0%
14-24	130	19	14.6%
25-39	180	47	26.1%
40-49	43	17	39.5%
50+	12	3	25.0%
Total	372	86	23.1%
Males			
<15	4	0	0.0%
14-24	117	6	5.1%
25-39	441	51	11.6%
40-49	147	43	29.3%
50+	54	5	9.3%
Total	763	105	13.8%

Table 1. HIVST reach and results by sex and age within APC 2.0

Conclusions: Implementation of community-based delivery of HIVST identified people not previously identified and reaffirms the higher burden among women. Though reactivity rate was higher amongst females, HIVST helped identify men and could help Botswana meet its testing goals for older men.

Cross-collaborations: governmental/non-governmental and local/regional/national

PED489

Measuring youth engagement in African HIV research: a mixed-methods analysis of a crowdsourcing open call

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Background: Adolescents and young adults (AYA) across Africa are developing innovative strategies to engage in HIV research. AYA engagement is critical. Understanding AYA engagement can improve study design and foster youth leadership. We organized a crowdsourcing open call, a mechanism for group problem solving and collaborative strategy development, to solicit creative examples of how AYA (14-24 years old) have been engaged in HIV research in Africa and develop an AYA engagement typology.
Methods: Following guidance from the WHO, we formed a steering committee including AYA; promoted the open call using social media in English and French; judged submissions by an independent committee, and recognized top entries through prizes. Submissions included text, images and videos and were evaluated on innovation, feasibility, clarity, engagement, and scalability. We measured engagement based on a modification of Hart's ladder (absent/minimal/moderate/substantial). We used a mixed-methods approach informed by a youth participatory action research framework to analyze the data.
Results: We received 95 submissions from 15 countries; 74 met eligibility criteria. Many submissions were from Nigerians (32/73, 44%), AYA (56/74, 76%), men (41/74, 55%), and researchers (31/74, 42%). AYA engagement was absent in 13 (18%) submissions, minimal in 27 (36%), moderate in 13 (18%), and substantial in 21 (28%). Fifty-three (72%) studies focused on HIV prevention and 21 (28%) focused on treatment or care. Three major themes emerged as forms of youth engagement in HIV research: youth-led behavioral research (26 submissions), peer-based support (11 submissions), and digital crowdsourcing (eight submissions). Youth-led behavioral studies included AYA in all stages of the research process. Peer support strategies provided emotional, cognitive, and social support for at-risk youth and youth living with HIV. Digital crowdsourcing strategies to increase HIV testing or encourage treatment initiation spurred strong engagement from youth as participants, judges, and steering committee members.
Conclusions: Our crowdsourcing open call identified diverse methods of AYA engagement, providing a strong foundation to create a new typology of engagement. The findings enhance our understanding of the extent and methods of AYA involvement in HIV research and can be used to enhance AYA HIV engagement across the life of research studies in Africa.

PED490

HIV testing in COVID-19s context. "Active Search" testing program for Venado Tuerto citizens, Argentina

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Background: In Venado Tuerto City, Santa Fe province, AHF Argentina actively participated in the "Búsqueda Activa" (Active Search) program, a locally-adapted municipal version of the national "DetectAR" plan. The program includes the active search of potentially COVID-19 infected people to carry out diagnosis of SARScov2 while also providing HIV prevention kits, information about HIV and STD as well as free HIV rapid testing at the same location and time.
Methods: As part of the "Búsqueda Activa" ("Active Search") program, AHF Argentina along with the Municipality of Venado Tuerto, the Ministry of Health of the Province of Santa Fe and the University of Gran Rosario trained 40 university students and volunteers in both COVID-19 and HIV testing. For 14 days (11/2/2020 to 11/16/2020) 4562 homes were visited in 12 neighborhoods of the City of Venado Tuerto, offering rapid COVID-19 tests (Abbott Panbio™ COVID-19 Ag) to people with COVID-19 compatible symptoms and rapid HIV test (Alere™ HIV Combo) to all visited persons. All those people who were diagnosed positively were linked to the public health system.
Results: 4562 families were visited. 324 rapid COVID-19 tests were performed, of which 118 tests turned out to be positive. 217 rapid HIV test were performed (Female 65.9% average age 40 years old, Male 33.6%, average age 35 years old, Trans gender Women 0.5%, average age 50 years old). 4 tested positive. 100% of the people who tested positive were linked to the health system. All new HIV diagnoses reported having been tested for the first time. 78% of the people expressed they previously intended to get tested but did not know how to proceed.
Conclusions: Joint work between the Government, Civil and Academic societies provide answers to current health issues. Before the syndemic situation we are facing, AHF Argentina's experience in early HIV diagnosis helped developing concrete actions to reach rapid diagnosis for COVID-19. The pandemic and the consequent restriction measures (social distancing, etc) still in force, should not be a barrier to access HIV and other STI diagnose and care. The HIV services must be available, accessible and known by the entire population.

Scale up of viral load monitoring

PED492

Differentiated Service Delivery (DSD) model to increase access to HIV – 1 RNA viral load testing in four states in Nigeria

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Background: Despite improvements in access to viral load (VL) testing in Nigeria, coverage remains low amongst priority sub-populations including pregnant and breastfeeding women (PBFW), children (0-9years) and adolescents and youth (10-25years). We describe the strategies implemented by RISE-Nigeria to increase access to VL testing services in 90 project-supported health facilities across four states (Akwa Ibom, Adamawa, Cross River and Niger) in Nigeria.

Description: RISE-Nigeria implemented a novel client-centric differentiated service delivery model for VL (DSD4VL) to increase access to VL testing services for sub-populations including PBFW, children, adolescents and youth. During the COVID-19 lockdown period, RISE secured passes from the Government to allow movement by VL Champions who provided targeted VL services at the facility and community levels between April and September 2020. VL Champions were provided with line lists of clients eligible for VL testing weekly; samples were collected at each encounter with the clients in the community, home or facility; dried blood spots for VL were collected for children, and a turnaround time (TAT) register was used to track daily samples collected and results returned to clients. We compared VLC, viral load suppression (VLS) for different sub-populations and changes in TAT of results before (Oct19 – Mar20) and after the intervention (Apr20-Sept20).

Lessons learned: Between the two periods, overall viral load coverage (VLC) increased from 71% (24,325/35,583) to 96% (45,403/47,482), p<0.0001 and VLS from 83% (20,950/25,325) to 89% (45,403/47,482), p<0.0001. VLC increased by 20% for children, 20% for adolescents and young people, and 72% for PBFW; all of these differences were significant at p<0.0001. Similarly, VLS increased by 19% for children (p<0.001), 6% for adolescents and youth (p<0.000), and 18% for PBFW (p<0.02), 2% males >24 years (p<0.001), and 2% non-pregnant females>24 years (p<0.01). Median TAT of results reduced from 35 days at pre-intervention to 25 days post implementation.

Conclusions/Next steps: The implementation of DSD4VL resulted in increases in both VLC and VLS for PBFW, children, adolescents and youth receiving services at RISE supported sites. Integrating routine VL services into existing ART DSD implementation models enabled uninterrupted, client-centered ART and VL collection services, even in the context of the COVID-19 pandemic.

PED493

Disparate HIV viral load suppression rates between rural and urban populations of Uganda from July 2019 through June 2020

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Background: Persons living with HIV (PLHIV) in rural areas face challenges in accessing HIV diagnosis and care, including limited access to viral load testing and treatment facilities. Uganda achieved a significant overall increase in viral load suppression (VLS; ≤1,000 copies/mL) from 58% in 2016 to 92% in 2020 for all tested PLHIV on antiretroviral therapy (ART). We investigated the difference in VLS between rural and urban populations in order to guide national efforts in addressing the remaining gap.

Description: We analyzed national HIV surveillance system data for all PLHIV on ART in Uganda. We examined VLS during the period July 2019–June 2020. PLHIV residences were extracted from the national surveillance data system and categorized into urban (city, municipality, division, town council, town board) versus rural (areas not categorized as city, municipality, division, town council, town board) on the March 2016 national census. We performed logistic regression on the rural/urban categorical outcome variable and VLS, multi-month ART dispensing (MMD), and 12-month retention.

Lessons learned: More than one million PLHIV received a viral load test (1,024,123) during the period of analysis. Of these, 337,612 (33.0%) and 686,511 (67.0%) were rural- and urban-based, respectively. A significantly greater proportion of rural clients received prescriptions for 90 or fewer days (54.0% vs. 39.0%, P<0.0005), while a significantly smaller proportion received prescription refills for 180 or more days (2% vs. 10%, P<0.0005). Twelve-month retention was statistically lower for rural compared with urban residents (75.6% vs. 76.4%, P<0.0005). Rural PLHIV achieved statistically lower VLS as compared with urban PLHIV (87.0% vs. 93.0%; P< 0.0005) and viral load coverage (85.6% vs 88.1%, P< 0.0005) compared with urban PLHIV. We found the same statistical differences when excluding Kampala.

Conclusions/Next steps: Lower VLS among rural PLHIV poses a significant challenge for the success of HIV epidemic control in Uganda, given more than 76% of the population lives in rural areas according to the World Bank Development Indicators, 2019. This work reveals the need to scale up client-centered interventions among rural populations, particularly interventions focusing on retaining PLHIV on ART, such as MMD and psychosocial support for improved adherence and retention on ART.

PED494

As older patients meet viral suppression targets, young people continue to lag behind: results from a patient chart audit in Côte d'Ivoire

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Background: The World Health Organization recommends viral load (VL) monitoring as a key clinical outcome for HIV-positive patients on lifelong antiretroviral therapy (ART). National guidelines in Côte d'Ivoire recommend VL testing annually for adults and every six months for children. We assessed VL among children, adolescents, and adults on ART in Côte d'Ivoire.

Methods: In June-November 2020, we conducted a cross-sectional study in 29 high-volume health facilities in Côte d'Ivoire. We abstracted variables such as age, date of ART initiation, and date and result of most recent viral load (VL) from patient charts and other facility registers. Records were selected consecutively from a facility-generated list of patients active in care in March 2020, sorted in descending order by date of ART initiation.

We describe timing and result of the most recent VL as well as the results of logistic regression models of unsuppressed VL (defined as ≥1000 copies/mL) adjusting for age, sex, and time on ART.

Results: We reviewed 41,525 patient files (80% of active ART patients). Viral suppression was highly correlated with age (Table 1), and was the strongest predictor of suppression in adjusted models for all ages. Children under age 2 were more likely to have unsuppressed VL compared to older children ages 6-9 (OR 3.0, 95% CI: 1.7-5.3), and male children were more likely to have unsuppressed VL than female children (OR 1.5, 95% CI: 1.2-2.0). Among pregnant/breastfeeding women, 13% had an unsuppressed last VL.

	Patients ages 0-9 (N=865) N (column %)	Patients ages 10-19 (N=1523) N (column %)	Patients ages 20-34 (N=6558) N (column %)	Patients ages ≥35 (N=32596) N (column %)
Has VL result				
Yes	841 (97.2%)	1490 (97.8%)	6222 (94.9%)	31672 (97.2%)
No	24 (2.8%)	33 (2.2%)	336 (5.1%)	924 (2.8%)
Most recent VL within last 6 months (among those with VL result)				
Yes	523 (62.2%)	895 (60.1%)	3035 (48.8%)	14147 (44.7%)
No	318 (37.8%)	594 (39.9%)	3186 (51.2%)	17524 (55.3%)
Most recent VL within last 12 months (among those with VL result)				
Yes	784 (93.2%)	1385 (93.0%)	5311 (85.4%)	26540 (83.8%)
No	57 (6.8%)	104 (7.0%)	910 (14.6%)	5131 (16.2%)
Most recent VL result (among those with VL result)				
Undetectable (< 40 copies/mL)	440 (52.3%)	760 (51.0%)	4474 (72.9%)	24976 (79.1%)
Detectable, suppressed (40-999 copies/mL)	159 (18.9%)	292 (19.5%)	841 (13.5%)	3896 (12.3%)
Unsuppressed (≥1000 copies/mL)	242 (28.8%)	438 (29.4%)	907 (14.6%)	2720 (8.6%)

Table 1

Conclusions: While overall VL coverage within 12 months was relatively high in Cote d'Ivoire during this period—particularly given the COVID-19 pandemic—these data indicates a large proportion of children had not received VL testing within the recommended six months. The 90% VL suppression target has been met in Cote d'Ivoire among adults 35 and older, but children and adolescents continue to lag behind.

National financing initiatives and country ownership

PED495

Cost analysis and economic evaluation of CEPHEID XPERT HIV -1 QUAL ASSAY using whole blood protocol versus PCR by ABBOT SYSTEMS in Malawi

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Background: Timely diagnosis of HIV exposed and infected infants remains a challenge. In Malawi, 40,000 infants annually are HIV exposed. However, current polymerase-chain-reaction using dried blood spots (PCR) based testing at central laboratories results in turn-around times (TAT) of 2 to 3 months, leading to loss to follow-up of infants. Point-of-care-testing (POCT) of HIV minimizes diagnostic delays and may be more cost-effective. We assessed whether POCT Cepheid Xpert HIV-1 Qual assay whole blood (XpertHIV) was more cost-effective than PCR.

Methods: We randomly selected one out of every three caregivers recruiting 200 caregivers among those participating in the mixed methods study assessing sensitivity, specificity, TAT, time to initiation of antiretroviral therapy, acceptability and usability of XpertHIV at Mulanje District Hospital, Malawi from July-August 2018. We explored the cost comparison of XpertHIV which uses 100ul of venous or capillary blood, run by laboratory technicians versus PCR. We conducted a cost-minimisation and cost-effectiveness analyses of XpertHIV and the standard of care PCR from a provider perspective using TAT of results as the outcome measure.

Results were extrapolated from the study period (29 days) to a year (240 working days). We performed sensitivity analyses to characterize individual and joint parameter uncertainty; and estimated patient cost per test.

Results: During the study period, XpertHIV was cost-minimizing at $42.34 per test compared to $66.66 for PCR. Over a year, XpertHIV remained cost-minimising at $16.12 compared to PCR at $27.06. From the patient perspective (travel, food, lost productivity), the cost per test was $2.45. XpertHIV had a mean TAT of results of 7.10 hours compared to 153.15 hours for PCR and was cost-effective, with an incremental cost-effectiveness-ratio of $0.17/hour of waiting time at health facility reduced.

Cost-effectiveness acceptability curves for testing strategies showed that XpertHIV had higher probability of being cost-effective for all willingness to pay values ($0.10 to $200) that were simulated; except at $0.10 where PCR had the probability of 0.63 and XpertHIV 0.37, the probability of being cost-effective rose to 0.72 for XpertHIV at $0.20 and above 0.90 from $0.70 to $200.

Conclusions: This preliminary evidence suggests that the Malawi government will pay less by adopting POCT XpertHIV.

PED496

Reaching absent and refusing individuals during home-based HIV testing through self-testing: a costing perspective

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Background: In the HOSENG trial (NCT03598686) in 2018, secondary distribution of oral self-tests for persons absent or refusing to test during a home-based HIV testing campaign in rural Lesotho resulted in an increase in testing coverage of 21%. This study aims to determine the unit costs per person enumerated, eligible for testing, tested and confirmed new HIV+ during the home-based HIV testing with and without secondary distribution of self-tests.

Methods: We conducted a micro-costing study to estimate the cost of home-based HIV testing with and without secondary self-test distribution from a provider's perspective. A mixture of top-down and bottom-up costing was used. We estimated both the financial and economic per patient costs of each possible testing cascade scenario.

Results: The overall provider cost for delivering the home-based HIV testing with secondary distribution was US$36'481 among the 4174 persons enumerated and 3094 eligible for testing in the intervention villages, compared to US$28'620 for 3642 persons enumerated and 2727 eligible for testing in control. The cost per person eligible for testing was US$11.79 in intervention versus US$10.50 in control. This difference was mainly driven by the cost of distributed oral self-tests. The cost per person tested was, however, lower in intervention villages (US$15.70 vs US$22.15) due to the higher testing coverage achieved through self-test distribution. Cost per person confirmed new HIV+ was US$889.79 in intervention and US$753.17 in control.

Conclusions: A self-testing strategy yielding high coverage and the optimal integration of the self-test follow-up in the existing health system resulted in low cost of secondary self-test distribution during home-based HIV testing in Lesotho. These results may inform the current large-scale roll-out of HIV self-tests in Africa – also driven by the COVID-19 pandemic – and should be taken into account in home-based testing policies in similar settings.

PED497

Piloting social contracting mechanisms for government procurement of HIV services in the EECA region

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Background: Countries that are in the transition from donor to budget financing of services are looking for approaches and mechanisms for the procurement of HIV services using budget funds. For 5 years, Institute for Analysis and Advocacy has been working on the analysis of public contracting mechanisms and advocacy for their implementation in countries. This made it possible to develop the main criteria for a successful transition to public contracting mechanisms.

Description: We analyzed the experience of different countries, where progress was noted in the development and use of contracting mechanisms. In Ukraine, we chose a mechanism for the electronic procurement of services through a tender. In Moldova, in 2020, they created a precedent for purchasing services from NGOs from the prevention fund of the National Insurance Company. In Georgia, in 2020, the model was used for 6 months, when the main recipient of public money was GHRN, which, in turn, entered into contracts with NGO service providers in the regions. All of these models had their advantages, but also showed gaps that needed to be eliminated and refined in the mechanisms.

Lessons learned: The main criteria that we consider important for the effectiveness of public contracting are accountability, transparency of the procurement process, sustainability of allocated funding and ensuring continuity of services. In this vein, the most optimal approach is a model close to the primary health care financing mechanism - payment for a service. The transition to such a model is complex. The main points that should be worked on in any model are the regulation of services and their adaptation to government regulations, standards, financing procedures.

Conclusions/Next steps: In 2020, some of the EECA countries launched the development of tariffs, service standards, and began the process of reallocating funds for HIV services. For the sustainable use of social contracting, it is important to have protected lines in the budget for services, to regulate the very concept of HIV services, to increase the capacity of NGOs to work in new funding models, and also to ensure the possibility of operational changes and improvements in mechanisms based on the results obtained in countries' annual experience.

PED498

Cost of opioid substitution therapy provision: a global systematic review of unit cost estimates

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Background: Opioid substitution therapy (OST) is effective in reducing risks of HIV, HCV, and overdose. Due to varied implementations of OST across and within countries, there is a lack of evidence synthesizing the economic cost of OST programs to guide policymakers. We conducted a global systematic review of unit costs of OST provision.

Methods: From January-October 2020, we conducted searches of 11 peer-reviewed literature databases and 5 grey literature sources using both economic and intervention-specific terms, with no geographic,

date or language restrictions. Articles were excluded if they:
1) reported on costs other than OST program (e.g., only drug costs);
2) had no primary cost data for OST; and
3) only presented claims data or patient charges.
Relevant data on study attributes, intervention details, cost categories were extracted from eligible studies. The outcome of interest was the monthly OST cost per person. All costs were adjusted to 2020 US Dollars.
Results: From 98 eligible studies, 189 cost estimates across 32 countries were obtained, representing only 44% of 72 countries with known OST programs in 2017. Most cost estimates originated from the US (n=64,34%) or Australia (n=25,13%), with only 9% (n=15) from low-middle income countries. Methadone was the main drug costed (66%), with the remainder assessing buprenorphine or buprenorphine/naloxone. Most estimates (83%) were derived using micro-costing as opposed to top-down approaches.
Most studies adopted a provider perspective (85%) with the remaining adopting societal/patient perspectives. Mean OST provision costs per person per month were highest for high-income countries ($664,IQR: $272-$708) compared to middle/low-income countries ($86,IQR: $26-$54).

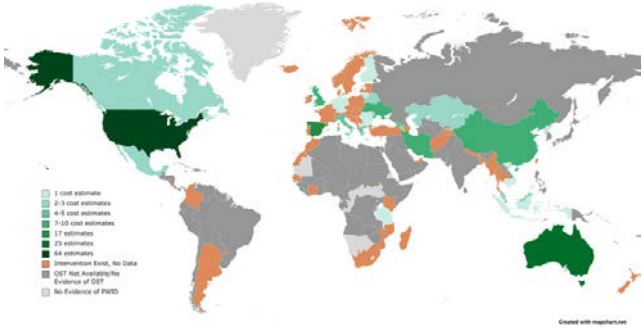

Figure 1. OST unit cost estimates obtained from a global systematic review

Conclusions: Cost data was unavailable for most countries with known OST programs, with key data gaps in lower/middle-income countries. Greater efforts to assess the cost of OST provision are needed to ensure effective HIV prevention interventions are financed.

PED499

Extrapolating country-level cost of opioid substitution therapy provision using global systematic review data

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Background: Opioid substitution therapy (OST) is implemented in many countries to treat opioid use disorder and prevent HIV, HCV, and overdose. Our recent global systematic review found OST cost data from 44% of countries with known OST programs. We developed a regression model suited for extrapolation of unit costs of OST for countries with no estimates.
Methods: We used estimates of the cost of OST provision per person per month (n=170 cost estimates across 31 countries) obtained from our global systematic review. All costs were converted and inflated to 2020 USD. We conducted linear mixed-effects modeling with random country-level intercepts to assess the association between the outcome, log monthly cost of OST provision per person, and the independent variable, log country-level per-capita gross domestic product (GDP). Other covariates that were considered included prevalence of injection drug use, HIV prevalence among PWID, and country-level OST coverage. We used stepwise backward elimination to generate the most parsimonious model. Cost estimates of Iran were excluded to assess the internal validation of the model's performance.
Results: Only the log per-capita GDP was retained in the final model. For every unit increase in the log per-capita GDP, the log monthly cost of OST provision per person would increase by 0.81 dollars (p<0.001) (Figure 1), with country-level random-effects (0.59,SD 0.77,p<0.001).
Conditional R-squared accounting for both random and fixed effects in the model revealed a substantial portion (65%) of the variability of the mean log OST costs could be explained by the log per-capita GDP. The log cost of OST provision for Iran predicted by the model lied within the 95% prediction interval.

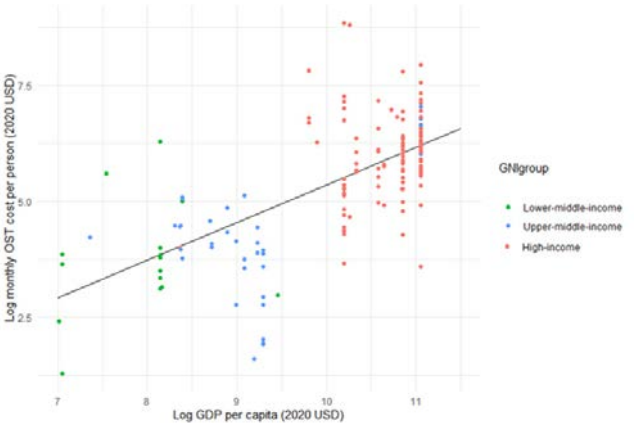

Figure 1.

Conclusions: A simple regression model using per-capita GDP can be useful in extrapolating OST unit costs in countries without data, and may be useful in determining optimal resource allocation for prevention of HIV, HCV, and overdose interventions.

Transitional financing

PED500

Costs and costs-at-scale of provision of HIV self-testing kits by civil society organisations to key populations and their sexual partners in Côte d'Ivoire, Senegal and Mali

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Background: Despite significant progress on the proportion of individuals who know their HIV status in 2020, Côte d'Ivoire (76%), Senegal (78%), and Mali (48%) remain far below the 90-90-90 targets. Key populations including female sex workers (FSW), men who have sex with men (MSM), and people who use drugs (PWUD) are the most vulnerable groups with

HIV prevalence at 5%-30%. HIV self-testing (HIVST) was introduced in West Africa in 2019 as a new testing modality through the ATLAS project coordinated by the international partner organisation Solthis (IPO).

Methods: We estimated the costs of implementing HIVST through twenty-three civil society organisations (CSO)-led models in Côte d'Ivoire (N=7), Senegal (N=11), and Mali (N=5). We modelled costs for programme transition (2021) and early scale-up (2022-2023).

Results: Between July-2019 and September-2020, a total of 51,028, 14,472 and 34,353 HIVST kits were distributed in Côte d'Ivoire, Senegal, and Mali, respectively. Across countries, 64%-80% of HIVST kits were distributed to FSW, 20%-31% to MSM, and 5%-8% to PWUD. Cost per HIVST kit distributed ranged from $12-$15 (FSW), $14-$27 (MSM), to $15-$143 (PWUD), driven by personnel costs at various intervention levels (53%-78% of total costs), and HIVST kit costs (2%-15%). Predicted costs at scale-up ranged from $5-$13 (FSW), $5-$24 (MSM), to $13-$53 (PWUD), and were mainly explained by the spreading of IPO costs over higher HIVST distribution volumes (Figure 1).

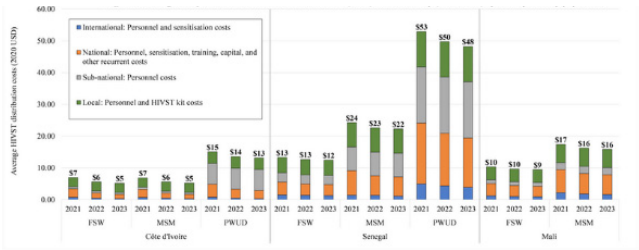

Figure 1. Average cost per HIVST kit distributed in transition (2021) and at scale-up (2022-2023) by country and key population

Conclusions: In all countries, CSO-led HIVST kit provision to key populations showed relatively high costs related to the progressive integration of the programme to CSO activities and contextual challenges (e.g. country security issues).

In the transition to scale-up and further integration of the HIVST programme into CSO activities, this model can become less costly. This is particularly relevant as it remains today the most promising strategy for reaching key populations and their sexual partners not accessing HIV testing.

Impact of donor agencies' policies and international financing initiatives

PED501

HIV funding and access to treatment in sub-Saharan Africa

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Background: From 2004, Global Fund to Fight AIDS, TB, and Malaria (GF) and the United States President's Emergency Plan for AIDS Relief (PEPFAR) have disbursed $79 billion for the HIV response. Still, in 2019, HIV treatment coverage was only 67% along with 1.7 million new infections and 690,000 AIDS-related deaths. This raises concerns regarding the prioritization, accountability, and impact of this significant global public health investment.

Methods: From 2010 to 2019, we abstracted HIV funding data for 40 countries in sub-Saharan Africa (70% global and >99% regional HIV burden, respectively). Complete PEPFAR planned funding and GF disbursed amount data were available. Domestic HIV spending was available for 2012-2018 (UNAIDS National AIDS Spending Assessment). Further, we adjusted for purchasing power parity and looked at the impact of GF+PEPFAR funding per person living with HIV (PLHIV) on ART coverage, viral suppression, AIDS-related deaths and new HIV infections in 2018 using regression analysis.

Results: During 2010-2019, there was ~$52 billion funding for 40 countries in sub-Saharan Africa (range: $12 million to $8 billion per country). Domestic funding per country ranged from $0 to $3.2 billion. Global Fund funding averaged $306 million for 2010-2019 ($1.9 million to $1.1 billion). Overall, PEPFAR funding was $32 billion (average $1.4 billion per country; range $0.89-4.3 billion) for a subset of 22 countries. For the 40 countries, among PLHIV, known HIV status averaged 80% (11%-94%), ART coverage averaged 64% (9%-90%) and viral suppression ranged from 8%-87%.

For 2010-2019, the *adjusted GF+PEPFAR funding per PLHIV* averaged $2,387 (range $30-$12,252) and was significantly correlated with 2018 ART coverage, viral suppression and deaths. On average, a 10% higher *adjusted GF+PEPFAR funding per PLHIV* was associated 4 percentage points higher ART coverage and viral suppression both, and 2.2 lower deaths per 1,000 PLHIV.

Conclusions: The 90-90-90 target is feasible in challenging settings if resources are used efficiently. However, despite the significant investment, many countries have not reached the minimum 90-90-90 target (73% viral suppression). Greater attention to efficiency and prioritizing testing and treatment targets will be required to reach at least 90-90-90 and end AIDS in Africa.

PED502

FY19-20 local vs. international PEPFAR prime partner performance

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Background: In 2018, PEPFAR announced that by the end of fiscal year (FY) 20, 70% of funding from each implementing agency within a PEPFAR supported country should be provided to local prime partners. By the close of FY19, PEPFAR allocated 48% of global funding to local prime partners and, by the close of FY20, allocated 52%, remaining short of the target.

We analyzed FY19-20 local vs. international prime partner financial, epidemiological, and comparative value per result performance to evaluate how local prime partner investment has contributed to PEPFAR programmatic goals on the path to reaching the 70% target.

Description: FY19-20 (October 1, 2018-September 30, 2020) global PEPFAR expenditures and ten key PEPFAR indicator results are included. PEPFAR's two global commodity procurement mechanisms, GHSC-PSM and GHSC-RTK, and any partners with unknown local partner designation are excluded.

Lessons learned: Of key PEPFAR care and treatment, testing, orphans and vulnerable children, PrEP, and voluntary medical male circumcision indicators, local prime partners contributed 55% of FY 19 and 62% of FY 20 results while outperforming international prime partners in three, then six, indicators from FY19-20.

Additionally, in FY20, local prime partners accounted for 53% of total expenditures, but only 14% of indirect costs and 38% of Program Management expenditures. Local prime partners demonstrated greater value for result in 6/10 key indicators when combining FY19-20 expenditures/results.

Conclusions/Next steps: Results indicate local prime partners positively contributed to FY19-20 PEPFAR financial and programmatic success. Future analysis should replicate the study at the subrecipient partner level.

Figure. Local prime partners increased share of indicators where they outperformed international prime partners from three to six indicators from FY 19-20

Figure. Local prime partners had better value per result than international prime partners in 6/10 key PEPFAR indicators from FY 19-20

included equity analyses and 11 (46%) NSPs prioritized key populations. Five (11%) funding requests directed key populations and human rights catalytic funding towards NSP interventions. Models focused narrowly on HIV outcomes, undermining Universal Health Coverage (UHC).

Less than 50% of NSPs referenced UHC. Seventeen (71%) NSPs had resource mobilization strategies, but just eight (18%) countries aligned Global Fund co-financing to these.

Figure 1. Total number of references to NSPs, by funding request section

Conclusions: Inadequate design and use of prioritization approaches contributes to the inefficient use of scarce resources. Deliberate timing of NSPs vis-a-vis funding requests could improve alignment. Greater local ownership and capacity is needed to strengthen prioritization methods.

Political economy of HIV

PED503

Broken telephone: Improving the alignment of economic methods in priority setting, national strategic planning, and Global Fund grants, for a more efficient and effective AIDS response

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Background: The world is off-track to end AIDS by 2030. A 30% resource shortfall is further constrained by COVID-19. Countries often lack efficiency analysis and current prioritization approaches fail to effectively reduce incidence and address inequalities. The AIDS response must become more focused. To improve decision-making, UNAIDS, WHO, UNDP and the World Bank commissioned a review of prioritization methods and approaches in economic models, national strategic plans (NSPs), and Global Fund requests.

Methods: The team reviewed modeling for 15 countries, NSPs for 24 countries, and funding requests for 44 countries. Sampling sought a diversity of epidemic profiles, funding landscapes, and health system dynamics. The sources were evaluated for their own merit according to a quality framework. Prioritization methods were compared to assess alignment.

Results: Economic and modeling analyses used as inputs to NSPs and funding requests were focused on meeting existing targets, rather than optimizing resource allocations. Cost-effectiveness was explored in 13 (86%) modeling analyses, 12 (50%) NSPs sought resource efficiencies, but just two (5%) funding requests expressly used these same approaches to prioritize allocations. Funding requests commonly drew on NSPs to illustrate country context, but seldom to describe prioritization approaches, value for money, and efficiency (Figure). Poor prioritization disadvantaged vulnerable groups. Eleven (71%) modeling exercises in-

Innovative financing mechanisms (e-financing, partnerships, etc.)

PED504

Mobilization of an international community-based network and community-based expertise to rapidly and effectively respond to the needs of key populations during the COVID-19 health crisis

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Background: The COVID-19 health crisis has impacted the work of community-based organizations (CBOs) which provide health-related comprehensive services for people living with HIV (PLHIV) and/or hepatitis. National public health responses have largely failed to implicate CBOs and therefore, prevention messages and services do not meet the needs of key populations (KPs). Drawing on decades of community expertise and established relationships with institutional partners, an international network of CBOs constituted an emergency fund to meet the needs of member CBOs and their beneficiaries in the context of the COVID-19 crisis.

Description: Coalition PLUS is an international network of CBOs involved in the fight against HIV/AIDS and viral hepatitis, active in 52 countries in the Global North and South. From April 2020, Coalition PLUS constituted an emergency fund using a portion of their institutional funding (Agence française de développement, Expertise France, Unitaid, Robert Carr) in addition to their own funds. This fund aimed to assure the continuity of a minimum package of services for PLHIV and KPs, COVID-19 information and awareness activities and to respond to basic and therapeutic needs of KPs.

Lessons learned: A total of 1.4 million euros was available to the Coalition PLUS network; 45 CBOs in 34 countries received funds, ranging from 5 000 € to 181 000 €. CBOs were increasingly faced with providing basic

needs (personal hygiene items, food) for the most marginalized, thus broadening their role. This mobilization was complementary to national responses, and sometimes constituted the unique answer for marginalized populations. The constitution of this emergency fund made Coalition PLUS learn a new way of interacting with its members and partners while maintaining a community-based approach, illustrated by the flexibility of the funds for a more adaptive and immediate response.

Conclusions/Next steps: Mobilization of the Coalition PLUS network and its proximity to KPs allowed the continuity of services and the provision of emerging needs related to the crisis. The structure of the organization showed its collective force to efficiently and effectively respond and adapt in a pandemic. This experience has reinforced the necessity to implicate CBOs, for their network and community-based expertise, in national health responses to meet the needs of KPs.

Impact of COVID-19 on HIV funding

PED505

Estimated cost-based generic prices for key ARVs and effect of COVID-19 on manufacturing costs

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Background: India is a key site for antiretroviral (ARV) manufacturing. The COVID-19 epidemic has affected Indian medicine markets through export bans, disruption in base ingredient trade with China, demand interruptions, and currency fluctuations. The cost of active pharmaceutical ingredient (API) is a significant determinant of the cost-of-production. This analysis evaluates effects on HIV API markets and calculates estimated cost-based generic prices for key ARVs.

Methods: API price data were collected from an Indian customs database (Panjiva). Annual weighted mean cost/kg were calculated for 2018-2020. Cost-based generic prices were calculated using an established algorithm, accounting for per-tablet API costs, excipients, assumed formulation cost ($0.01/unit), a 10% profit margin, and tax obligations on profits. WHO defined daily doses (DDD) were used to calculate cost per patient per year at estimated cost-based generic prices, (except for ritonavir: 200mg/day assumed).

Results: With the exception of emtricitabine, API costs continued to decline through 2020 (Table 1), suggesting that in general ARV API costs were not affected by COVID-19.

	2018 exports API cost (2020 USD/kg)	2019 exports API cost (2020 USD/kg)	2020 exports API cost (2020 USD/kg)	Estimated generic price per patient per year (2020 USD)
atazanavir	846	812	733	108
dolutegravir	2,450	948	715	21
efavirenz	125	151	118	34
emtricitabine	359	258	553	50
lamivudine	225	188	201	30
lopinavir	475	563	507	185
ritonavir	463	668	662	63
tenofovir disoproxil fumarate	171	55	30	8
zidovudine	236	279	241	86

Table 1. 2018-2020 API costs/kg for key HIV medicines and estimated generic price per patient per year

**Insufficient data available for bictegravir, nevirapine, raltegravir, rilpirivine, and TAF.*

Estimated cost-based generic prices were lowest for widely used first-line ARVs (US$8/year for TDF) and higher for second- and third-line ARVs (US$108 for atazanavir). As fixed-dose combination once daily tablets, cost-based generic prices per year were estimated to be $80 for TDF/3TC/DTG (first line) and $191 for AZT/3TC/ATV/r and $256 for AZT/3TC/LPV/r (second line).

Conclusions: Prices of ARVs are a key factor in determining access to treatment. API costs continue to decrease despite COVID-19 interruptions. Possible explanations for observed API price resilience include: well-established ARV markets, with predictable demand and largely centralized procurement. However, this analysis is limited to India, and cannot establish whether disruptions occurred elsewhere in the supply chain downstream from API.

Changes in policy and practice

PED506

The global advanced HIV disease toolkit: a resource for the rollout of the World Health Organization package of care for advanced HIV disease

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Background: Advanced HIV Disease (AHD) significantly drives HIV-related mortality. A toolkit was identified by various stakeholders as critical to support the introduction of the World Health Organization package (WHO) of care for AHD in Low- and Middle-Income Countries (LMICs). The Global AHD toolkit (GAHDT) was subsequently developed. We describe the GAHDT, approach to development, dissemination and lessons learned.

Description: The GAHDT is a comprehensive resource featuring; programmatic, patient literacy, job aids and training materials. It was designed to minimize complexities during rollout of the WHO AHD package in 9 focal LMICs: Uganda, Nigeria, Tanzania, Malawi, Lesotho, Botswana, South Africa, Zimbabwe and India. Development, led by Clinton Health Access Initiative (CHAI) and a consultant, in collaboration with partners under the AHD Implementation Steering Committee of the Unitaid/CHAI AHD Initiative, spanned June-September 2019. It involved: a needs assessment, call for and collaborative review of existing tools submitted, collaborative development of lacking/novel tools, finalization and launch. Guiding principles were: focus on the 2017 WHO AHD package; consideration of Ministries of Health (MoHs) goals, engagement with the patient community, healthcare workers (HCWs) and implementing partners as beneficiaries; and a 'Hub-and-Spoke' approach to rollout. Released as an offline resource in September 2019, the toolkit was subsequently hosted at https://differentiatedservicedelivery.org/Resources/Resource-Library/Global-Advanced-HIV-DiseaseToolkit in collaboration with the International AIDS Society in April 2020.

Lessons learned: MoHs in at least 5 focal LMICs have adapted these tools and delivered HCW-trainings on the AHD package. Other focal countries are at various stages of review/adaptation. Lessons include:

- The toolkit provided the much-needed suite of tools to facilitate country-level review, introduction and implementation of the AHD package.
- Multi-stakeholder engagement (donors, partners, academia, HCWs, civil society, MoHs) was critical during development to improve buy-in and relevance to LMICs.
- The call for existing tools improved content diversity, encouraged partner participation and reduced development timeline.
- The transition to open-access online hosting accelerated dissemination to other LMICs.

Conclusions/Next steps: The GAHDT is the first multi-partner resource to support implementation of the WHO AHD package in LMICs. Its continued availability is a critical enabler for improved access to the AHD package to reduce HIV mortality. Other LMICs may leverage the GAHDT for introduction efforts.

PED507

HIV treatment in sub-Saharan Africa: delays in transition to dolutegravir

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Background: In July 2018, WHO assumed a regulatory role and issued a "safety signal" regarding dolutegravir (DTG) based on preliminary Botswana *Tsepamo* neural tube defects study data. Regulatory evaluations of rare neonatal adverse reactions are complex and require considerable subject area expertise. In July 2019, WHO reversed itself and recommended DTG as part of the preferred first-line HIV treatment for all adults. The year delay, mixed messaging, and confusion regarding DTG safety may have impacted national level adoption.

Methods: We collected 35 HIV guidelines published after 2015 for 20 countries in the sub-Saharan Africa (94% regional HIV burden in 2019, 24 million people living with HIV). We abstracted publication date and DTG-specific recommendations. Months delay to revised national guidelines after the WHO 2019 DTG recommendation were calculated.

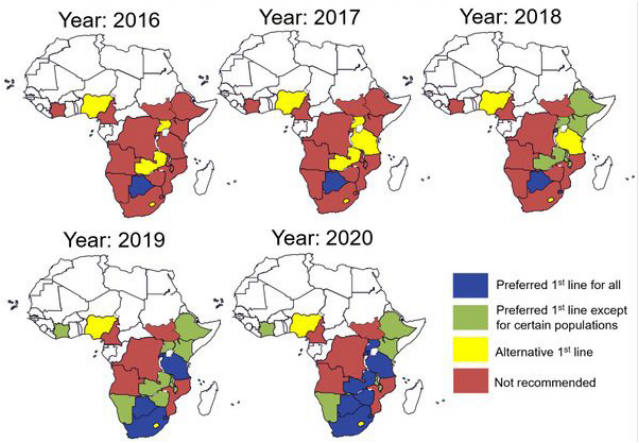

Figure. DTG recommendation in 20 countries, 2016-2020

Results: As of February 2021, only eight countries (55% regional burden) recommend DTG for all adults per WHO 2019 guidelines. Five countries (15% regional burden) recommend DTG with exception of pregnant women and/or women of childbearing age (WHO 2018 recommendations) and two countries (9% regional burden) recommend it as an alternate regimen (WHO 2015 recommendations). DTG is still not recommended in five countries (15% regional burden). The average time lag of WHO 2019 guidelines adoption was 5 months (range 3–7 months). Assuming that the remaining 12 countries adopt DTG for all adults by February 2021, the average time lag will increase to 12 months.

Conclusions: Adoption of DTG in sub-Saharan Africa is delayed. The 2018 false alarm and ensuing confused messaging about safety may be contributing to the delay. Monitoring uptake of WHO guidelines provides an opportunity to learn lessons and take corrective actions. Millions of lives depend on establishing a critical pathway for the rapid translation of science to service delivery while holding people and agencies accountable for accelerating or delaying proposed national policy changes.

PED508

Improving access to ART and documentation for patients unable to reach their parent health facilities due to COVID-19 restrictions in East Central, Uganda

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Background: To reduce the rapid person-to-person spread of COVID-19 during 2020, the Government of Uganda implemented a lockdown, curfew hours, and suspension of public transport which left a number of people living with HIV (PLHIVs) stranded far from their parent ART facilities hindering access to antiretroviral drug (ARV) refills. This prompted patients to visit the nearest health facility, however, this posed a challenge of how to serve them without compromising accountability for the antiretroviral treatment (ART) drugs and disrupting the stocks for the existing patients in their respective health facilities.

Description: During April-June 2020, with support from the district leadership, 58 health facility teams in eight districts in East Central Uganda were supported to: Develop, distribute and orient ART clinic teams on a tool to capture key details of 'visiting' clients (*Name/ART No., Mother ART Site, ART Regimen, Quantity of ARVs Dispensed)* ; conduct monthly physical counts to ascertain the current stock status of ARVs; conduct inter-facility redistribution of ARVs to mitigate stockouts between distribution cycles; compile facility ARV orders to national ARV warehouses, document ART dispensations to visiting clients.

Lessons learned: During the period April-June 2020, 1,954 visiting clients were provided ARVs refills by 58 health facilities across 8 districts which ensured uninterrupted treatment. This accounted for 5% (1,954/41,674) of the patients served in the same period at these facilities. Majority of the visiting patients 85% (1,655/1,954) refilled from non-ART parent sites. Proper documentation put in place using the new tool ensured ART facilities and districts quantified for the proportion of non-regular patients receiving ART refills, improved accountability for ARVs dispensed. Stock outs due to the sudden increase in consumption were also minimized through inter-facility communication, focused redistributions and documenting the extra consumption in the subsequent ARV orders.

Conclusions/Next steps: Proper documentation of key details of visiting PLHIVs receiving ART at facilities where they are not enrolled improves accountability and availability for ARVs. The documentation of refills on visiting clients and quantification improves accuracy of ARV orders to national warehouses and enables inter-facility communication for focused ARV redistribution to mitigate stockouts.

PED509

Improving viral load testing and suppression through implementation of differentiated service delivery models during COVID-19 in five counties in Kenya

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Background: As COVID-19 continued to spread, HIV programs in Kenya are experiencing disruptions. Safeguarding the gains of the national HIV response requires accelerating differentiated service delivery (DSD) interventions while minimizing potential exposure of health care workers and patients to COVID-19. The USAID-funded Afya Nyota ya Bonde (ANyB) project implemented by FHI 360 in five counties in Kenya adapted and scaled-up DSD interventions to improve viral load (VL) testing uptake and suppression.

Description: Beginning January 1, 2020, the following models were implemented to ensure treatment adherence and improve viral suppression, and to improve VL coverage: VL sample collection aligned with clinical and antiretroviral therapy (ART) refill appointments; implementation of *papa-mama* clinics for family-oriented services; operation triple-zero clinics targeting adolescents and young women; community ART refill groups established; and weekly tracking of missed opportunities for VL. The project also implemented a hub-and-spoke model to strengthen VL sample collection and transportation in 172 ART sites using 20 laboratory hubs. Motorcycle riders picked and transported samples to reduce turnaround time.

Lessons learned: From a baseline VL testing coverage of 84% and suppression rate of 89% in December 2019, both increased to 93% by September 2020 among 62,195 eligible clients. The greatest increase in site-level VL testing coverage was among adults (20+ years), with an average 13% increase per site from 80% to 93% (p=0.012) compared to adolescents aged 10–19 years with an increasefrom 88% to 95% (p-value=0.957), and children <10 years (82% to 92%; p=0.371). Site-level viral suppression increased from 75% to 81% for adolescents, from 72% to 76% for pediatric patients, and from 91% to 94% among adults and this was statistically significant for all population groups (p<0.001).

Conclusions/Next steps: ANyB's implementation of DSD models targeting different population groups, along with strengthening its referral system through the hub-and-spoke model, led to improvements in VL testing coverage and suppression despite challenges posed by COVID-19. Scale-up of these models should continue during and beyond COVID-19 to ensure high VL testing coverage and suppression rates.

PED510

The DREAMM (Driving REduced Meningoencephalitis Mortality) project: initial results from Tanzania

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Background: Central nervous system (CNS) infection is a leading complication of advanced HIV disease (AHD), causing up to a third of HIV-related deaths in African low-and middle-income countries (LMICs). DREAMM (Driving REduced AIDS-associated Meningo-encephalitis Mortality) is to our knowledge the first implementation science project designed to reduce mortality and prospectively determine the epidemiology of CNS infection in African LMICs.

Methods: Led and informed by African leadership in 5 Ministry of Health (MoH)-supported hospitals in Tanzania, Malawi and Cameroon, DREAMM is divided into 3 phases: Observation, Training, and Implementation. The DREAMM intervention combines:

1) Health system strengthening (including mapping and optimising of clinical and laboratory pathways, and increased physician-laboratory communication);

2) Delivery of a co-designed education program focused on mortality-reducing interventions;

3) Implementation of an algorithm for diagnosis (using bedside rapid diagnostic tests alongside standard microbiology) and treatment, including WHO recommended regimens for cryptococcal meningitis, and,

4) Combined weekly clinical/laboratory communities of practise.

Results: People living with HIV (PLHIV) presenting to 2 secondary-level hospitals with probable CNS infection in Tanzania were prospectively enrolled. Standard of care prior to DREAMM was empirical therapy with antibiotics and fluconazole with 3/76 receiving a diagnostic lumbar puncture (LP). 2- and 10- week mortality were 58.5% (38/65, 95% CI: 0.46-0.71) and 64.6% (42/65, 95% CI: 0.52-0.76), respectively, excluding 11 lost to follow-up (LFU); and 64.5% (49/76, 95% CI 0.53-0.75) and 69.7% (53/76, 95% CI 0.58-0.80), respectively, with LFU=died.

Following DREAMM implementation, for the 99/150 with confirmed CNS infection, 2- and 10-week mortality were 29.2% (28/96, 95% CI: 0.20-0.39) and 48.4% (46/95, 95% CI: 0.38-0.59), respectively, excluding 4 LFU; and 31.3% (31/99, 95% CI 0.22-0.41) and 50.5% (50/99, 95% CI 0.40-0.61), respectively, with LFU=died. Cryptococcal meningitis (59.6%, 59/99) and tuberculous meningitis (34.3%, 34/99) were leading causes of CNS infection.

Conclusions: The results suggest the DREAMM intervention can substantially reduce mortality for PLHIV with CNS infection in Tanzania. DREAMM provides an effective model of in-patient AHD care with the majority of infections detected through LP. DREAMM's novel methodology is a powerful implementation vehicle bridging the gap between emergence of new trial data and evidence to inform policy and practice for scale-up.

PED511

Antiretroviral therapy refilling in people living with HIV during COVID-19 outbreak in China: a qualitative study among key stake holders

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Background: Antiretroviral therapy (ART) refilling among people living with HIV (PLHIV) in China was challenged during the COVID-19 outbreak. On Jan 26, 2020, the Chinese Center for AIDS/STD Control and Prevention issued a nationwide directive to relax restrictions on location and frequency PLHIV could obtain ART. This qualitative study was conducted to document unexpected barriers under this directive and future recommendations of ART delivery.

Methods: Between February 11 and February 15 2020, in-depth interviews of 4 groups of stake holders related to ART refilling (i.e., PLHIV, community-based organization (CBO) employees, Center for Disease Control and prevention (CDC) staff, infectious disease physicians and nurses), were conducted via WeChat. Pre-specified themes were applied before interviews: (1) barriers to getting ART refilling during the early stage of COVID-19, (2) recommendations for ART delivery. Data were managed by NVivo 11.0 and transcripts were coded using thematic analysis.

Results: Sixty-two interviewees were investigated: 16 PLHIV, 17 CBO employees, 15 CDC staff, 10 infectious disease physicians and 4 nurses. The main barriers to refilling ART during the early stage of COVID-19 included:
(1) meticulous proof materials;
(2) lack of ART refilling protocol and patient-friendly and customized drug delivery services;
(3) suboptimal communication between different stake holders;
(4) shortage in drug reserve and varying regimen.
Besides, different stake holders shared their recommendations on the optimization of ART refilling frequency and drug allocation mechanism amidst major public health emergencies.

Conclusions: Interviews of key stake holders resulted in a deep understanding of the barriers to ART refilling among PLHIV during COVID-19. ART refilling protocol, smooth administrative procedure, as well as concerted collaboration among key stake holders, are essential to alleviating ART refilling interruption among PLHIV during major public health emergencies.

PED512

The path to universal testing policy: leveraging testing and treatment evidence from a HIV social impact bond to influence national service commissioning

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Background: Health policy changes are required for England to reach the estimated 6,700 residents unaware of their HIV-positive status (PHE, 2019) and meet its goal of ending new transmissions by 2030 (GOV.UK, 2019). The Zero HIV SIB has built evidence of effective interventions within the London boroughs of Lambeth, Southwark, and Lewisham (LSL), where 1,000 of those people live (LSL SRH, 2019). Applying that evidence to influence national HIV policy is an essential function of our programme.

Description: The Zero HIV SIB tested interventions with two key outcomes: (1) New patients diagnosed with HIV and engaged in care, and (2) Previously diagnosed patients re-engaged in HIV care. 10 organizations were contracted for corresponding services: opt-out testing in ED and primary care, targeted testing by community groups, and recall systems for people who have left care. Anonymised patient data was collected by provider organizations and shared with the SIB for validation and analysis.

Lessons learned: Since provision began in November 2018, more than 280 people have been brought into HIV care in LSL, with 63.9% of patients found "late" (CD4<350). These results imply improved individual health outcomes and significant cost savings to the national health system. Initial analysis estimates more than £200,000 savings per individual linked to care, based on avoided acute care episodes and avoided future transmissions. This is especially striking as cost of HIV test in acute or primary care is less than £7.
England's HIV Commission was developed to understand current state of HIV services and inform future governmental policy. SIB evidence was incorporated into their recommendation to adopt universal testing at national scale. Their report resulted in a governmental pledge to develop a National HIV Action Plan. SIB staff and clinicians reinforced this by presenting detailed evidence to the All Party Parliamentary Group on HIV/AIDS.

Conclusions/Next steps: Robust evidence is necessary but insufficient to achieving policy change. While 2016 UK NICE Guidelines recommended routine HIV testing in high prevalence areas, this has not yet been implemented outside of independent trials. Evidence from the SIB has been crucial within national recommendations, and we aim to continue influencing the emerging HIV Action Plan.

PED514

Achieving increased uptake of viral load monitoring through task shifting to Data Clerks in Malawi

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Background: High uptake of routine viral load (VL) monitoring is crucial for epidemic control of HIV. The Malawi Ministry of Health adopted an annual viral load monitoring policy in 2019. In Malawi, VL monitoring is challenging due to provider shortages. We sought to increase VL testing by task shifting the identification of patients due for routine VL monitoring from providers to facility-based Data Clerks.

Description: Partners in Hope (PIH) is a Malawian non-governmental organization supporting HIV care and treatment in 8 districts. PIH employs Data Clerks, whose tasks involve overall facility data management including data entry, extraction from paper and electronic medical records, and reporting. In order to improve fidelity of annual viral load testing, we engaged Data Clerks to review and flag medical charts of patients due for routine VL testing. We developed a standard operating procedure, conducted onsite trainings, and provided mentoring and coaching in March 2019. We implemented and evaluated the task shifting strategy between March 2019 and September 2020.

Lessons learned: Our task shifting strategy contributed to a dramatic increase of routine VL testing by 200% from April 2019 to December 2020 (Figure 1). National stock outs of reagents and COVID-19 restrictions affected performance in Jan-Sept 2020. Rapid demonstration of clear benefits overcame initial institutional resistance to change.

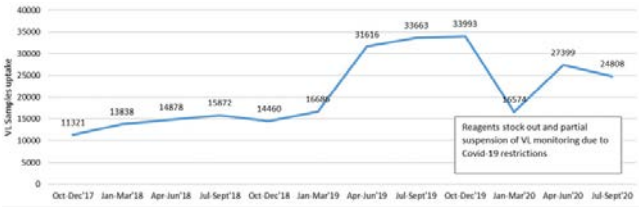

Figure 1. Viral uptake trend Oct 2018 - Sept 2020 at 101 Health facilities in Malawi

Conclusions/Next steps: A simple task shifting initiative contributed to dramatically increased uptake of VL testing. Data Clerks and other lay health workers may also play crucial roles supporting other steps along the VL cascade, such as identifying patients with high VL results for tracing, flagging availability of new VL results at the next clinic visit and real-time results updating to optimize electronic VL system alerts.

PED515

Policy changes to prevention, diagnosis and treatment to HIV during COVID-19 pandemic

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Background: COVID-19-pandemic and need for social distancing was a new challenge for the HIV prevention and care policy, recognized for its broad and qualified performance. To deal with this, Ministry of Health(MoH) has taken some measures to guarantee access to the health system and minimize the impact of COVID-19 in people living with HIV and key populations. This summary intend to present changes in public policies related to HIV during pandemic.
Description: With the aim to ensure care for people living with HIV, guarantee access to antiretrovirals(ART) and viral suppression(VS) and also minimize the pandemic impact on access to diagnosis and prevention, MoH implemented several innovative measures. The validity of ART prescriptions to PLWHIV were extended to up to an year and ART pills were provided for a longer period, from 30 days to now 60 or 90 days. Also, MoH added digital prescription and electronic signature to ART and encouraged the use of telemedicine. For PrEP, in addition to the digital services described above, it was also allowed to distribute a larger number of drugs and use the self-test for the diagnosis of HIV. This measures avoided new visits to medical appointment and health services. Target-testing was also implemented using self-test technology for vulnerable groups. Finally, with the national immunization program, vaccination for PLWHIV and CD4 below 350 was guaranteed as a priority.
Lessons learned: These actions reflect an important increase in PLWHIV seeking remedies for more than 60 days in treatment and PrEP. This measure was made possible by increasing the quantity of pills distributed to local pharmacies. This change were essential to ensure that PLWHIV to maintain adherence to ART, and ensured the maintenance of the percentage of VS. Focused testing allowed an increase in the number of tests performed, compared to 2019.
Conclusions/Next steps: The pandemic is challenging for the health-system. The actions taken were essential, mainly because they are a set of actions that reflect on the success of the follow-up of this population. New ways of monitoring, further increasing the number of pills and allowing access to vaccine to all PLWHIV are challenges that MoH has to be implemented.

Capacity-building initiatives

PED516

Timely pediatric regimen optimization at health facilities in Malawi is achievable despite COVID-19 pandemic restrictions with use of a virtual pediatric optimization toolkit and dedicated family ART clinic days

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Background: Pediatric ART coverage in Malawi has dramatically improved, however viral load suppression (VLS) among children remains suboptimal. New pediatric ART regimens provide hope for improved VLS. Despite Malawi's early establishment of a robust pediatric optimization policy, implementation was complex with multiple pediatric weight based regimens including use of LPV/r granules and complicated further by COVID-19 pandemic movement restrictions suspending in-person training and supervision.
Description: To facilitate transition to optimized pediatric ART regimens despite COVID-19 restrictions, we:
1) created and disseminated a virtual pediatric optimization toolkit (V-POT) consisting of a case based asynchronous self-study for clinical mentors, a decision-making tool to guide regimen transition, and an educational video for guardians on LPV/r granule administration, and;
2) established family ART days to facilitate phone consultation by experienced clinical mentors and encourage guardian peer support.
V-POT was disseminated to clinical and lay health staff via email and WhatsApp. Using V-POT's decision-making tool, facility-based providers recorded a child's ART regimen, weight, and latest viral load result, and clinical action guidance was provided by phone with experienced mentors. V-POT was implemented at 120 health facilities from April - December 2020.
Lessons learned: With delivery of V-POT, children receiving optimized ART regimens increased from 29% in December 2019 to 93% by December 2020 (figure 1).
V-POT was easily implemented with good uptake and allowed identification and consultation of complex cases.

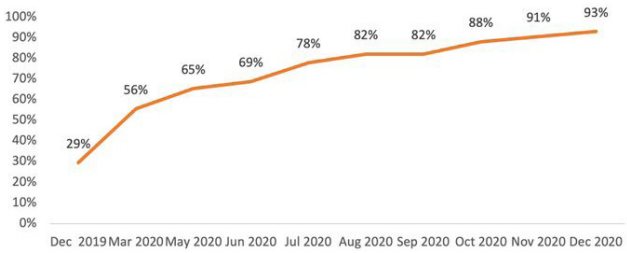

Figure 1. Proportion of clients on peds regimens on optimized regimens

Conclusions/Next steps: Use of a virtual package of support and family ART clinics facilitated mentorship resulting in timely regimen transition for children in Malawi despite limited in person support related to COVID-19. Next steps include adaptation of V-POT to facilitate continued VLS monitoring post-regimen optimization, as well as use for the DTG transition for children <20kg. V=POT can be adapted to different clinical topics to address other complex management decision.

PED517

Improving paediatric viral load coverage and suppression through scale-up of service quality assessments and viral load committees in Ndola District of Zambia

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Background: Despite notable progress toward reaching UNAIDS 90-90-90 targets in Zambia, paediatric HIV Viral Load testing Volume (VLV) and VL Suppression (VLS) remains suboptimal. Government data from Ndola District, Zambia showed that VLV and VLS for paediatrics (0-14 years) stood at 688 and 328/688 (48%) in quarter one (Q1) 2019, respectively, respectively. The Clinton Health Access Initiative (CHAI) works in partnership with the Zambia Ministry of Health (MoH) to accelerate testing and treatment coverage for children living with HIV.

Description: In Q2 2019, CHAI and MoH implemented paediatric Service Quality Assessments (SQAs), recommended in the MoH Quality Improvement and Assurance Guidelines for Health Workers in Zambia. This was done in 10 facilities in Ndola to comprehensively monitor performance against service delivery quality standards related to infrastructure, human resources, equipment, clinical practices, data documentation and commodities and supplies for the paediatric population. SQA roll out involved establishment and training of district- and facility-level multidisciplinary teams to utilize the SQA tools, developing data dashboards to visualize real-time results and developing standard operating procedures.

Lessons learned: Baseline SQA findings revealed 3/10 (30%) facilities monitored VL according to national guidelines, 6/10 (60%) facilities documented receipt of adherence counselling, and 5/10 (50%) facilities had complete ART clinical teams with all members trained in paediatric HIV management. These findings prompted the establishment of district- and facility-level VL Committees to implement targeted remedial measures, including VL data audits and review meetings, coordinated sample management and referral, and targeted paediatric HIV clinical mentorship. A Welch's t-test was conducted on VL testing volumes and suppression following the intervention, finding a significant increase in paediatric VL testing volumes (668 *vs* 5,016 tests; p=0.0000001), and VLS (48% *vs* 84%; p=0.0000000001), from Q1 2019 to Q2 2020.

Conclusions/Next steps: Scaling up comprehensive and structured quality improvement (QI) approaches such as SQAs and establishment of VL committees to implement targeted remedial measures resulted in major improvements in VLC and VLS among children 0-14; and can be important strategies to achieve Zambia's HIV epidemic control goals by 2030.

PED518

Human resources for health investments increase cervical cancer screening among women visiting HIV clinics in Malawi

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Background: Cervical cancer is the most common malignancy among Malawian women, accounting for 45% of all cancer diagnoses. Cervical Cancer Prevention (CECAP) services, VIA screening and treatment of pre-invasive lesions, are effective in preventing morbidity and mortality, but coverage is low mainly due to shortages of trained providers. Available trained Ministry of Health CECAP providers are frequently deployed to other health care activities due to competing priorities, creating gaps in CECAP service delivery. Between October 2019-September 2020, we sought to extend CECAP services for women attending HIV clinics at 9 Partners in Hope (PIH) supported high-burden health facilities in Malawi using a rapid training and deployment strategy.

Description: PIH engaged 13 facility-based and roving Community HIV Nurses and provided two-week theoretical and practical trainings to them to ensure continuous CECAP services during HIV clinics. In addition, PIH distributed CECAP job aids and conducted monthly mentorship by senior staff using a standardized CECAP mentorship toolkit. Investments were: nurses salaries/effort USD 99,450; training USD 29,000; mentorship USD 3,490 and job aids USD 272.

Lessons learned: Between October 2019-September 2020, we provided CECAP services to 21,629 women on antiretroviral therapy. CECAP service was partially suspended in April-May due to Covid-19 measures. Service provision quantity increased by 60% during the intervention period (quarter 1 vs. quarter 4; *Figure*). 432 women were VIA positive (2%), of whom 301 (70%) received same day treatment and 126 (29%) were referred due to large lesions. In 1% of women, treatment was postponed for non-documented reasons.

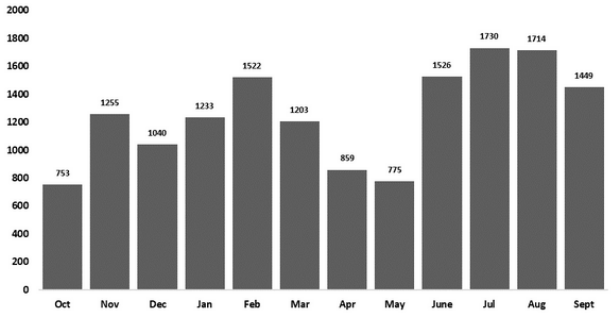

Figure. VIA screening among women on ART at 9 Malawian health facilities, Oct 2019 - Sep 2020

Conclusions/Next steps: Limited investments in training and mentorship strongly increased CECAP achievements despite challenges related to the Covid-19 epidemic. Consistent availability of dedicated, trained staff is crucial for optimizing CECAP service uptake among high-risk Malawian women attending ART clinics.

Reduction of socio-structural barriers and stigma discrimination

PED519

The impact of HIV stigma on time to art initiation in four African countries

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Background: HIV-related stigma poses a major barrier to antiretroviral therapy (ART) access and adherence, but little is known about the quantitative impact of stigma on time to ART initiation. To assess this relationship, we analyzed data from the nationally representative Population-based Impact Assessment (PHIA) surveys conducted in Eswatini, Malawi, Tanzania, and Zambia between 2015-2017.

Methods: This retrospective cohort analysis included adults ≥ 18 years who self-reported as HIV+ in one of the four surveys, had a reactive HIV test, provided dates of their first HIV+ test result and ART initiation, and completed the survey stigma module. The stigma module asked about:

1. feeling the need to hide one's HIV+ status when seeking health care, and;
2. having been denied health services because of HIV status in the last 12 months.

Time to ART initiation stratified by demographics and stigma status was analyzed via inverted Kaplan-Meier curves. The association between stigma and the probability of ART initiation was assessed via proportional hazards regression accounting for survey design.

Results: Among 9,376 HIV+ adults, 5,384 reported an ART initiation date with complete data. Just over half (55%) reported initiating ART within one month of HIV diagnosis, 72% within one year, and 78% within two years, cumulatively. 9.3% of all HIV+ adults reported feeling the need to hide their HIV status at a health care facility and 2% reported being denied health services.

Individuals who reported experiencing stigma were significantly less likely to initiate ART at all time points compared to those who did not ($p < 0.001$).

After adjustment for demographics and year of diagnosis, compared to those who reported experiencing stigma ("Yes" to each questions), those who did not report needing to hide their status (HR: 1.19 [1.03-1.38]) and those who did not report being denied healthcare (HR: 1.46 [1.02-2.07]) were significantly more likely to report a shorter rime interval between HIV diagnosis and ART initiation.

Conclusions: These representative findings from Eswatini, Malawi, Tanzania, and Zambia quantify the impact of HIV-related stigma on timely initiation of ART. Strengthening stigma reduction policies and programs has the potential to accelerate progress toward the UNAIDS 95-95-95 goals.

PED520

Implementing a patient satisfaction survey to identify factors responsible for missed appointments amongst PLHIVs in Nigeria

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Background: Patient Satisfaction Surveys (PSS) have been used in previous studies as a measurement tool to assess providers' ability to successfully deliver health services that meets patient expectations and needs. This is based on the premise that satisfaction with health care amongst HIV/AIDS patients helps in good adherence and favorable outcomes such as backstage distributions, survival, and low incidence of opportunistic infections. We implemented a PSS in on of the largest HIV AIDS program in Nigeria to identify the reasons for missed appointment among PLHIVs.

Description: Multi-stage sampling technique was used to select 14,058 people living with HIV (PLHIV) from selected ART clinics across seven states from 367 sites: Ekiti, Oyo, Ogun, Osun, Ondo, Ogun Plateau and Benue where APIN iCARES program is being implemented. Data was collected using a semi-structure questionnaire which was interviewer-administered to the respondents during clinic days.

Lessons learned: Out of the 14, 058 questionaire participants, 8710 (62%) were females and 5348 (38%) were males. Most respondents 2620 (18.6%) were aged 26-30 years, 7909 (56%) were employed and 5686 (40%) had secondary education. It was also reported that 54% respondents spent more than 1 hour waiting to receive care in ART clinics which does not meet IOM's recommendation to see 90% of clients waiting within 30 minutes. Service charges was identified as a cause of missed appointment and varied from 34-77% across health facilities considered for the study.

Lack of transport fare 7393 (53%), travel 2371 (16.8%), forgetfulness 2441 (17.4%) and farming activities 2021 (14.4%) were factors responsible for missed appointments amongst PLHIV. Most respondents 8120 (57.8%) suggested that increase appointment spacing to 3 months or more and sending SMS reminder 1 to 2 prior to the schedule clinic day would help them keep to clinic appointment.

Conclusions/Next steps: Improving the quality of care is core in achieving optimum retention in HIV care. Implementation of changes ideas such as optimal tracking and appointment system, sending pre-appointment reminders and providing multi-month dispensing (MMD3-5, MMD6) to all eligible clients are sure strategies of improving retention in HIV care.

HIV services in the aftermath of humanitarian crises and natural disasters

PED521

HIV and syphilis testing/treatment study in the context of COVID-19 outbreak in Cordoba, Argentina

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Background: During the first year of the COVID-19 pandemic, HIV testing has found significant decreases in many countries. The purpose of our work was to deliver free HIV and Syphilis testing/treatment and prevention strategies to several Cordoba neighborhoods with low healthcare systems accessibility, during the COVID-19 outbreak.

Description: Cordoba is the second most populated city in Argentina, bearing 1,3 million of people. In our city, there is a SARS-CoV2 testing programme in low resources areas presenting outbreaks where we offer:

1) Free PCR testing to individuals presenting symptoms or with close contact with a COVID-19 positive patient; or,

2) Serum based antibody detection to all individuals for epidemiologic studies.

During September and October 2020, our team used the structure of this programme to offer HIV and Syphilis testing and prevention services (condom and information delivery), as well as contacting and treating individuals who turned out to be positive.

Lessons learned: During the two months of the study, 92% (3827) of the individuals tested for COVID-19 antibodies also accepted to be tested for HIV and Syphilis. Of the individuals studied, 0,6% (n=21) were positive for HIV. Of them, 13 were already receiving antiretroviral therapy, 5 were new diagnoses and initiated treatment, 1 reinitiated treatment and 2 couldn´t be contacted. Also 1,3% (n=61) of the individuals tested had an active Syphilis infection and 92% (n=56) of them accessed to penicillin-based treatment.

Conclusions/Next steps: Our findings remark the importance of offering HIV and Syphilis testing and follow up to those populations with low accessibility, guaranteeing integrative perspectives and strengthening the system in a context of a humanitarian crisis. Similar actions involving women in prison, LGTBIQ+ associations and youth associations are being executed and will be reported shortly.

PED523

Long appointment spacing: expedited differentiated service delivery in Kenya to mitigate COVID-19 infection among HIV populations

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Background: Differentiated service delivery (DSD) can help mitigate the potential spread of coronavirus disease 2019 (COVID-19) in HIV settings while ensuring sustained access to antiretroviral therapy drugs. At the early phase of the pandemic, Kenya issued policy requiring all facilities to implement DSD through long appointment spacing for all HIV patients regardless of age and clinical stability status. We assessed appointment spacing practices before and after the policy.

Methods: We used a pre–post study design to compare DSD practices during pre-COVID-19 (1 February 2020 to 15 March 2020) and COVID-19 (1 April 2020 to 15 May 2020) period. We analyzed patient-level data from the Kenya National HIV Data Warehouse, a longitudinal data repository from 1,190 facilities in 45 out of 47 of Kenya's counties. We measured appointment spacing in months as the difference between patient visit date and corresponding next appointment date with long appointment spacing defined as ≥3 months.

Results: We analyzed data from 390,385 patients, with 154,919 (39.7%) visiting facilities during pre-COVID-19 and 235,466 (60.3%) during COVID-19 period. Females were 68.4% (267,065) and median age was 39 years (IQR 30–48). In pre-COVID-19 period, median appointment spacing was 34.5 days (IQR 28.6–84.8) with 25.2% (39,016) having long appointment spacing. During COVID-19 period, median appointment spacing was 84 days (IQR 35–96) and 56.3% (132,646) had long appointment spacing. Compared to males, fewer females in both pre-COVID (24.2% vs 27.4%, p<0.0001) and COVID-19 periods (55.1% vs 59.1%, p<0.0001) had long appointment spacing. Younger patients had long appointment spacing in both pre- and COVID-19 periods (p<0.0001).

Age at last visit	Pre-COVID-19 period (N= 154,919)		COVID-19 period (N= 235,466)		Total
	Non-DSD	DSD	Non-DSD	DSD	
<15 years	11,320 (96.3%)	433 (3.7%)	11,230 (62.5%)	6,746 (37.5%)	29,729
15-24 years	12,625 (92.5%)	1,022 (7.5%)	12,661 (56.9%)	9,586 (43.1%)	35,894
25-34 years	26,972 (81.1%)	6,282 (18.9%)	25,148 (52.8%)	22,482 (47.2%)	80,884
35-44 years	31,852 (71.9%)	12,445 (28.1%)	27,281 (41.3%)	38,795 (58.7%)	110,373
45-54 years	20,001 (64.3%)	11,094 (35.7%)	16,109 (33.2%)	32,427 (66.8%)	79,631
55+ years	12,968 (62.7%)	7,720 (37.3%)	10,391 (31.5%)	22,610 (68.5%)	53,689
Missing age	165 (89.2%)	20 (10.8%)	0(0%)	0(0%)	185
Total	115,903 (74.8%)	39,016 (25.2%)	102,820 (43.7%)	132,646 (56.3%)	390,385

Table 1: Appointment spacing by age

Conclusions: Long appointment spacing significantly increased between pre- and COVID-19 periods. Impact of long appointment spacing on patient outcomes should be assessed, especially among unstable patients. DSD implementation enabled continuity of HIV service delivery in Kenya despite the pandemic.

PED524

Direct and indirect consequences of COVID-19 and lockdown measures among HIV-positive patients in Italy

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Background: During the first wave of the COVID-19 pandemic, Italy implemented the earliest, longest and most radical lockdown measures outside of China. Between Mar 9th and May 4th 2020, non-essential businesses were closed and restrictions to citizen's free of movement were introduced. Most services for HIV-positive patients were converted to COVID-units, thus limiting patients access to non-urgent care.

Methods: After the lockdown was lifted, all consecutive patients presenting for care were asked about the impact of COVID-19 on their life, access to health-services and treatment adherence, using a structured interview. Possible associations between patients' characteristics and risk of treatment discontinuation or viral rebound were explored.

Results: Between May 5th and Sep 30th, 243 patients were interviewed (21.4% women, 81% Italians, 27.1% MSM, 21.4% >60 years old). Among them, 4 (1.6%) had had COVID-19, 18 (7.4%) previous symptoms of COVID-19 with no testing, 31 (12.7%) a close contacts with confirmed/suspected cases of COVID-19. Overall, 19 patients (7.8%) had been subject to quarantine, 7.8% had relatives or friends died of COVID-19, 4.9% permanently lost their job, 20.2% reported significant economic losses, 25.1% suffered severe psychological distress. Two thirds (68.3%) of patients had their HIV-appointments postponed while 49.8% had other health appointments canceled or delayed.

Incomplete adherence was reported by 22 (9%) patients; 13 (5.3%) reported ARV discontinuation for >48 hours (6 for >30 days). The most common reason for ARV interruption was missed drug refill due to fear to leave home (5 patients) or movement restriction (5 patients). Four patients had a viral rebound to >200 copies/ml.

Migrants had significantly higher rates of treatment interruption (19.6% versus 2%; P<0.001) and virological failure (8.7% versus 1%; P<0.001) than Italian-born patients. Also, a trend towards higher rates of treatment discontinuation was present in women (9.6% versus 4.2%; P=0.126). No association was found with other characteristics, such as age, risk factors for HIV, time since ARV initiation and CD4 count.

Conclusions: Containment measures of COVID-19 can have indirect effects on HIV-treatment adherence and patients wellness. Proactive strategy to reinforce adherence and grant access to HIV-services is important in the most fragile groups, such as migrants and women.

Monitoring and evaluation of prevention

PED525

Discontinuation and inadequate adherence to pre-exposure prophylaxis of HIV: a systematic review and meta-analysis

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Background: Poor persistence and adherence hamper the maximized benefits of oral pre-exposure prophylaxis of HIV (PrEP). This study aimed to understand the rates and reasons for the discontinuation and inadequate adherence to PrEP among key populations.

Methods: A systematic review and meta-analysis were conducted by searching longitudinal studies from three databases from inception to December 18, 2020. Studies were included if they investigated and presented data on discontinuation or inadequate adherence to oral PrEP. Discontinuation was defined as initiated oral PrEP but stopped taking it.

Inadequate adherence to PrEP was defined as using PrEP with fewer doses than required to achieve an estimated protective drug level. Data were extracted and assessed for risk of bias, and the quality of evidence was rated according to GRADE approach. We did random-effect meta-analysis.

This study was registered with PROSPERO (CRD42020155675) and followed the Cochrane guidelines.

Results: We identified 87 longitudinal studies with 54,313 individuals across 21 countries (30 studies reported stopping, 28 reported inadequate adherences, and 29 reported both). The PrEP discontinuation rate within six months after initiation was 36.0% (95% CI 20.8-51.3%, I^2=99.7). Discontinuation rates in six months after PrEP initiation among various populations: gay, bisexual and other men who have sex with men (GBMSM) (31.3%, 95% CI 13.4-49.3%, I^2=99.7), heterosexuals and HIV negative partner in serodiscordant couples (32.6% ,95% CI 8.2-72.5%, I^2=99.0), clinical and pharmacy records without pre-specified population (62.7%, 95% CI 57.0-68.5%, I^2=39.6).

Among GBMSM, the provision of two regimens (daily and on-demand) was associated with a lower rate of discontinuation, compared with the provision of a single regimen (daily) (12.3% vs. 31.4%, P<0.001).

The inadequate adherence in six months after PrEP initiation remained around 41.1% (95% CI 29.2-53.0%, I^2=99.4) among all populations. Structural barriers, seasonal risk and risk perception, side effects,s and concerns for long-term side effects were reasons for discontinuation to PrEP.

Conclusions: One-third of PrEP users stopped oral PrEP within half year after initiation, while more than one-third were using it with inadequate adherence. PrEP discontinuation and inadequate adherence should be addressed by guidelines in implementation, by PrEP providers before initiation, and by the research of intervention and support.

PED526

Live share technology: remote quality improvement monitoring in resource constrained programs in rural Kenya

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Background: Most donor funded development programs are constrained with inadequate resources to support both administrative and operational cost amidst the need to sustain quality implementation. Thus, project staff sometimes cannot effectively ascertain the quality of work done by field staff in hard-to-reach rural areas.

With funding from Global Fund, CMMB's HIV program leveraged on live share technology, an open-source android application, to remotely track service providers and duration they took to deliver such. The application was embedded on WhatsApp to enable group use.

Description: CMMB rolled this among 30 community adolescent girls and young women (AGYWs) mentors between December 2020 and January 2021 during their mentorship sessions. The three-hour sessions majorly take place in remote, hard to reach parts of rural areas to reach the unreached girls over a five-week period.

All mentors had android enabled phones and installed WhatsApp and live share applications and were incorporated into one WhatsApp group administered by a program staff. Prior to the commencement of any session, mentors began the Live share via the group's WhatsApp page hence enabling everyone, including the supervisor, to view their location in real time during the session.

All supervisors were sensitized on monitoring using the live share technology. They reviewed onsite presence of mentors and participants (through real-time activity photos), session duration and location and triangulated these with the mentors' sessions daily reports for consistency. Any variations taken up with the mentors.

Lessons learned: Realtime monitoring of implementation patterns curbed lateness into sessions as well absenteeism by mentors, standardized session timeframes, and ensured adherence to the facilitation guidelines Mentors' availability and consistency into sessions moved from 66.7% to 100% with the adherence to session timeline from 73.3% to 93.3%. An increase in pre-absence requests was reported among mentors before the Live share could unearth the absenteeism. Overall, 94.46% mentee completion rates was reported as of January 2021.

Conclusions/Next steps: Live location Sharing technology can be efficient and effective in enhancing the quality-of-service delivery especially in resource constrained and vast geographical settings. It is also cost effective hence its replicability and scalability can be achieved with very little effort.

Monitoring and evaluation of testing

PED527

Quality and effectiveness of index testing among individuals with recent HIV infection in Vietnam

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Background: HIV viral burden is the primary predictor of HIV morbidity, mortality, and transmission. Recently infected individuals are likely members of active HIV transmission networks. Therefore, facilitating voluntary participation in index testing among these individuals is an epidemic control priority.

This analysis compares index testing performance among index clients with confirmed recent HIV infection and chronic HIV infection in Dong Nai, Tay Ninh, and Tien Giang provinces.

Methods: We reviewed program data among all newly diagnosed HIV-positive individuals in three provinces from October 2019 to September 2020. Data on index testing at public health facilities were extracted from DieuTriARV.vn, and data on index testing in the community from the Reach 4.0 platform, both health information systems developed by the USAID/PEPFAR-funded USAID SHIFT project. We applied t-test and chi-square test to assess potential significant differences between recently and chronically infected clients at points along the index testing cascade.

Results: Among 1,637 newly diagnosed with HIV, 1,117 (68.2%) were tested for recent HIV infection. Among those, 90 (8.1%) had confirmed recent infection and 1,027 (91.9%) had chronic infection. We found no significant difference in index testing acceptance rates between the two (45% and 42%; 95% confidence level [CL]; p=0.562). Clients with recent HIV infection provided fewer contacts on average (2.5 contacts per recent vs. 3.3 contacts per chronic; 95% CL; p=0.046).

There was no difference found between number of contacts tested. The proportion of tested contacts who were newly diagnosed with HIV was higher among recently infected index clients (23.6%) than among chronically infected clients (19.1%), but it was not statistically significant (95% CL: p =0.338).

Conclusions: Given the epidemiological significance, programs should ensure no missed opportunities to offer and support participation in voluntary, ethical index testing among recently infected individuals. We found no significant difference in index testing acceptance between recently and chronically infected individuals, but participation in both groups was low, though chronically infected individuals named more contacts on average.

Both of these factors could contribute to our finding no significant difference in case-finding between the two groups, pointing to opportunities to strengthen client-centered index testing approaches to improve performance.

PED528

Profiling the case characteristics of individuals with recent HIV infection among those newly confirmed HIV-positive in Vietnam

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Background: Vietnam has made substantial progress toward reaching its HIV epidemic control commitments. Approximately 87% of people living with HIV (PLHIV) in Vietnam know their status. With smaller numbers of PLHIV left undiagnosed, programs must use data to target HIV testing and other services. Because recent infection highlights active transmission, we identified factors associated with recent HIV infection among newly diagnosed clients to sharpen the focus of programming in Dong Nai, Tay Ninh, and Tien Giang provinces.

Methods: From October 2019 to September 2020, staff at public HIV testing sites secured informed client consent and collected blood samples to complete recent HIV infection confirmation concurrent with blood draws for HIV confirmation.

Reactive rapid tests for recent HIV infection were confirmed via viral load testing. Using provincial HIV testing systems, we collected case characteristics of PLHIV newly diagnosed in the last year. We used the x^2 test to assess dependent relationships between case characteristics and confirmed recent versus all other new HIV confirmations.

We constructed a multivariate logistic regression model incorporating characteristics with significant bivariate relationships ($p \leq 0.05$) to calculate odds ratios reflecting associations between these characteristics and the likelihood of having recent HIV infection.

Results: Among 1,637 newly diagnosed HIV clients screened in the three provinces, 5.50% (90/1,637) were confirmed to have recent HIV infection. In the multivariate model, factors that independently increased the likelihood of recent HIV infection were being below the age of 25 years (odds ratio [OR]= 3.2, p-value= 0.001, 95% CL: 1.62 to 6.24) and self-identifying as men who have sex with men (MSM) (OR=2.6, p-value=0.019, 95% CL: 1.17 to 5.74). In different subgroups, the highest proportion of recent HIV infection was found among MSM below 25 years old (9.97%). Recent infection was detected less frequently among men who did not report sex with men, and women ages 35 to 44 years (2.17%).

Conclusions: Our findings suggest more active HIV transmission among young people (<25 years) and MSM in these provinces. The program is enhancing efforts to interrupt active HIV transmission by differentiating HIV testing, prevention, and treatment services for these groups.

PED529

HIV testing efficiency has progressively improved in Kenya, 2018-2020

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Background: With the reducing pool of people living with HIV who do not know their status, Kenya has employed testing strategies aimed at reducing the number of tests required to identify a positive case, including conducting HIV risk assessment prior to testing. The impact of these strategies has not been assessed. We provide a temporal trend analysis of testing efficiency over the last 3 years in Kenya.

Methods: We used aggregate testing data reported from 2018 to 2020 from 3772 facilities covering 42 out of the 47 counties under the PEPFAR program in Kenya. Calendar time was stratified into quarterly time periods. We conducted time trend analysis of HIV-1 testing efficiency, defined as the number of individuals needed to be tested to identify 1,000 HIV-1 cases using linear regression. We assessed if these trends differed significantly by age and sex.

Results: Overall**,** the number of HIV tests needed to identify 1,000 HIV positive cases reduced from 117,877 in quarter 1 of 2018 to 38,708 in quarter 4 of 2020 at a rate of 6,255 per quarter, (test for trend, p=0.0001). For children aged below 15 years, testing efficiency increased from 309,044 in quarter 1 of 2018 to 64,831 in quarter 4 of 2020 at a rate of 20,514 tests per quarter (test of trend, p=0.0001) while among adults aged 15 years and above, testing efficiency increased from 106,775 tests to 5,591 over the same period (test of trend, p=0.0001). Trends in children and adults differed significantly (p=0.0001)**.** Testing efficiency among male increased from 160,191 tests to 35,952 at a rate of 8,944 per quarter (test of trend, p=0.0002) while efficiency among female increased from 100,051 to 40,189 at a rate of 5,006 (test of trend, p=0.0001). Trends in males and females differed significantly (p=0.0001)**.**

Conclusions: Kenya progressively improved testing efficiency between 2018 and 2020 across different sub populations albeit at different rates. Though the rate of reduction was high among children, the number needed to test remained relatively high; there is need for continued review of existing strategies to further bring this number down.

PED530

A high number of HIV-positive sex partners identified through assisted partner notification services in Namibia, most previously diagnosed HIV-positive

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Background: Trials evaluating assisted partner services (APS) have reported case-finding indices (# newly diagnosed partners/index cases) of 0.2 – 0.4. Many nations are implementing large APS programs. We report program outcomes of intensified APS implementation in Namibia, a nation nearing HIV epidemic control.

Description: Healthcare workers (HCW) in four public clinics offered APS to HIV patients newly diagnosed and previously diagnosed with viral loads >1,000 copies/mL (HVL). Using a structured interview guide, HCWs elicited information on index cases' sex partners from the prior 24 months and offered HIV testing to partners who had not been previously HIV diagnosed and not tested HIV-negative within 30 days. We analyzed APS program data collected May 2019-May 2020.

Lessons learned: HCWs provided APS to 333 (70%) of 479 newly diagnosed index cases (Figure 1); they identified 461 sex partners, of whom 325 were eligible for HIV testing, 141 tested and 43 (30% of tested) were newly diagnosed HIV-positive. Ninety-nine HVL index cases received APS naming 121 partners, of whom 34 tested and 9 (26.5% of tested) were newly

diagnosed HIV-positive. The case-finding index was higher among newly diagnosed compared to HVL index cases (0.13 vs. 0.09). A total of 170 index cases (39%) identified ≥1 HIV-positive partner, of whom 132 (72%) had been previously diagnosed and 122 (92%) were receiving HIV care. All 52 newly diagnosed HIV-positive individuals were linked to HIV care.

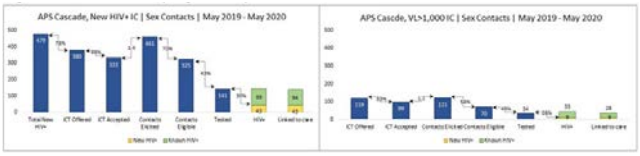

Figure 1. APS cascades for newly diagnosed HIV-positive and HVL index cases

Conclusions/Next steps: Although HIV positivity was high and almost half of index cases identified an HIV-positive partner, case-finding was lower than reported in APS trials and particularly low in HVL index cases. Further investigation is needed to determine if an HVL threshold exists above which HIV-positive partners are most likely to be identified for more targeted APS. Most HIV-positive partners were previously diagnosed, which may be expected from APS implementation in countries nearing HIV epidemic control.

Monitoring and evaluation of treatment and care

PED531

Leveraging web-scraping to examine HIV prevalence and care status among people incarcerated in county jails, North Carolina (US), 2018-2019

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Background: Most US epidemiologic research of incarcerated people with HIV (PWH) has focused on state prison systems and a few massive urban jails. Few smaller county jails have supported HIV research, including the provision of HIV data, despite these facilities comprising most correctional facilities in the US. In response, we developed a novel approach utilizing public incarceration information and confidential HIV surveillance records to examine HIV prevalence in numerous US jails and to examine viral suppression before and after incarceration.
Methods: From 07.01.2018 to 06.30.2019 we used webscraping to automate the routine collection of incarcerated persons' personal identifiers and entry and exit dates from the public websites of 26 North Carolina (US) county jails. We linked individual-level incarceration records created from these public data to the state Department of Public Health's (DPH) records of PWH diagnosed in the state since 1989; for 01.01.17 to 02.01.20, DPH records also included statewide viral load (VL) laboratory results and dates, allowing us to assess the first VL preceding and proceeding the incarceration. Data were de-identified prior to analysis. Primary outcomes were overall and jail-specific HIV prevalence. Secondary outcomes were pre- and post-incarceration VL suppression (<20 copies/mL). Incarceration was the unit of analysis.
Results: We identified 189,162 incarcerations. The overall HIV prevalence was 0.93% (n=1,761) and across jails the median HIV prevalence was 0.62 (interquartile range [IQR]: 0.23, 0.94). The incarcerated population of PWH was composed predominantly of men (80%) and Black persons (75%); the median length of stay was 4 days (IQR: 1-24). Prior to incarceration, 36% were suppressed, 48% were unsuppressed, and 16% had no VL test. Among those with 12 months post-incarceration follow-up (n=973), following jail release 32% were suppressed, 51% were unsuppressed and 17% had no VL test.
Conclusions: In most jails, HIV prevalence exceeded that of the general population (0.3%). Similar to existing studies of massive urban jails, a minority of PWH in smaller county jails achieved viral suppression before or after incarceration, signaling an opportunity to improve treatment outcomes and diminish transmission. Leveraging public data provides a feasible strategy to enhance HIV surveillance but raises issues of equity and data privacy.

PED532

Viral load suppression during rapid scale-up of antiretroviral therapy and transition to dolutegravir-based regimens, Enugu, Nigeria, March 31, 2019-September 30, 2020

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Background: In 2018, Enugu State, Nigeria had an estimated 59,124 people living with HIV (PLHIV), of whom 17,820 (30%) were receiving antiretroviral therapy (ART). In April 2019, Enugu began rapid ART scale-up and transition to dolutegravir-based regimens using client-centered facility and community-based case finding and continuity-of-care strategies. To assess these initiatives' impact, we analyzed progress to reach the UNAIDS target of 90% viral load suppression (VLS) among PLHIV receiving ART.
Methods: We analyzed programmatic and medical data from PEPFAR-supported sites for PLHIV on ART between March 31, 2019-September 30, 2020. We analyzed VLS (<1,000 copies/mL) by sex for clients newly-initiated on Tenofovir-Lamivudine-Dolutegravir (TLD) (≤30 days from ART initiation date) versus existing clients before and after TLD transition (viral load [VL] results 90–392 days following TLD transition). We used $\chi 2$ test to compare VLS categorical variables (<50, 50–199, 200–499, 500–999 copies/mL) for existing clients before and after TLD transition.
Results: Total number of PLHIV on ART increased from 17,820 to 28,783; proportion receiving TLD increased from 4% to 86% (September 30, 2020 = 24,883). Among 10,569 existing clients with pre-TLD transition VL results, 9,017 (85%) had VLS (males = 85% [2,487/2,929]; females= 85% [6,530/7,640]). After TLD transition, 94% (8,699/9,251) of existing clients had VLS (males = 93% [2,310/2,481]; females = 94% [6,389/6,770]). Existing clients with VLS had lower VL post-TLD transition (p<0.005). Among 1,552 existing clients without VLS pre-TLD transition, 842 (54%) had VL results after TLD; 768 (91%) reached VLS (males = 91% [217/239]; females = 91% [551/603]). Among 8,682 newly-initiated clients, 2,976 (34%) had VL results; 2,791 (94%) had VLS (males = 94% [1,081/1,147]; females= 93% [1,710/1,829]).
Conclusions: VLS among existing and newly-initiated clients improved during ART scale-up and antiretroviral optimization with TLD, with PLHIV (male and female) reaching VLS rates above the global target in

a programmatic setting. Concurrent increased ART coverage and optimized antiretroviral therapy can lower patient morbidity and mortality, and prevent infections following VLS. Continued program and patient monitoring will track VLS rates with longer TLD duration and barriers to attaining VLS among patients receiving TLD, including potential drug resistance.

PED533

Monitoring of HIV indicators during COVID-19 in Mozambique, 2020

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Background: Mozambique declared the first case of SARS-CoV-19 by the end of March 2020 and after declared state of emergency. These measures impacted the continuity of services, and National HIV Program (PNC) had to move quickly to make adjustments in the field to mitigate the negative impact of SARS-CoV-19.

Description: With the added pressure on the health system, there was the need for quick visualization and interpretation of the programmatic data through a dashboard.

The analyses of the data allowed for almost real-time discussion with the provinces on ART data, developing action plans for potential problems. From the start of the pandemic there was an increase in the numbers of defaulters in all regions from 4.4 to 6.5% (south), 12.5% to 15.7% (center) and 12.9 to 16.4% (north) in January to April.

In terms of ART pick-ups that was stable from January to April, however starting in April a drop was observed till June (South 384,565 to 345.555; Center 310,922 to 240,356; North 111,582 to 96,170), that stabilized after rapid intervention.

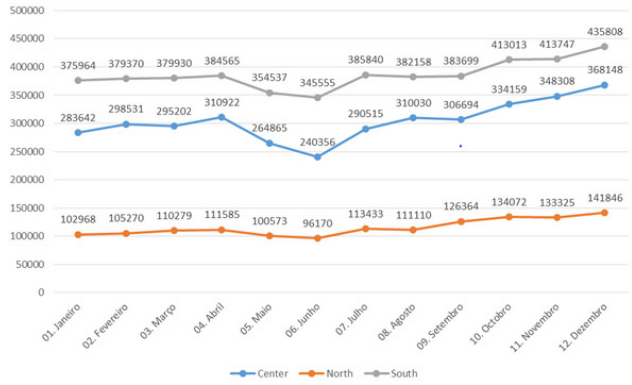

Figure. Number of ART pickups by region, Mozambique

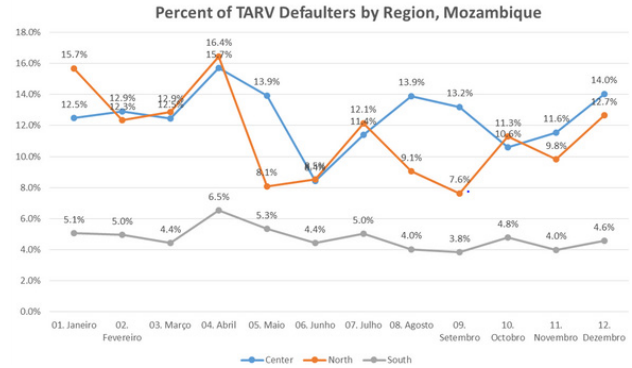

Figure. Percent of TARV defaulters by region, Mozambique

Lessons learned: Close monitoring of indicators and follow up with the provinces can lead to improved results and allow timely corrections to be implemented at the field.

Conclusions/Next steps: The use of a dashboard for monthly monitoring of indicators, supplemented by calls with the provinces, was crucial to mitigate the negative impact of SARS-CoV-19. Data analyses is very important and crucial to guide programs in times of emergency.

PED534

The impact of SARS-CoV-19 on the HIV/AIDS care and treatment program in Mozambique

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Background: The impact of the SARS-CoV-19 in Mozambique was unknown when the first case was detected on March 22, 2020. Shortly after, the virus was found throughout the country and a national state of emergency was declared in April 1, 2020 that continued for the next 6 months. There was little understanding of the impact of SARS-CoV-19 on people living with HIV and the need for improved monitoring of patient adherence was clear.

Description: The National Control Program of HIV/AIDS and STIs (PNC) is the government entity responsible for the continued care and treatment of people living with HIV with approximately 1.4 million people on treatment. In order to understand the impact from the spread of SARS-CoV-19 a monthly report was implemented in January 2020 for the number of missed ART appointments by more than 7 days. From March to April 2020, the number of defaulters jumped from 8.6% to 11.4%, or approximately 24,000 patients nationally. Three month drug dispensing (3MDD) was rolled out with a larger inclusion category in April 2020, resulting in an increase from March to June of more than 320,000 patients, helping to drastically decrease defaulter rates as seen below in the graphic.

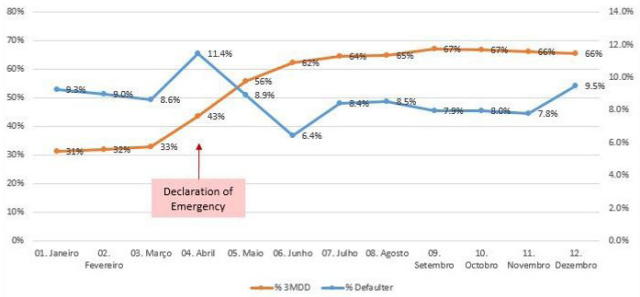

Figure. Percent of ART patients on 3MDD & percent of ART patients defaulting an appointment >7 days

Lessons learned: News and fear of the first case of SARS-CoV-19 had a profound impact on the number of defaulter appointments, even though the national number of positive cases remained low for much of 2020. However, the immediate push for an increased eligibility for DSD models, especially 3MDD, helped to quickly bring the number of missed appointments back down to pre-declaration levels.

Conclusions/Next steps: With data to inform decisions, and the ability to act rapidly, the country of Mozambique was able to quickly address and mostly avoid a potential health crisis with missed ART appointments.

Monitoring and evaluation of HIV cascade

PED535

Custom indicator reporting to improve PEPFAR key population data quality

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Background: The quality and availability of data among key populations (KPs) can be lacking as many face stigma and discrimination and are reluctant to seek care or disclose as KP at health facilities. To overcome these barriers, KP-friendly models often rely on peer support and client referral to antiretroviral treatment at health facilities. Although PEPFAR's Monitoring, Evaluation, and Reporting (MER) system routinely collects data on HIV clinical cascades, KPs including sex workers, men who have sex with men, and transgender people, are often undercounted because referral to services cannot be counted using MER indicators. Custom indicators are needed to accurately capture KPs who were referred and verified for treatment initiation, retention, and viral load (VL) suppression.

Description: USAID has effectively utilized custom indicators to improve monitoring of its PEPFAR KP programs across HIV cascades. In Mozambique, MER indicators showed that less than 10% of 6,875 KPs newly identified as HIV-positive by USAID KP programs were linked to ART.

However, program staff verified within treatment records that 96% initiated treatment. Likewise, USAID Thailand's KP treatment linkage appears low (48%) according to MER data but jumps to 93% including custom treatment verification data. Thailand's custom and MER indicators showed 6,970 HIV-positive KPs currently on treatment with 86% eligible for VL testing.

Of those eligible, 4,612 (77%) received a VL test during the past year and 4,524 (98%) achieved viral suppression. Roughly half would have been uncounted without custom indicators.

Lessons learned: Supplementing standard PEPFAR MER reporting with custom indicators has significantly improved the accuracy of cascade monitoring among KPs. Critically, it has enabled a more complete assessment of how to improve services for these vulnerable populations. Data systems must account for contributions of referral models used to overcome structural barriers and stigma that exclude KP from services and being counted in HIV cascades.

Conclusions/Next steps: Custom indicator reporting should be prioritized for PEPFAR KP programs and integrated with existing data systems. As differentiated service delivery expands, programs must remain accountable for outcomes of patients who access services at the community level; custom indicators provide a model where integrated data systems are unavailable.

PED536

Progress towards the UNAIDS 95–95–95 targets among pregnant women in South Africa: results from the 2017 and 2019 national antenatal HIV sentinel surveys

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Background: The UNAIDS 95–95–95 targets aim to ensure 95% of HIV-positive people know their HIV status, 95% of people diagnosed with HIV receive antiretroviral therapy (ART), and 95% of people on ART have viral suppression by 2030. This study assessed progress towards the 95–95–95 targets among pregnant women of age 15–49 years in South Africa.

Methods: Data were obtained from two national cross-sectional antenatal HIV sentinel surveys conducted between 1 October and 15 November among pregnant women in 2017 and 2019. Data on age of participant, awareness of HIV status, ART initiation, and geographical location (province) were extracted from medical records. A blood specimen was collected from each woman and tested for HIV. Viral load tests were performed on HIV-positive specimens.

Descriptive and multiple logistic regression analyses were performed examining factors associated with viral suppression (defined as viral load <50 copies/mL). All analysis took into account the survey design.

Results: Of 10 065 and 11 321 HIV-positive women included in the 2017 and 2019 surveys, respectively, 96.0% (95% confidence interval(CI): 95.6–96.4%) and 97.6% (95%CI: 97.3–97.8%) knew their HIV-positive status; 86.6% (95%CI: 85.9–87.3%) and 96.0% (95%CI: 95.6–96.4%) of those who knew their HIV status were receiving ART; while 64.2% (95%CI: 63.2–65.2%) and 66.0% (95%CI: 65.1–66.8%) of those receiving ART were virally suppressed.

In a multivariable analysis adjusting for survey year, gravidity, and education, the odds of viral suppression significantly varied by province (adjusted odds ratio (AOR) ranged from 0.2 to 1.0 across provinces, using Gauteng province as a reference), age (AOR for 15–24 years vs 25–49 years: 0.7, 95%CI: 0.6–0.8) and timing of ART initiation (AOR for ART initiation during pregnancy vs before pregnancy: 0.4, 95%CI: 0.5–0.6).

Conclusions: Although in 2019 the first and second 95 targets were achieved among pregnant women, meeting the third 95 target remains a challenge. Interventions to improve progress towards the third 95 target should promote early ART initiation and prioritize young women.

In addition, interventions to address health system bottlenecks that affect viral suppression at provincial level should be identified and implemented.

PED537

Who is missing from the HIV care cascade? Factors associated with not achieving the 90-90-90 targets among adults living with HIV in four African countries

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Background: While most attention is paid to the achievement of 90:90:90 UNAIDS targets, knowledge of characteristics of those who do not achieve these is important. We used population-based HIV impact assessment (PHIA) survey data from Eswatini, Malawi, Tanzania, and Zambia, to examine characteristics of adults living with HIV (ALHIV) who did not achieve these targets.

Methods: Between 2015-2017, blood samples from consenting ALHIV were analyzed for HIV RNA and detectable antiretrovirals (ARV). Participants who reported no prior HIV diagnosis and had no detectable ARV were classified as unaware. Participants who were aware, reported not receiving treatment, and had no detectable ARV were classified as untreated. Participants on ARV with a nonsuppressed viral load (NVL) ≥1000 c/ml were classified as NVL. Logistic regression using weighted data were used to determine factors associated with each step of the cascade.

Results: Of 9,465 ALHIV identified, 30.7% were unaware of their status, 9.1% were untreated, and 10.9% were nonsuppressed. Residing in Malawi, Zambia or Tanzania, male sex, younger age, being divorced, having tested but never receiving results, and not using condoms at last sex were associated with higher odds of being unaware of HIV status (Figure 1). ALHIV between 25-39 years, not attending a health facility in the last year, reporting denial of health services due to HIV status, and initiating treatment more than a year prior to the survey were associated with higher odds of being untreated. Younger age, reporting need to hide HIV status, and suboptimal adherence were associated with higher odds of NVL.

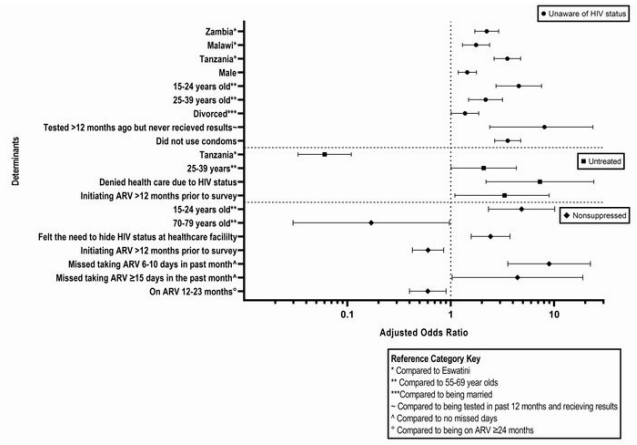

Figure 1. Adjusted odds ratio of determinants of those who did not achieve 90:90:90 targets

Conclusions: We found critical demographic and behavioral factors associated with gaps in 90:90:90 cascade. Efforts need to focus on case finding, particularly among young men. Stigma and other factors at the individual and health facility levels continue to inhibit the achievement of durable benefits from treatment for individuals and communities.

PED538

Record linkage without patient identifiers: a proof of concept using laboratory and clinical data from South Africa's HIV program

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Background: South Africa's National Health Laboratory Service (NHLS) National HIV Cohort and Three Integrated Electronic Registers (TIER.Net) provide complementary information on clinical indicators for patients in HIV care. Integrating the two databases could provide comprehensive patient data for longitudinal analyses and patient care. We assessed whether the databases could be matched without patient identifiers using data on laboratory results contained within both databases.

Methods: We used de-identified CD4 and Viral load data from July 2014 to May 2019 for a cohort of HIV positive postpartum mothers (PPM) receiving care in 9 health facilities in Gauteng province. We previously identified all NHLS and TIER.Net records for this cohort using patient identifiers, providing a gold standard for validation. We used three record linkage algorithms matching records on age, gender, health facility, laboratory test type, test date, and test value. Algorithm 1 included all variables; algorithm 2 excluded the test value; and algorithm 3 excluded the test date. We evaluated performance of each algorithm relative to the share of true matches (gold standard).

Results: Among the 710 PPM in the cohort, 309 (36.0%) had records in both TIER.Net and NHLS. Of those, 243 PPM (78.6%) could be matched using patient identifiers and 21.4% could not be matched. Excluding patient identifiers, record linkage algorithm 1 matched 120 PPM (49.4% of the 243). Despite the relatively low yield, records matched achieved 100% accuracy relative to the gold standard. Algorithm 2 matched 122 PPM (50.0%) with 92.9% accuracy; and algorithm 3 matched 169 PPM (69.5%) with 64.8% accuracy (Figure 1).

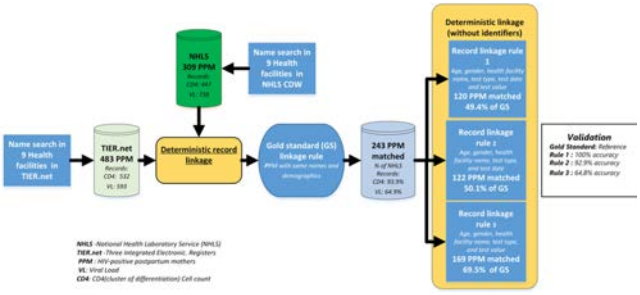

Figure 1. Record linkage algorithms without the use of direct patient identifiers for NHLS and TIER.net laboratory data

Conclusions: For HIV patients with laboratory records in both NHLS and TIER.Net databases it is possible to match records with high accuracy without patient identifiers. Still, our findings indicate that a minority of patients contained laboratory results in both databases, highlighting the need for other approaches to data integration.

PED539

PrEP reversals as proxies for suboptimal rates of retention in PrEP care

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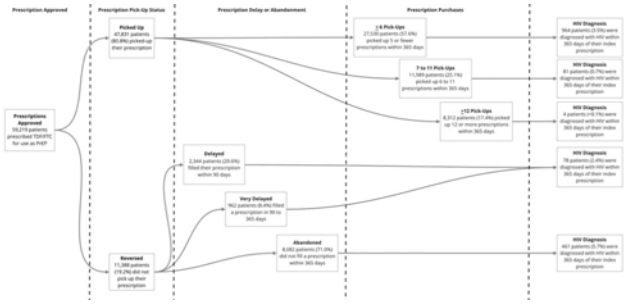
Background: Up to half of HIV pre-exposure prophylaxis (PrEP) patients in the United States (US) will not be retained in PrEP care at 12 months post-initiation. Many are lost to care at the pharmacy point-of-sale; however, these challenges are not well understood. We used a nationwide US pharmacy claims database to develop proxy measures for PrEP care retention at the pharmacy point-of-sale.

Methods: Data included nationwide PrEP claims (N=3,393,745) from October 1, 2015 to September 30, 2019. We calculated the percentage of individuals newly prescribed PrEP who: reversed (i.e., pharmacy withdrew an insurance-approved claim because it was not picked up); delayed (reversed and then picked up within 90 days); were very delayed (reversed and then picked up between 90 and 365 days); or abandoned PrEP (not picked up within 365 days); and associated new HIV diagnoses.

Results: Among 59,219 individuals with new PrEP prescriptions, 19% reversed initial prescriptions (median time to pick up of 197 days), of whom 21% delayed initiation and 8% had very delayed initiation. Females reversed (39%) more than twice as much as males (17%;p<.0001). Over 71% who reversed their initial prescription abandoned it, 6% of whom were later diagnosed with HIV – 1.5 times as many as those picking up <=6 prescriptions and over 100 times more than those picking up 12+ prescriptions.



Conclusions: Nearly 1 in 5 patients newly prescribed PrEP reversed initial prescriptions, causing delays of up to 197 days, being lost to care, and dramatically higher HIV acquisition. These trends may reflect structural barriers that undermine PrEP access (e.g., copayments and deductibles) or concerns about PrEP, both of which culminate at the pharmacy point-of-sale and may be more prevalent for females. More research is needed to understand these phenomena; the first 90 days post-prescription nevertheless presents intervention opportunities to retain patients in PrEP care and reduce HIV risk.

PED540

An analysis of viral load suppression among key populations using 2020 PEPFAR program data

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Background: Progress has been made in reaching HIV global targets of 90-90-90. However, heterogeneity exists in viral load suppression (VLS) achievements geographically and among different populations. The HIV epidemic disproportionately affects key populations (KPs) and VLS data availability poses a challenge for assessing progress among KPs. While the 2017 WHO BBS guidance recommends inclusion of VLS biomarkers in biobehavioral surveys (BBS), the availability of VLS data from surveys remain scant.

Methods: We obtained program data from the President's Emergency Plan for AIDS Relief (PEPFAR) in 43 countries where both KP and general population (GP) VLS data were reported in fiscal year 2020 (Oct 2019-Sept 2020) (N=43). We analyzed differences between reported VLS results among KPs and GP by region. General population estimates were calculated as total program results minus the sum of all KP-specific results. Regional VLS rates were weighted by the number of KP receiving viral load testing relative to the total viral load tests within a given region.

Results: VLS among KPs were higher than GP in Asia/Europe (94% vs. 91%), Latin America (83% vs. 76%), and West Africa (93% vs. 88%), mostly driven by high VLS among men who have sex with men (MSM) and female sex workers (FSW). When data were stratified by each KP group (i.e., MSM, FSW, transgender (TG), people who inject drugs (PWID), and prisoners), VLS among prisoners was consistently lower than GP in all regions. VLS among PWID was lower than GP in East Africa, Southern Africa, and Latin America. VLS among TG was lower than GP in Southern Africa. Between-region differences were larger than between-population differences.

Conclusions: The higher proportions of VLS among MSM and FSW are promising, while programmatic improvements may be needed for PWID and prisoners. One limitation of this assessment is the unknown completeness of KP group identification in PEPFAR reporting; it is possible that KPs receiving viral load testing were also more likely to be virally suppressed. Nonetheless, these findings provide important insights on what progress has been made and what challenges remain among KPs on viral load suppression in reaching the third ninety of HIV global targets.

Monitoring and evaluation of health systems

PED541

Effective supplier performance monitoring- a pre-requisite to improving the delivery of HIV/AIDS commodities in Uganda

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Background: Monitoring supplier performance is critical in ensuring that suppliers deliver quality and cost-effective health commodities in the right quantities and in compliance with agreed timelines. Poor supplier performance can cause operational delays, financial waste, and the risk of delivery of substandard commodities. We describe Medical Assess Uganda Limited (MAUL)'s experience in monitoring supplier performance and its impact on the delivery of HIV/AIDS commodities.

Description: Supplier performance was monitored based on an evaluation framework that assessed and scored suppliers on the following parameters: ability to deliver quality products (35%), price competitiveness (20%), order fulfillment (10%), on-time delivery (20%), contract compliance (10%) and support services (5%). The scores are used to provide feedback to the suppliers on their areas of strength and weaknesses as well as inform selection of suppliers during the evaluation of procurement bids. We assessed the performance of 14 suppliers who were awarded 79 orders of HIV/AIDS commodities during the period April 2017 to December 2019. Data were analyzed to measure the impact of supplier performance monitoring on On-Time Delivery in Full (OTIF) and On-Time Delivery (OTD) outcome indicators.

Lessons learned: Delivery of quality HIV/AIDS commodities improved from 93% to 98% (Only 2% of sampled commodities failed quality tests in an independent laboratory). There was an improvement in suppliers' adherence to contractual obligations from 92% to 99%. Price competitiveness increased from 96% to 98.7%, an indicator that MAUL was consistently awarding suppliers quoting the lowest commodity prices. Order fulfilment improved from 67% to 98.5% and supplier flexibility to MAUL's needs and communications channels remained at 100% since 2017. Consequently, OTD improved from 82% to 87% and OTIF from 70% to 88% during the review period.

Conclusions/Next steps: Supplier performance monitoring can improve delivery outcomes of HIV/AIDS commodities including OTD and OTIF. The model can be adapted to evaluate suppliers for other essential commodities to foster continual improvement in performance and service delivery.

PED542

Mother to child transmission of HIV prevention in Brazilian maternity hospitals: results from an national assessment

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Background: Brazil has healthcare policies that offer universal and free access to HIV testing during antenatal care, antiretroviral treatment(ART) for all pregnant women living with HIV(PW-HIV) and breastfeeding pharmacological inhibition. Monitoring maternity hospitals' actions for HIV prevention of mother-to-child transmission (HIV-PMTCT) during birth have is important for reducing HIV maternal and infant morbidity and mortality. Our aim was to verify adherence to HIV-PMTCT prophylactic measures applied by those services

Methods: In 2020, Brazilian Ministry of Health conducted a national survey to evaluate HIV-PMTCT actions in public maternity hospitals. Data were collected through an online questionnaire. Three recommendations were grouped to analyses actions maternity hospitals: i.intravenous Zidovudine administration in PW-HIV at delivery; ii.breastfeeding pharmacological inhibition; iii.Prophylactic ART to HIV-exposed children. For analysis, maternity hospitals were classified into two types: institutions performing more than 500births/year(n=487) and institutions performing less than 500births/year(n=314). The Chi-square test was used for the analysis.

Results: A total of 801 maternity hospitals from all around the country participated in this study. They were responsible for 48% of deliveries in 2019. Of these 56,7%(n=464) referred to apply all recommendations for HIV-PMTCT. However, there were significant differences between maternity hospital groups. When comparing institutions by number of births/year, performances of type 1 were much better (76.8% maternities type-1 and 25.5% maternities type-2; p< 0.001) (Figure 1).

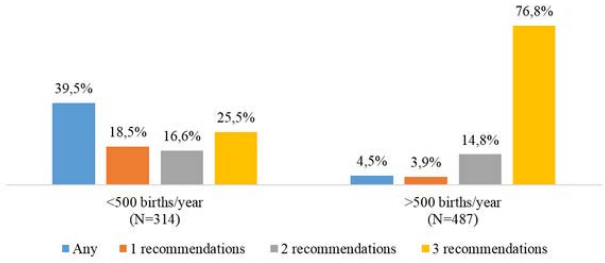

Figure 1. Percentage of recommendations for HIV-PMTCT performed in maternity hospitals, according to classification by institutions by number of births/year. Brazil, 2020

Conclusions: Missed opportunities for HIV-PMTCT were identified in maternities hospitals in Brazil, notably in type-2 facilities. Thus, it is important to establish a routine monitoring of healthcare services, especially maternity hospitals, in order to identify improvement opportunities and strategies to expand HIV-PMTCT public policies.

PED543

Strategies to prevent HIV mother-to-child transmission through breastfeeding: results of a national survey in Brazilian Maternity Hospitals, 2020

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Background: Brazilian Ministry of Health (MoH) provides pharmacological breastfeeding inhibition for women living with HIV (WL-HIV) and formula feeding for HIV-exposed children (HIV-EC). Over the years, the government has been promoting strategic programs (Projeto Nascer, Rede Cegonha, Apice-on and others) to ensure humanized maternal care and the integration of healthcare facilities, including maternity hospitals. The goal of this study is to demonstrate an association between the adoption of HIV mother-to-child transmission prevention (HIV-PMTCT) practices through breastfeeding and maternity hospital participation in MoH strategic programs.

Methods: In 2020, MoH conducted a national survey to evaluate actions to HIV-PMTCT in public maternity hospitals. Data were collected through an online questionnaire referring to pharmacological breastfeeding inhibition in WL-HIV at delivery time; provision of formula feeding for HIV-EC; counseling about prevention of HIV transmission through breastfeeding; scheduled appointment to reference clinic for monitoring WL-HIV and HIV-EC. The maternity hospitals were evaluated according to compliance with national recommendations and classified according to participation in programs offered by the MoH. The Chi-square test was used for data analysis.

Results: 801 institutions participated in the national survey, representing 48% of 2,849,146 live births in 2019; 520 (65%) reported its participation in BMoH programs and 281 (35%) did not participate in any program. Maternity hospitals reporting adherence to integration programs had better results in fulfilling the recommendations (Table1).

Prevent HIV mother-to-child transmission through breastfeeding	Maternities hospital had participation in programs offered by the MoH:				p-valor
	Yes		No		
	n	%	n	%	
Pharmacological breastfeeding inhibition in WL-HIV at delivery time	424	89%	204	63%	<0.001
Provision of formula feeding for HIV-EC	428	90%	241	74%	<0.001
Counseling about prevention of HIV transmission through breastfeeding	457	96%	275	84%	<0.001
Scheduled appointment to reference clinic for monitoring WL-HIV and HIV-EC	307	65%	174	53%	0.001

Table 1. Proportion of maternity hospitals that adopt strategies to prevent HIV mother-to-child transmission through breastfeeding, according to compliance with national recommendations.

Conclusions: Brazil has a consolidated HIV-PMTCT policy with updated national recommendations, in agreement to the latest scientific evidence and it provides free access to diagnosis, antiretroviral therapy, prophylaxis and drugs to inhibite breastfeeding of WL-HIV. Maternity hospitals participation in national programs seems to be a potential strategy for health planning and implementation of actions in the context.

Strengthening social and behavioural data collection and analysis

PED544

Validation of the combined Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) among people with HIV on antiretroviral therapy in Vietnam

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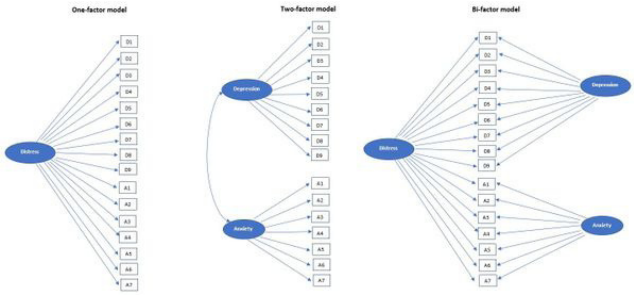
Background: Developing and validating optimal mental health screening tools is an important first step in improving mental health for people living with (HIV). The Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) combines both depression and anxiety components from the Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorders-7 (GAD-7) to measure distress. Our study aims to examine the factor structure, validity, and reliability of the PHQ-ADS among PWH on antiretroviral therapy (ART) in Vietnam.

Methods: Baseline data from an alcohol-reduction intervention trial among ART clients in Thai Nguyen, Vietnam was used for this analysis (n=1547). A score ≥10 on the PHQ-9, GAD-7 and PHQ-ADS scale was considered having clinically meaningful depression, anxiety and distress symptoms. Factor structure of the combined PHQ-ADS scale was validated using confirmatory factor analysis, and three models were tested: a one-factor, a two-factor, and a bi-factor model. Reliability and construct validity were examined.



Results: The prevalence of clinically meaningful depression and anxiety symptoms was 7% and 2%, respectively, while 19% had distress symptoms. The bi-factor model had the best fit to the data (RMSEA=0.048; CFI=0.99; TLI=0.98). The Omega index of the bi-factor model was 0.97. The scale showed good construct validity through significant negative associations between depression, anxiety, distress symptoms and quality of life.

	One-factor model	Two-factor model	Bi-factor model
No. parameters	64	65	80
Chi-square (df)	1314.129 (104)	817.586 (103)	402.127 (88)
P-VALUE	<0.001	<0.001	<0.001
RMSEA	0.087	0.067	0.048
CFI	0.95	0.97	0.99
TLI	0.94	0.97	0.98

Table. Goodness-of-fit indices of the one-factor, two-factor, and bi-factor models
Notes: df: degrees of freedom; RMSEA: root mean squared error of approximation; CFI: comparative fit index; TLI: Tucker-Lewis index

Conclusions: Our study supports the use of a combined scale to measure general distress for PWH, which has good validity, reliability and is unidimensional enough to justify the use of a composite depression and anxiety score.

PED545

Comparison of question-based and dates-based measures for sexual network degree among men who have sex with men in the United States

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Background: Momentary mean degree — the average number of ongoing sexual partnerships in a network — is an important measure of network connectivity in HIV/STI epidemiology. Mean degree can be estimated from direct questioning about extant persistent partnerships, which may inaccurately represent future partnership persistence, or reported partnership start and end dates, which may introduce recall bias. UNAIDS recommended the latter in 2009 for heterosexual networks, but the relative advantages of these approaches are unknown for men who have sex with men (MSM) in the United States who have more partnerships with higher rates of turnover.

Methods: With cross-sectional data from ARTnet, a 2017–2019 web-based study of 4,904 MSM, we compared mean degree estimates based on a direct question asking about persistent partnerships at the time of survey participation ("day-of-survey method") against estimates from reported partnership dates at specified months prior to survey participation ("month-offset method"). We used linear regression to assess trends in the month-offset method.

Results: The day-of-survey mean degree (1.19) was most comparable to mean degree at 3- and 4-month offsets (1.20, 1.19) across all partnerships (Figure 1).

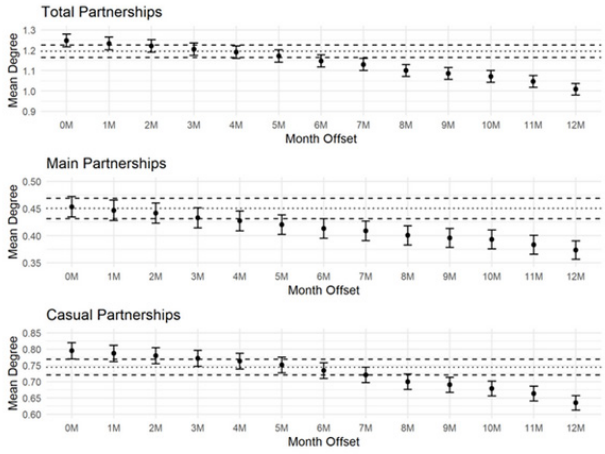

Figure 1. Mean Degree Comparison by Number of Offset Months and Day-of-Survey Method amon All, Main, and Casual Male Sexual Partnerships of 4,904 ARTnet Participants. Day-of-survey mean degree estimates are represented by dotted lines and dashed lines for the 95% confidence intervals. Points and corresponding vertical lines represent mean degree estimates and 95% confidence intervals estimated by the month-offset method.

For main partnerships, day-of-survey mean degree was comparable to month-offset mean degree between 0- and 2-month offsets (0.45 versus 0.45, 0.44) and for casual partnerships at 5- and 6-month offsets (0.75 versus 0.75, 0.73). Mean degree declined linearly from 0- to 12-month offsets. Regression models adjusted for race, age, and partnership duration estimated that this decline was associated with total reported partners, especially for casual partnerships (estimate: -0.157; 95% CI: -0.190, -0.124).

Conclusions: The day-of-survey and month-offset methods are not interchangeable, but comparable estimates suggest bias may be reduced when partnership dates are considered within six months of study participation. Potential biases were stronger in higher-turnover casual partnerships, suggesting intensive efforts are needed to better understand behavior in these partnerships.

PED546

Estimating proportions of hidden populations under respondent-driven sampling

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Background: Hidden populations, such as people living with HIV, present a methodological challenge in obtaining samples from which inferences about population characteristics can be drawn. This study presented and simulated an estimation procedure for samples obtained through respondent-driven sampling (RDS).

Methods: Nonparametric bootstrap estimator was proposed in estimating population proportions of hidden populations that are networked. Performance of the proposed estimator was benchmarked against RDS II estimator and estimator under simple random sampling without replacement (SRSWOR) across networked populations with varying sizes and levels of heterogeneity. Mean squared error (MSE), bias, and variance of each estimator were estimated through Monte Carlo method with k = 2,000 iterations.

Results: Results suggest that the nonparametric bootstrap estimator (r = 1,000 replicates) is an efficient and consistent estimator of the population proportion with negligible bias. Performance of the proposed estimator was comparable to the estimator under SRSWOR at low levels of heterogeneity. In populations with high levels of heterogeneity, the proposed estimator performed as well as the estimator under SRSWOR, but lower MSE was achieved at larger sample sizes. The simulation results also suggest that the proposed estimator performs better than RDS II estimator across all population sizes, levels of heterogeneity, and sample sizes.

Conclusions: The simulation results provide evidence in support of the applicability of the nonparametric bootstrap estimator in estimating population proportions of hidden populations under respondent-driven sampling. With the continuing problems afflicting hidden populations that are mostly marginalized, the study offers a suitable methodological approach that may further our understanding of hidden populations and, consequently, of interventions and programs that are aimed toward addressing the problems these populations face.

PED547

'Finding' young voices: lessons learnt from remote research with adolescents and young people living with or closely affected by HIV in South Africa during the time of COVID-19

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Background: Adolescents and young people (AYP) living with or closely affected by HIV are among those bearing the indirect effects of COVID-19, yet their voices are often not heard. Remote methodologies are needed to engage them safely and meaningfully during COVID-19.
We report on lessons learnt from remote research with South African AIDS-affected AYP in two studies: Teen Advisory Groups (TAG), an art-based, participatory research project; and the Helping Empower Youth Brought up in Adversity with their Babies and Young Children (HEY BABY) longitudinal cohort study.
Methods: TAG explored the COVID-19 experiences and challenges of AIDS-affected AYP (n=41, ages 15-23) using telephonic in-depth, semi-structured interviews (n=40) and nine weeks of art-based, participatory online group activities. Participants were HIV-positive or living in AIDS-affected households in a mixture of urban, rural and peri-urban areas in the Eastern and Western Cape provinces.
HEY BABY conducted telephonic cognitive interviews on resilience items of the Child and Youth Resilience Measure with adolescent mothers (n=9, ages 15-24) in the Eastern Cape.
Results: We faced significant barriers including:
1. remotely contacting a highly mobile group with frequently changing phone numbers;
2. participant access to technology, time and space to participate in crowded homes during lockdown;
3. poor connectivity and power outages; and
4. responding to participant disclosures of extreme need (e.g. food, psychosocial support).
This research also created new possibilities. Research 'facilitators', opportunities and adaptations included:
1. building on long-standing participant-researcher relationships;
2. designing research questions and methods in response to participant technology access, time, home environments and preferred research platforms;
3. using social media to re-configure the researcher-participant relationship, shift power and elicit different types of evidence;
4. ensuring adequate resources to support participants in extreme need;
5. establishing rapport using of informal, polite language; and
6. listening for verbal and 'invisible' queues, especially when discussing sensitive and emotional issues.
Conclusions: Remote methods can pose significant challenges, necessitating dedicated time and financial resources. Despite this, responsive and adolescent-friendly research is possible remotely. Designing remote research based on the contexts, needs and interests of AIDS-affected AYP offers an opportunity to shift power, engage participants differently and generate rich, context-specific evidence.

Mixed methods, integrated approaches and synergies in HIV research and intervention

PED549

A novel approach to the definition of a syndemic: the case of Substance Abuse, Tuberculosis and HIV/AIDS in South Africa (SATHA)

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Background: In 2020, a mixed-method baseline assessment of the health-related Sustainable Development Goals in 15 South African mining communities was undertaken. A triangulation of the qualitative and quantitative data strongly suggested the existence of three co-occurring epidemics: Substance Abuse, Tuberculosis and HIV/AIDS (SATHA).
The validation of syndemics is typically based on quantitative methods for the detection of interaction across the diseases involved in the syndemic. Given the lack of suitable data to quantitatively identify SATHA as syndemic, we aimed to develop a novel qualitative approach.
Methods: We conducted a two-step analytic review using elements of realist synthesis. In the first step, we used existing theoretical literature to develop a modified multi-criteria decision matrix containing key criteria for establishing a syndemic. This matrix was used as a tool in the second step to assess the degree of evidence supporting the existence of a SATHA syndemic and to guide a coherent syndemic response. Each of the pairwise components of SATHA were appraised against existing applied literature to determine the extent to which their co-occurrence satisfied the proposed criteria, privileging studies from Sub-Saharan Africa and South Africa in particular.
Results: The developed syndemic criteria included:
1) overlap in time & space;
2) biological plausibility;
3) shared causal pathways across social, behavioural, and biological domains;
4) greater burden as a result of interaction;
5) shared social and structural drivers; and,
6) potential for increased treatment and/or control costs.
After synthesising the literature, we found supportive evidence for five of the six criteria across all three pairwise comparisons: less robust evidence were available for criterion 4. Several shared structural drivers operating via similar causal mechanisms were identified, including income poverty, food insecurity, housing conditions and marginalisation.
Conclusions: In the absence of available quantitative data, we applied a novel qualitative approach to confirm the existence of a SATHA syndemic among mining communities in South Africa. This method can support not only the identification, but also the understanding of the causal structure of the synergies underlying a postulated syndemic. As such, our method can contribute to the development of future optimal response strategies to HIV-related syndemics.

Qualitative and ethnographic methods in HIV research

PED550

Cyclical engagement in HIV care: a qualitative study of clinic transfers to re-enter HIV care in Cape Town, South Africa

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Background: Long-term patient engagement and retention in HIV care is an ongoing challenge in South Africa's strained health system. However, some patients thought to be "lost to follow-up" (LTFU) may, in fact, have "transferred" clinics to receive care elsewhere.
This study explored the relationship between clinic transfer and long-term patient engagement and investigated the motivations for clinic transfer among people living with HIV (PLWH).
Methods: We conducted 19 semi-structured, qualitative interviews, from June to August 2019, in Gugulethu, a township in Cape Town. We recruited PLWH, who self-identified clinic transferring at least once since starting antiretroviral therapy (ART), through a purposive and snowball technique by partnering with a local NGO. Transcripts were analyzed using inductive and deductive thematic analysis to identify and explore key themes.
Results: On average, participants (10 female, 9 male) had been living with HIV for 14 years and had transferred clinics four times since starting ART. Rather than linear progress through the care cascade, we found patient engagement is often fluid, as PLWH cycle in and out of care multiple times during their lifetime. We identified five themes that relate to patients' cycle of engagement:
1) persistent challenges to remaining in care,
2) failure to live up to the ideal patient role,
3) wide variety of motivations to return to care,
4) clinic transferring as a tool to re-enter care, and,
5) patients remaining in clinics where they felt supported.

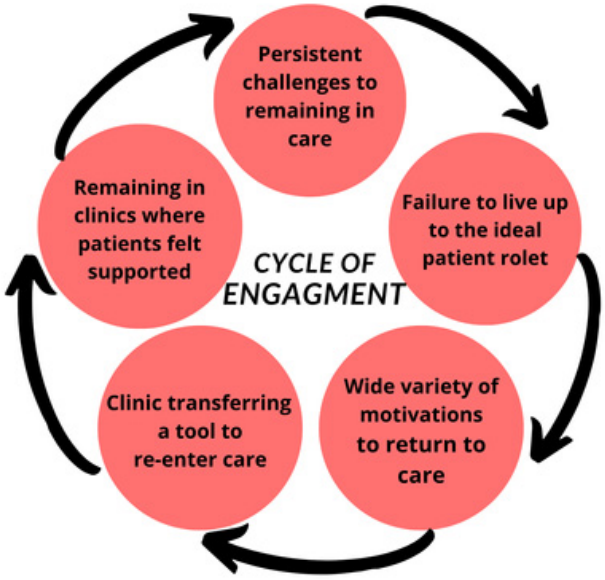

Figure. Cycle of engagement.

Conclusions: The linear care cascade model has represented the health systems perspective on HIV care but poorly describes the lived realities of PLWH. Participants used clinic transferring to navigate a complicated, sometimes punitive health care system, resulting in a cyclical process of engagement and re-engagement in care.
Further research is needed to explore strategies for reducing unplanned clinic transfers and offer more supportive care to new and returning patients.

PED551

"This is what I want": qualitative study exploring HIV care intervention options for mobile youth living with HIV (YLWH) in Eastern Africa

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Background: Population mobility contributes to delays in achieving the last two 90s of UNAIDS goals in sub-Saharan Africa. Mobile YLWH in this region access care within systems largely designed for adults and stable populations, leading to lapses in HIV-care and incomplete adherence to treatment.
Methods: This qualitative study, embedded within a study of mobility (R01MH104132) in 12 communities in western Kenya and southwestern Uganda, sought to identify scalable interventions to meet the HIV-care needs of mobile YLWH. Semi-structured in-depth interviews and hierarchical card sorting exercises were conducted in 2020 with a gender-balanced purposively-selected sample of mobile YLWH aged 16 – 24 years (n=22 females; n=18 males).
Participants included fishermen, traders, *bodaboda* (motorcycle taxi), barmaids, construction-workers, and students. Interviews, and card sorting exercises using *who, where, when* and *what* to explore preferences for HIV-care delivery models, were conducted in local languages, audio recorded, transcribed and translated into English. Transcripts were coded using Dedoose v8.3.43 and data analyzed using interpretivist theoretical approaches.
Results: While mobile YLWH wanted care provision from health-care providers in clinic settings, they preferred youth-friendly satellite clinics where they anticipated more comfort and freedom from discrimination, unlike adult clinics. Peers, teachers, community/village health teams and 'condom-callers' were recognized as necessary but secondary to clinicians. For youth facing challenges with transportation to and from clinics, and non-disclosure of their status within families, workplace or community-based care was preferable. Whereas stigmatized youth preferred care in non-clinic setup, attending clinics during morning hours met their need to circumvent being seen and intimated by adults receiving care, underscoring their preferences for short waiting times at the clinics, and friendly and trustworthy health-care providers. To strengthen their HIV treatment and make it compatible with their mobility, they preferred longer ARV-refills (3-6 months), frequent viral load monitoring, and adherence support. YLWH also valued access to malaria, TB, STI and reproductive health services.

Conclusions: Trust, freedom, comfort are key concerns for youth and should inform design of HIV-care interventions for them. Longer ARV-refills and frequent supervision of treatment outcomes may help to meet the care needs and improve treatment adherence among mobile YLWH.

PED552

Critical hope as a research method in HIV research: lessons learned from multi-method qualitative research with transgender women of colour

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Background: Hope was a central facet of affected communities' responses to HIV at the beginning of the pandemic, characterized as essential for healing and for envisioning possibilities. Critical hope reflects the centrality of hope in struggles for social justice and equality, and the urgency to develop constructive resolutions. Yet over time, HIV research has largely overlooked critical hope with a predominate focus on danger, infection, and prevention. Such narratives of risk have been applied to transgender (trans) women of colour in ways that obscure agency, pleasure and strengths.

Description: We conducted a community-based study with trans women of colour in Toronto, Canada. We first conducted a focus group (n=8) and consultation (n=2) with trans women of colour to adapt an evidence-based HIV prevention intervention. Participant narratives revealed resistance to this focus on HIV risk, and called for a focus on self-love in contexts of social exclusion. We held 3 focus groups with trans women of colour (n=18) to pilot-test 3 arts-based methods: affirmation cards to share supportive messages to other trans women, hand-held mirrors to write messages of self-acceptance, and pictures of anatomical hearts to colour/write coping strategies.

Fig. 1

Lessons learned: Through creating and presenting their art to the group, participants generated solidarity and community through shared stories of journeys to self-acceptance within larger contexts of pain, exclusion and loss. Participant narratives revealed individual and collective agency, whereby self-acceptance was nurtured through connection to community. Pleasure in creating and sharing art and connecting with others signal this as an enjoyable research method. Critical hope emerged as a key take-away from this process, whereby participants shared personal and collective optimism for the future sparked from arts-based activities (Fig.1)

Conclusions/Next steps: Arts-based methods focused on self-acceptance and solidarity can nurture resistance to dominant biomedical risk discourses among trans women of colour through generating critical hope essential for transforming reality.

PED553

"For me, it is my faith that helps me": interface of faith and health for women living with disabilities and HIV in Port Harcourt and Uyo, South-South Nigeria

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Background: Faith and spirituality influence how most people in Africa experience disease and disability. When women who live with disabilities receive an HIV positive diagnosis, they struggle to make sense of life causing them to question their identities and self-worth. Within the context where disability and HIV are often understood as caused by supernatural forces, it is their spirituality that helps to adjust and to cope with their experiences with stigma and discrimination. Faith and spirituality often provide renewed hope, facilitate adherence to treatment and enhance human flourishing. Yet, an exploration of the interface of faith and health for holistic care is often lacking. My research sought to understand the role of Christian faith for women living with the challenges of disability and HIV; and who suffer the social consequences of triple stigma – gender, disability, and HIV.

Methods: In May 2018, I conducted a pilot study for 3 weeks during which time I identified twelve Christian women living with disabilities and HIV for my research. These women live with different types of physical disabilities between the ages of 28 and 56. Among them were single, married, and widowed women. With the use of ethnographic fieldwork as well as the analysis and interpretations of field work data, I engaged in participant-observation, interviews, focus group discussions, fieldwork note-taking and writing. The women used stories to share their experiences of faith, disability, and HIV. All data were audio-recorded, transcribed, analysed and interpreted guided by the social model theory.

Results: Women's positive faith understanding, and faith experiences impacted greatly on their perception of disability and HIV. Women who claimed a transformed identity based on her faith tended to have a more positive outlook to life, meticulously adhered to treatment, and built strong support systems for women with similar challenges. They viewed HIV treatment as part of the miraculous gifts of God. This view is opposed to that of many Christian leaders who teach healing without scientific or medical intervention to negative results.

Conclusions: An exploration of the faith and spirituality and how they interface with health is vital for a holistic care response to HIV and disability.

PED554

Alien time capsules an online participatory- and arts-based research method for COVID-19 research with HIV-affected South African adolescents and young people

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Background: COVID-19 has created unprecedented challenges, including for adolescents and young people (AYP) living with, or closely affected by HIV in South Africa. Their voices are crucial to the design and delivery of effective health and social responses, but are often not included in decision making. Remote research methods hold the potential to engage AYP meaningfully during COVID-19. We report on the 'alien time capsule' methodology for COVID-19-related research with AIDS-affected South African AYP.

Methods: In a series of phone conversations, adolescent advisors (n=8, ages 15-23) suggested topics, methods and platforms for remote COVID-19 research with AYP. Based on their advice, we developed an on-line multi-media arts-based participatory research method.

Two mixed-gender teen advisory groups (ages 15-23) in the Western Cape (n=23) and Eastern Cape (n=18) were engaged in weekly art-based activities over 9 weeks in closed Facebook groups. Participants are HIV-positive or living in AIDS-affected households in a mixture of urban, rural and peri-urban areas.

Results: During study design, adolescent advisors suggested four key components. First, research questions should focus on COVID-19-related experiences, challenges and coping strategies of AYP. Second, the use of remote participatory and arts-based methods including writing, pictures, audio and video. Third, Facebook is an accessible platform that can be used data-free and password-protected for adolescents without personal devices. Finally, on-line group activities can help AYP stay connected and engaged.

To add a playful element, align with Afrofuturism's imagining of a different world and create conceptual distance to allow participants to engage more freely, a science fiction scenario was presented: "*Kind Aliens have come to Earth and want to know what young people are experiencing with COVID-19 so they can help. As Earth's ambassadors, let's fill up this time capsule to give to these Aliens!*".

Conclusions: Engaging AYP as knowledge-holders is a powerful way to inform context-specific research during COVID-19. Adolescent advisors are well-placed to co-develop research questions, tools and methods responsive to their own contexts, interests and needs. Arts-based and participatory methods are possible remotely, can elicit rich data, shift power in the researcher-participant relationship, and leverage the expertise of AYP in HIV and health-related research.

PED555

A mile in our shoes - transect walk community mapping for design of a youth sexual and reproductive health intervention in Chitungwiza, Zimbabwe

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Background: Understanding community spaces, structures, and challenges is critical for developing effective, locally-relevant HIV interventions. The Zvatinoda! study aims to develop a feasible and acceptable intervention to increase young people's demand for and use of high-quality, youth-friendly health services in Zimbabwe. Our objective was to conduct participatory community mapping in Zvatinoda! study communities to understand available infrastructure, youth hangouts and lived realities of young people.

Methods: In November 2020, two transect walks were conducted in the geographical catchment of Zvatinoda! project sites in Chitungiwza, a high-density suburb of Harare. A transect walk is a systematic walk along a defined path (transect) conducted together with local stakeholders to explore prevailing conditions by observing, asking, listening, and co-creating a transect diagram. Youth Advisory Research Panel, Health Centre Committee, health care workers and Zvatinoda! study coordinator conducted participatory transect walks using a pre-tested guide. Data collection included sketch maps, observation field notes, photo-documentation, and interviews with community-members encountered during the walk following informed consent. We used inductive content analysis to extract key themes.

Results: Transect walk teams were composed of study coordinator, community stakeholders(1-2) and YP(4-5) and averaged 3 hours in length. Twelve community members (7 YP 18-24 years; 5 parents) encountered 'en route' were interviewed. Referral networks for organizations providing complimentary services for YP were mapped. Youth hangouts and 'risk hotspots' for substance misuse and transactional sex among vulnerable and out-of-school youth were identified. Informal service-providers including religious prophets and herbalists were viewed as the first 'point-of-contact' by many YP for sexual and reproductive health services. COVID-19 lockdown was viewed as having exacerbated the pressures and risks of urban life for YP and further limiting health service access.

Conclusions: Transect walks are an effective participatory method for engaging YP and community stakeholders in mapping local infrastructure, formal and informal referral networks, and understanding lived realities for development of context-appropriate HIV interventions. The method is limited by its potential failure to identify marginalized or 'invisible' populations that may be most-at-risk. Findings will be used to inform Zvatinoda! intervention recruitment and intervention strategies, including work with community insiders for purposive identification and outreach among marginalised, at-risk youth.

Community engagement in research and research dissemination

PED556

Community engagement and research on violence and mental health among female sex workers in Nairobi, Kenya: lessons learned from the Maisha Fiti study

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Background: Violence and mental health research with marginalized populations requires careful thought to ensure that the study is relevant to the target community. It is also important that participation causes no harm to the study subjects or the research team.

Description: The Maisha Fiti study was conducted between June 2019- Feb 2021 with the main aim of understanding the biological mechanisms between HIV risk and violence experience, poor mental health, harmful alcohol and substance use.

Key ethical issues and challenges that required consideration included ensuring community buy-in for the study, the collection of novel biological samples (e.g. genital fluids collected in menstrual cups; hair samples), contacting study participants while protecting confidentiality, protecting participants from violent partners, designing and supporting referral pathways for participants, and protecting research staff from trauma transference and burnout.

Multiple strategies were implemented to address the challenges:

(i) meaningful and continued community engagement, which included the employment of ten community members as part of the study team,

(ii) not advertising the study as one on violence, mental health, or sex work,

(iii) comprehensive training of the study team,

(iv) designing a nurturing clinic environment which included free hand massages and nail polishing,

(v) conducting interviews in a safe space,

(vi) establishing clear referral pathways,

(vii) employing a full-time study counselor, and

(viii) weekly structured de-briefing meetings for the study staff.

Preliminary research findings were also presented to research participants through a series of webinars, which helped build trust and the interpretation of study findings.

Lessons learned: There was community buy-in for the study. The study enrolled the targeted 1003 participants within 6 months as planned and 98% of them consented to hair sample collection. 100% also consented to cervico-genital sample collection using vaginal cups. On the exit interviews, 97.6% of participants reported being satisfied and relieved of stress after participation. Finally, staff members felt protected from burnout and trauma transference.

Conclusions/Next steps: Meaningful community engagement is key to overcoming ethical and methodological considerations inherent in violence and mental health research. Creating safe spaces for both the study subjects and staff members is recommended for success.

PED557

The language of science in the languages of trust: media science café program pivots to deliver essential service in mother tongue

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Background: The Media Science Café Program in East and Southern Africa in four priority countries for HIV prevention seeks to create an enabling environment for HIV science to thrive through media convenings which equip cadres of health journalists with the knowledge, skills and networking opportunities to report HIV clinical and social science accurately.

Hosted by health journalism associations Media for Environment, Science, Health and Agriculture (MESHA, Kenya), Health Journalists Network of Uganda (HEJNU, Uganda), Media Science Café (MESICA, Zambia) and Humanitarian Information Facilitation Centre (HIFC, Zimbabwe), these convenings, dubbed cafés, serve as regular information exchange zones between scientists, civil society and journalists aimed at unpacking HIV Research & Development progress.

Description: The science literacy and social science competencies learnt and developed at media science cafés mean journalists are able to translate complex science (for example antibody-mediated prevention, innovation in vaccine science platforms, etc) to their audiences. Moreover, an appreciation of clinical science principles helps them pre-emptively counter misinformation and harmful narratives that can stem from a misunderstanding of R&D processes. A program innovation – to intentionally provide a second layer of science translation into mother tongue languages - intensified the café program's reach and impact with attendees reporting increased ability to report in ways that fostered trust in health information and created product demand.

Lessons learned: Jargon-free, but now also into first language, science translation at a hyper-local level means that essential information about communicable disease interventions can be broadcast on vernacular radio stations in Dholuo, Teso, Luhya, Giriama, Luganda, Runyankore, Acholi, Bemba and Shona in rural Kenya, Uganda, Zambia and Zimbabwe respectively - languages which evoke familiarity for media audiences residing in geographies of high HIV incidence. This meets the need that indigenous populations are exposed to and participate in media conversations that enable them to make better health choices.

Conclusions/Next steps: Research by *Trusting News* shows a direct relationship between the relatability of news and trust. The role of vernacular language in building trust is also well documented. Consequently, local language convenings will be expanded in the media café program to increase access and comprehension and foster buy-in and demand for essential HIV services.

PED558

Zvatinoda! (what we want!): participatory methods for community-led formation of a youth advisory research panel in urban Zimbabwe

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Background: In Zimbabwe, young people (YP) are at greatest risk of new HIV infection and have low uptake of essential HIV services. Youth participation in developing, implementing, and evaluating research increases demand for and uptake of resulting interventions. The Zvatinoda! study aims to develop a feasible and acceptable intervention to increase demand for and use of youth-friendly health services among 18-24 year olds. Our objective was to use participatory methods to form a Youth Advisory Panel (YAP) for the Zvatinoda! study.

Methods: From November-December 2020, community stakeholders (YP, parents, health care workers, and Health Centre Committees) at 2 study sites were engaged in the participatory identification, selection and co-development of Zvatinoda! YAP scope of work. Comprising of 8-10 YP residing in study communities, the YAP's role is to support intervention co-design and feedback on any problems or community concerns during study implementation.

Results: Two YAP formation meetings were conducted with 46 community and health system stakeholders (7) and YP (39). A four-phase selection process was designed by community stakeholders to identify and engage YP in YAP selection. Community stakeholders emphasized importance of purposive recruitment of a diverse group of YP. A total of 24 YP were invited to 'contest' for YAP selection, presenting their unique perspective, experiences and skills. Progression to final selection was determined through joint deliberation by YP and community stakeholders and finalised by vote. YAP roles and responsibilities, structure, meeting times and places were co-developed. YAP members have received study protocol training and are leading Zvatinoda! logo design.

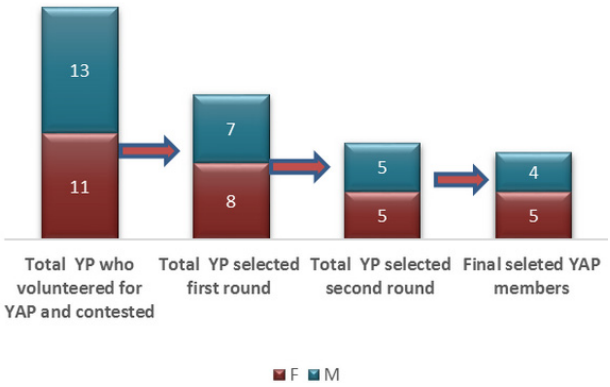

Figure. YAP formation cascade

Conclusions: YAP formation led by YP and community stakeholders increased participatory engagement and community ownership from Zvatinoda! study inception. The resultant YAP are a diverse group of talented young people with unique profiles and provide a platform for the voices of young people from study communities to be heard.

Research data disaggregation by factors such as sex, age, race/ethnicity, sexual orientation, etc.)

PED559

The intersectional relationship between levels of schooling, race/ethnicity with absence of ART initiation and AIDS fatality rates in Brazil

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Background: Brazil is one of the most unequal countries in the world, marked by profound racial and education inequities. This study tests whether the intersectionality of markers of lower socioeconomic position (SEP), such as lower schooling and black race, could exacerbate vulnerabilities, create barriers to antiretroviral therapy (ART) , and increase the risk of death among people living with HIV/AIDS in Brazil.

Methods: Intersectional positions were constructed on the basis of race/ethnicity (non- white versus white skin color) and schooling. We used Brazil's HIV/AIDS surveillance and mortality database for 2000-2018 to construct Poisson regression models that estimated the association between measures of the intersectionality between race/ethnicity and schooling, absence of ART initiation and AIDS fatality rates, adjusted for sex, age, exposure categories and region of residence. Pearson's $\chi 2$ tests and adjusted prevalence ratios (aRP) were estimated. In addition, model goodness-of-fit tests and multicollinearity calculations were performed.

Results: Of the 824,421 Brazilians diagnosed with AIDS between 2000 and 2018, 11.9% did not initiate ART and 27.3% died. During this period, the proportion of people with HIV that had not initiated ART decreased 31% ($p<0.001$) and AIDS fatality rates decreased 64% ($p<0.001$). Illiteracy (aRP: 2.85; CI: 2.66-3.05) and black skin color (aRP: 1.07; CI: 1.04-1.11) were positively associated with no ART initiation (aRP: 2.34; CI: 2.27–2.42) and AIDS fatality (aRP: 1.11; CI: 1.09-1.13). Those who were both illiterate and black had a 172% (aRP: 2.72; CI: 2.36-3.14) higher chance of not initiating ART and a 139% (aRP: 2.39; CI: 2.23-2.56) higher AIDS fatality rate.

Conclusions: The proportion of people with AIDS that have not initiated ART and AIDS fatality rates declined since 2000. However, these indicators are still high among those with lower SEP.

Analysis of intersectionality revealed that people with AIDS who are both illiterate and black are at greater risk of not starting ART and dying. Thus, health authorities should expand actions to more socially inclusive actions to tackle HIV/AIDS, especially among more disadvantaged populations.

Positive health, dignity, psychological well-being, and mental health

PED560

Digital opportunities to support mental health among sexual and gender diverse adults living with HIV During COVID-19: a multi-national cross-sectional survey

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Background: In 2021, digital tools offer opportunities to reach and support sexual and gender diverse (SGD) communities, especially those living with HIV (PLHIV). We sought to understand digital social support among SGD PLHIV during COVID-19 and if decreased support was associated with suboptimal mental health.

Methods: We analyzed self-reported data from 9,893 transgender or non-heterosexual cisgender adults in the COVID-19 Global Disparities Survey, deployed in 14 languages from October 25 to November 26, 2020 via Hornet, an SGD social app. We compared digital social support by HIV status. Among PLHIV, we used crude and adjusted Poisson regression to measure the association between decreased digital social support and a positive screen for depression or anxiety (≥3 on PHQ-4 depressive or anxiety sub-scales).

	People not living with HIV n = 8,288	People living with HIV (PLHIV) and detectable viral load (VL) n = 704	PLHIV with an undetectable VL n = 901	p-value
Mental Health Outcomes				
Screen positive for both possible depression and anxiety	2,627 (37.8%)	219 (38.5%)	263 (34.5%)	0.18
Average Digital Social Support for LGBT Identity since COVID-19				
Decreased	1,286 (23.3%)	98 (21.4%)	156 (24.1%)	0.56
Stayed the same	2,589 (46.9%)	215 (46.8%)	314 (48.5%)	
Increased	1,640 (29.7%)	146 (31.8%)	178 (27.5%)	
Sources of Digital Support Used during the COVID-19 Pandemic				
Remote therapy	337 (4.1%)	28 (4.0%)	75 (8.3%)	< 0.001
Suicide hotlines	94 (1.1%)	7 (1.0%)	10 (1.1%)	0.94
Crisis text lines	73 (0.9%)	9 (1.3%)	10 (1.1%)	0.48
Chatbots	65 (0.8%)	5 (0.7%)	10 (1.1%)	0.56
Hornet App	671 (8.1%)	53 (7.5%)	79 (8.8%)	0.66

Table 1.

Results: Participants' median age was 35 years (IQR: 28–43), with most residing in Russia (24%), Turkey (17%), or Brazil (16%). The majority were cisgender men (93.8%) with the remainder being nonbinary (4.2%), transfeminine (1.5%), or transmasculine (0.5%). About a third (37.5%) screened positive for depression or anxiety. Since COVID-19, digital social support remained stable or increased for the majority (76.7%). Use of tele- or virtual therapy was more common among PLHIV who reported an undetectable viral load (n=75/901, 8.3%) than PLHIV who reported a detectable viral load (n=28/704, 4.0%) or those not living with HIV (n=337/8288, 4.1%). Suicide hotlines (1.1%), crisis text lines (0.93%), chatbots (0.81%), and the Hornet app (8.1%) usage for support was low and similar across groups. In crude and adjusted models among PLHIV (Table 2), participants were significantly more likely to screen positive for depression or anxiety if their digital social support had decreased during COVID-19 (vs. increased or remained stable).

	Crude relative risk of screening positive for depression or anxiety	p-value	Adjusted* relative risk of screening positive for depression or anxiety	p-value
Since COVID-19, digital emotional support for LGBT identity has *(n=904)*				
Remained same or increased	REF	—	REF	—
Decreased	1.67	< 0.001	1.47	< 0.001
Since COVID-19, digital companionship support for LGBT identity has *(n=804)*				
Remained same or increased	REF	—	REF	—
Decreased	1.56	< 0.001	1.32	0.01
Since COVID-19, digital informational support for LGBT identity has *(n=815)*				
Remained same or increased	REF	—	REF	—
Decreased	1.59	< 0.001	1.32	0.01
Since COVID-19, digital tangible support for LGBT identity has: *(n=825)*				
Remained same or increased	REF	—	REF	—
Decreased	1.40	< 0.001	1.24	0.03

* Adjusted for gender, age, education, disability, employment, ability to meet basic needs, living alone, presence of interpersonal violence, use of alcohol, increased use of tobacco products or cannabis, self-reported happiness, and needing therapy but being unable to seek it. Data were multiply imputed for seven covariates (mean missingness: 3%).

Table 2.

Conclusions: Strategies to sustain or expand access to digital programming, outreach, and accessibility are needed to support the mental health of the SGD community, especially PLHIV.

PED561

HIV, multimorbidity, and health-related quality of life in rural KwaZulu-Natal, South Africa: a population-based study

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Background: Health-related quality of life (HRQoL) assesses the perceived impact of health status across life domains. Although research has explored the relationship between specific conditions, including HIV, and HRQoL in low-resource settings, less attention has been paid to the association between multimorbidity and HRQoL. As such, this study assessed the degree to which HIV contributes to HRQoL relative to other diseases and combinations of disease.
Methods: In a large sample of South African adults (N = 14,008), we documented disease histories (e.g., heart attack, stroke) and the presence of both infectious (e.g., HIV, tuberculosis) and non-infectious chronic diseases (e.g., blood pressure, diabetes). Five domains of HRQoL (mobility, pain/discomfort, self-care, usual activity, anxiety/depression) and one overall rating of health were measured with the EQ-5D HRQoL scale. We examined the degree to which number of co-morbid conditions and combinations of conditions impact HRQoL. Using ridge regression models, we assessed the relative impact of HIV, diabetes, stroke, heart attack, high blood pressure, and tuberculosis on the HRQoL domains. Finally, we assessed contribution of controlled versus uncontrolled disease for each condition. All models were adjusted for age and sex.
Results: Having more diagnosed conditions adversely affected overall health (r = -0.053) and all other HRQoL domains. However, having more infectious conditions was associated with better overall health (r = 0.045, driven by HIV), whereas having more non-infectious conditions was associated with worse overall health (r = -0.11, driven by stroke and heart attack). In the first set of models, combinations of non-infectious diseases were most detrimental for overall health, whereas positive HIV status predicted self-reported good health. In the second set, combinations of uncontrolled non-infectious conditions were predictive of poor health, whereas controlled HIV was strongly associated with self-reported good health.
Conclusions: In this sample, multimorbidity negatively affected HRQoL. Whereas the presence of non-infectious diseases, whether controlled or not, was associated with poor HRQoL, the presence of controlled HIV was associated with improved HRQoL. In South Africa and similar settings, where intersecting non-communicable and infectious disease epidemics are prevalent, incorporating multimorbidity into healthcare strategies and improving the integration of care may improve HRQoL.

PED562

Challenges adolescents and young people living with HIV face in adhering to ART: the Nigerian experience

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Background: Adolescents and young people living with HIV (AYPLHIV) in Nigeria face numerous challenges in adhering to their anti-retroviral drugs. These challenges include mainly stigma, lack of treatment literacy, lack of physical and social support systems, and lack of friendly healthcare services dedicated to AYPLHIV. Foundation for Better Health and Human Rights and I'm Emmanuel Foundation, local NGOs in Nigeria, commissioned a study to evaluate the effects of these challenges on the wellbeing of AYPLHIV who attended the AI NEST Support group meetings in Ebonyi state, Nigeria.
Description: Six (6) focused group discussions with a total of fifty-eight (58) AYPLHIV aged 14-24 who were in the AI NEST support group was conducted between October and November 2020 in Alex Ekwueme Federal teaching Hospital; the largest referral hospital in the state. AYPLHIV who attended the clinic at the time of study were also recruited for the study.
Lessons learned: The focus group discussions revealed that many AYPLHIV experience stigmas as a result of low level of knowledge among their friends and families and misconceptions about the condition, their greatest challenge was disclosure of status to friends or family. They had to device strategies to avoid stigma. A handful admitted they had to deal with changing the packaging of the medication to avoid easy detection but still taking the medication as recommended; some had to lie when they are seen by their peers taking their drugs while others had to skip the medication altogether. Some have difficulty with adhering to daily drug schedules, others emphasized on the need for psychosocial support as sometimes they cannot handle depression and anxiety that comes with living with HIV.
Conclusions/Next steps: The study highlighted AYPLHIV drug adherence challenges. Some recommendations are to identify context specific interventions like integrating ART services into existing youth friendly corners, increase psychosocial counselling and support for AYPLHIV. At policy level, the needs of adolescents should be included in the review and development of health strategic plans in order to enhance the country's chances of ending HIV epidemic.

PED563

Applying a lifecourse approach to understanding pathways from childhood protective service out-of-home care to clinical HIV outcomes among adult women living with HIV in Canada: longitudinal cohort findings

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Background: Life course epidemiology explores long-term health effects from childhood exposures. Childhood protective service (CPS) out-of-home care is associated with poorer health trajectories, yet scant research has explored pathways from CPS histories to HIV outcomes. We examined associations between CPS out-of-home care with HIV outcomes, and tested the mediating role of mental health, among women with HIV in Canada.

Methods: This three-wave longitudinal study with women with HIV in Ontario, British Columbia and Quebec examined CD4 counts (<200, 200-500, >500 cells/mm^3), current anti-retroviral therapy (ART) use, and viral load (VL) undetectability (<50 copies/mL) over five years. We used latent class growth analysis to identify outcome trajectories and assessed if CPS history of out-of-home care was associated with class membership.
We estimated a latent mental health construct (indicators: depression, post-traumatic stress disorder, SF-12 mental health, resilience) and conducted mediation analysis to test whether mental health mediated the association between CPS history and HIV outcome trajectories.
Results: Overall, 19% (n=272) of participants (n=1422, mean age: 42.8) reported CPS histories of out-of-home care. Four CD4 count trajectories included: consistently high (35%), consistently low (8%), consistently medium (15%), and U-shaped (42%). Individuals with CPS histories were 2-3 fold more likely to be in the 'consistently low' CD4 count class relative to any other class (βs=0.75–1.16, *p*s=0.002–0.02) and twice as likely to have a consistently detectable VL (β=0.72, *p*=0.02). Current ART use did not vary over time. Mental health at baseline mediated pathways from CPS history to (1) consistently detectable viral load (*β*=0.02, 95% CI: 0.005, 0.04, *p*=0.02), accounting for 27% of this association; and (2) consistently low CD4 count trajectory (*β*=0.005, 95% CI: 0.001, 0.01, *p*=0.04), accounting for 24% of this association.
Conclusions: Nearly one-fifth of women with HIV in Canada have CPS out-of-home care histories, which is 14-fold higher than the national Canadian prevalence (1.3%). CPS histories are associated with poorer HIV outcome trajectories (low CD4, detectable VL) through the mediating role of mental health challenges. Applying a life course epidemiological approach reveals that CPS history is a childhood risk factor linked with poorer adulthood clinical HIV outcome trajectories via psychological pathways of mental health.

PED564

Ethical issues surrounding HIV testing within the context of the HIV Treat All strategy implementation: the case of three hospitals in Cameroon

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Background: The World Health Organisation recommended the HIV Treat All strategy as the universal approach to controlling the HIV pandemic. Universal HIV testing constitute the main prerequisite for the overall success of HIV Treat All strategy. Unfortunately, HIV testing has known a series of barriers including high level of stigma and this has considerably attracted ethical concerns regarding HIV testing and linkage to care. This study described ethical aspects of the HIV diagnostic experiences of patients within the HIV Treat All implementation in Cameroon.
Methods: In-depth interviews were administered to 54 purposively selected recently diagnosed HIV positive patients, constituting 34 females and 20 males in three secondary level public facilities. For each site, 12 active and 6 inactive HIV positive patients were interviewed. The age of participants ranged between 24 – 55 years. The recorded interviews were transcribed in verbatim and field notes were integrated. A thematic analysis was done using QDA miner.
Results: The results revealed HIV provider initiated testing and counselling (PITC) and voluntary HIV testing and counselling (VCT) as the first and second most reported means HIV care entry. Majority of the respondents, irrespective of the HIV clinical stage at diagnosis, expressed a positive attitude with respect to the timing of their HIV diagnosis, and even wished they had been diagnosed and placed on ART much earlier.
A few patients reported being tested for HIV without their consent, and a majority of them were financially dependent. A majority of those diagnosed without consent indicated that they were not confortable about being tested without their consent, of which they were eligible to provide. Interestingly, like the majority of the participants, those diagnosed without consent indicated that they were happy about their timely diagnosis and their overall health outcome.
Conclusions: Some health providers still continue to conduct HIV test on patients without their consent. Although, majority of the patients tested without consent seemed to be in care and contented with the overall health outcome, there's a risk of psychological trauma to patients following HIV testing without consent. This highlights a need for health providers' training on ethical principles, notably the respect of persons.

Growing up with HIV: specific needs and interventions for children and adolescents

PED565

Health outcomes of operation triple zero for adolescents and young people living with HIV in selected high-volume sites in Kajiado County, Kenya

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Background: In 2019, the USAID-funded and FHI 360-led Afya Nyota ya Bonde Activity implemented a differentiated service delivery intervention—Operation Triple Zero (OTZ)—to improve viral load (VL) uptake and suppression among adolescents aged 10–19 years living with HIV in Kajiado County, Kenya,.
OTZ aims for zero missed clinical appointments, zero missed drugs, and zero missed viral load test. We describe VL outcomes after introducing OTZ in seven facilities in Kajiado County.
Description: The OTZ package of care interventions included virtual OTZ sessions with adolescent champions and clinical teams, virtual enhanced adherence counseling using mobile online platforms, and supportive-expressive group tele therapy. It also involved scheduling of clinical appointments and antiretroviral therapy (ART) refills three months and longer.
We compared pre intervention data extracted from service delivery registers for the period May- September 2019 and post intervention data covering October 2019 - September 2020.We used a paired t-test to assess the mean change in VL testing uptake and suppression rates.

Lessons learned: A total of 289 (37%) of the 784 children and adolescents who were receiving ART services in the seven facilities were enrolled in OTZ. From a pre-intervention VL testing uptake of 69% (411/596) and suppression rate of 72% (296/411), these increased to 90% (702/784) and 85% (598/702) at the end of September 2020.

The mean increase per site was 21% (CI=13–28%) for VL testing uptake and 12% (CI=5–19%) for VL suppression rate. This increase in site-level VL testing uptake and suppression rates was statistically significant: p=0.001 and p=0.005, respectively.

Conclusions/Next steps: The OTZ model of care is an effective intervention toward improving VL uptake and VL suppression among adolescents and young people living with HIV. There is a need to strengthen and scale up OTZ clinics to other facilities and counties with low VL testing uptake and suppression rates among adolescents and young people living with HIV.

PED566

Health facilities with PEPFAR orphans and vulnerable children programs attain higher levels of viral load coverage and suppression among children living with HIV – Zambia, 2020

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Background: Zambia has made substantial progress toward the UNAIDS 95-95-95 targets but children lag behind. While reported viral load suppression (VLS) among adults approaches 95%, only 86% of children living with HIV (CLHIV) under 15 years-old on ART are virally suppressed. Orphans and vulnerable children (OVC) programs support CLHIV and their families in continuity of care to achieve VLS.

We assessed whether the presence of OVC programs near a health facility (HF) impacts HF-level viral load coverage (VLC) and VLS among CLHIV in Zambia.

Methods: HF-level data were obtained from routinely collected indicators for the President's Emergency Plan for AIDS Relief (PEPFAR) program during October 2019-September 2020. PEPFAR-supported OVC programs were reported by 1,375 (36.3%) HFs in six of Zambia's ten provinces, based on historic programmatic decisions; analyses were restricted to these provinces. VLC was calculated as the number of children with a viral load (VL) result on record in the past year out of the total CLHIV on treatment from six months prior. VLS was calculated as the number of children with a VL<1000 copies/mL out of those with a VL result on record in the past year. T-tests were performed to assess differences between HFs with OVC program beneficiaries and those without. Analyses were weighted by the number of CLHIV on ART at each HF.

Results: In the six provinces, 37,399 CLHIV were eligible for VL testing in the past year, including 21,895 (58.5%) at HFs serving OVC beneficiaries 0-14 years old. There was no difference in age or sex between children at OVC- and non-OVC-serving HFs. VLC and VLS were both significantly higher at HFs serving OVC beneficiaries compared to those without (82.3% versus 74.2%; p<0.01 and 86.0% versus 82.0%; p<0.01, respectively).

Conclusions: CLHIV in HFs with access to OVC programs attained higher levels of VLC and VLS. Although not a direct patient-level measure of OVC program participation and outcomes, these results suggest offering OVC programming might improve clinical outcomes among CLHIV. Expansion of OVC programs could help reduce the gap in treatment outcomes between adults and children living with HIV in Zambia and progress toward an AIDS-free generation.

PED567

Influences on healthcare worker acceptability, feasibility and sustainability of an Adolescent Transition Package in Kenya

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Background: Successfully preparing and transitioning adolescents living with HIV (ALHIV) from pediatric to adult care is critical for ensuring adherence and retention in care. We developed and implemented an Adolescent Transition Package (ATP), which combines HIV disclosure and transition tools, in 10 clinics in Kenya as part of a cluster randomized clinical trial. Understanding healthcare worker (HCW) experiences with implementation of the ATP can identify influences on acceptability and feasibility that inform future scale-up and scale out of the ATP intervention.

Methods: Guided by the Consolidated Framework for Implementation Research (CFIR), we conducted 10 semi-structured focus group discussions (FGDs) (one per clinic) with 76 HCWs to evaluate factors influencing ATP implementation. FGDs were recorded and transcribed verbatim. An analysis of FGD debrief reports and a subset of full transcripts was conducted to identify key influences on implementation.

Results: HCWs believed the ATP intervention was acceptable, feasible and improved the transition process for HCWs and ALHIV. HCWs described how ATP tools met the needs of adolescents, and resulted in improved viral suppression, ART adherence, and retention. The ATP provided a relative advantage when compared to existing tools because it was 1) systematic and provided a step-by-step guide, 2) simple and easy for any provider, including peer educators, to use, and 3) comprehensive, covering both medical and psychological components. The Taking Charge booklet was the most valuable component, providing relevant content in multiple languages and including well-liked illustrations. Feasibility and acceptability were enhanced through systematic study-facilitated adaptations including designated roles for staff and group delivery of book chapters, through which HCWs optimized delivery within their clinic. Flexibility in ATP tools enabled HCWs to expand use to include adolescents and pregnant women outside the study. This underscores broad acceptability and potential for scalability of the intervention. While HCWs were enthusiastic about continuing and scaling implementation post-trial, barriers to perceived sustainability included HCW time and workload.

Conclusions: The ATP intervention improved HCW experiences with preparing ALHIV to transition to adult care. Strategies that support intervention scale-up should address identified barriers to implementation, and incorporate new ways to enhance ATP reach and versatility.

PED568

Relationships between mental health and the HIV care continuum for adolescents living with HIV: a scoping review of the literature

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Background: Prior review articles have summarized the literature on mental health challenges experienced by adolescents living with HIV, few have examined how mental disorders play out in regards to the HIV care continuum. We sought to examine research on mental health and engagement in all steps along the care continuum for adolescents living with HIV in sub-Saharan Africa (SSA).

Methods: We searched PubMed, CINAHL, EMBASE, and PsycINFO through March 31, 2020. Peer-reviewed articles were eligible for inclusion if they presented primary data from adolescents (age 10-19) living with HIV in SSA and assessed symptoms or diagnoses of mental disorders in relation to one or more steps of the HIV care continuum. Included studies were independently coded by two reviewers using standardized forms.

Results: Of 278 studies identified in the search, 36 met inclusion criteria. The majority of included studies came from South Africa (n=12), followed by Uganda (n=7), Rwanda (n=4), Zambia (n=4), and Kenya (n=3); Nigeria, Ghana, Namibia, Eswatini, Zimbabwe, and Malawi each had one study.

The majority of studies included both older (15-19) and younger (10-14) adolescents, with 3 focusing on only older and 2 focusing on only younger adolescents. There was a predominance of cross-sectional studies (n=25), followed by qualitative (n=5), mixed methods (n=3), case-control (n=2) and randomized controlled trials (n=1). Depression (n=24) and anxiety (n=8) were the most common disorders examined, with a few studies assessing post-traumatic stress disorder (PTSD) (n=6), suicide (n=4), and conduct problems (n=2); some studies examined multiple disorders (n=13).

Adolescents were commonly assessed at the "Linked to HIV Care" (n=17) or "Engaged or Retained in Care" (n=18) steps of the continuum. Most studies took place prior to the passage of Universal Test and Treat policies. For studies with comparison groups, there were mixed results as to the impact of mental health and HIV engagement regarding the continuum.

Conclusions: The results from this scoping review suggest mental health research generally focuses on adolescents engaged in HIV care in SSA. Greater attention to the HIV testing and viral suppression parts of the continuum could help identify adolescent mental health needs and priority timepoints for intervention.

Sexual and reproductive health, fertility, family planning, pregnancy, and abortion

PED569

Depressive symptoms and ART adherence among women late in pregnancy who are living with HIV in Durban, South Africa

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Background: Many women living with HIV (WLWH) have elevated levels of depression; some also experience HIV-related stigma and intimate partner violence (IPV), which may exacerbate depression symptom severity. In South Africa (SA), depression and related psychosocial challenges during late pregnancy may lead to poor HIV-related health outcomes and increase risk for HIV transmission to infants.

Methods: We ran three multivariable regression models among women who completed a baseline assessment and enrolled in a cohort study assessing postpartum attrition from HIV care to examine:

1. factors (e.g., IPV, social support, resilience, HIV stigma, healthcare trust, alcohol use) associated with depressive symptoms,

2. the relationship between depressive symptoms and self-reported adherence in the past 30 days, and (2a) viral load (VL).

Models controlled for age, gestational age at antenatal care enrollment, and number of prior pregnancies.

Results: Participants (N = 472, mean age of 28.8 years (SD = 5.3)) had a mean gestational age of 33.2 weeks (SD = 8.6) at the baseline assessment. Depression symptom severity across the entire sample was low (mean = 3.8, SD = 7.2); 5.9% (n = 28) met criteria (CES-D ≥ 16) for likely depression. The median VL was <20 copies/mL, and the median adherence score was 100%. IPV in the last year (b = 0.2, p < 0.001), low social support (b = -0.4, p < 0.001), HIV stigma (b = 0.08, p = 0.03), and low resilience (b = -0.1, p = 0.002) were significantly associated with greater depression symptom severity.

Depression symptom severity was significantly associated with lower ART adherence (b = -0.2, p < 0.001), whereas IPV was not. Depression was not related to viral load, and viral load was not correlated with self-reported ART adherence.

Conclusions: For some WLWH, the under-recognition of depressive symptoms late in pregnancy may compromise maternal engagement in postpartum HIV care. Although depression symptom severity was lower in this sample compared to levels reported in other SA-based studies, these findings suggest that interventions targeting depressive symptoms, related factors, and/or resiliency are needed before WLWH at risk for depression at the end of pregnancy leave regular antenatal care.

PED570

Risk factors for adverse birth outcomes among women living with HIV on ART in pregnancy

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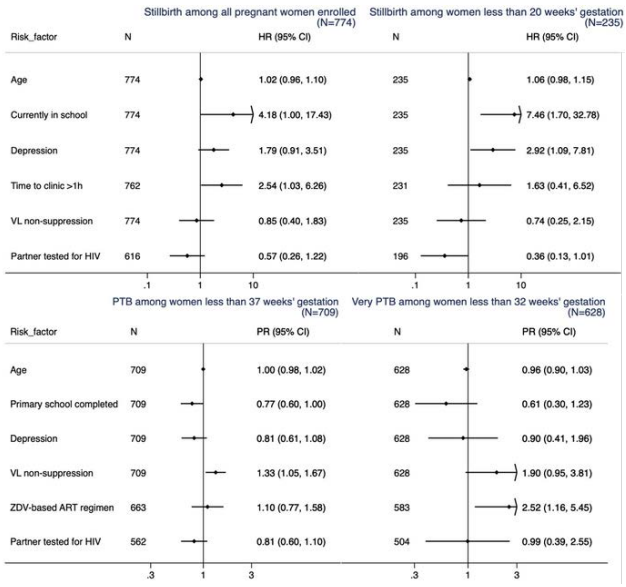
Background: It is important to understand predictors of adverse birth outcomes among women living with HIV on antiretroviral treatment (ART) to optimize prevention of mother-to-child transmission (PMTCT) care.

Methods: This study evaluated adverse birth outcomes including stillbirth (fetal death at ≥20 weeks' gestation), preterm birth (PTB, livebirth at ≤37 weeks; very PTB at ≤32 weeks) and neonatal death (≤28 days after birth), using data from a randomized clinical trial (NCT02400671). Gestational age was determined by last menstrual period. Women with miscarriage were excluded. Potential correlates were determined by site-adjusted Cox PH models and log-binomial models.

Results: Among 774 pregnant women at enrollment, median age was 27 years, median gestational age was 24 weeks (IQR 18-30), and 226 (29.0%) were virally unsuppressed (VL ≥1000 copies/mL). Half of women (55.1%) started ART pre-pregnancy. Most (89.1%) received tenofovir (TDF) with the remainder on zidovudine (ZDV)-based regimens. During 211.5 person-years of follow-up until delivery, 34 women had stillbirth (incidence rate 16.1 per 100 person-years). Stillbirth was associated with being in school and living >1 hour from clinic. Among women enrolled at <20 weeks' gestation, those whose partner tested for HIV had lower risk (HR 0.36; p=0.05) and those with depression (PHQ9>5) had higher risk (HR 2.92; p=0.03).Among 740 live births, 201 (27.2%) were PTB (31 vPTB) and 22 (3.0%) neonatal deaths occurred. PTB was associated with unsuppressed VL in pregnancy (PR 1.33; p=0.02) and non-completion of primary school (PR 1.30; p=0.05). vPTB was more frequent with ZDV- than TDF-based ART (12.9% vs. 4.4%, p=0.005). Neonatal death was associated with PTB (PR 2.46, 95%CI 1.10-5.51; p=0.03).



Conclusions: PTB risk was substantial and associated with VL non-suppression, ART regimen and neonatal death. Pre-pregnancy ART may decrease HIV transmission and PTB; underlying regimen-effects should be explored. Supporting education, depression counseling and partner involvement may help prevent adverse birth outcomes.

PED571

HIV and infertility stigmas intersect in the context of HIV-affected partnerships in rural southwestern Uganda

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Background: Men and women in HIV-affected partnerships may experience intersecting HIV and infertility stigmas. This qualitative study explores how infertility stigma informs reproductive goals and HIV prevention behaviors among HIV-uninfected women and their partners in rural Uganda.

Methods: The parent mixed-methods study was conducted with 131 HIV-exposed women with plans for pregnancy in rural Uganda. The study offered comprehensive safer conception (SC) services over nine months to evaluate HIV pre-exposure prophylaxis (PrEP) use. Thirty-seven women and 7 male partners participated in in-depth interviews to explore SC experiences, PrEP use and adherence. Guided by a socioecological framework, this secondary analysis explored how infertility experiences informed individual, dyadic, and community well-being of participants in the context of HIV-affected partnerships.

Results: The following themes emerged:

1. internal infertility stigma impacts mental health expressed as frustration, loss of hope, and feelings of inadequacy;
2. partnership conflicts evolving from mistrust and blame influence the pursuit of new partners and abandonment of SC and HIV prevention strategies;
3. community-level infertility stigma and pressures to have children exacerbate partnership strain; and,
4. healthcare that does not address infertility discourages care engagement.

We developed an overarching conceptual framework (Figure 1) highlighting how lack of infertility information and understanding may contribute to the four emergent themes described above and ultimately increase HIV transmission behaviors.

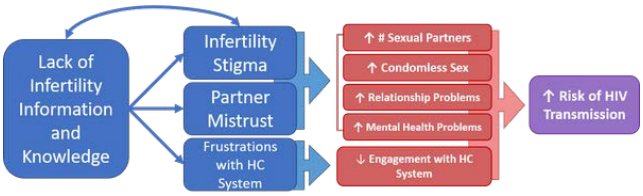

Figure 1

Conclusions: In the context of HIV-affected partnerships, HIV and infertility stigmas intersect, leading to social and relationship strains that may impact HIV prevention. Seeking to fulfill their reproductive needs, partners may unwittingly increase HIV transmission opportunities as they engage in more condomless sex with additional partners and decrease adherence to biomedical prevention strategies. Future research should explore the intersecting impacts of infertility and HIV stigma in HIV-affected couples, especially in settings that value fertility and have high HIV incidence.

PED572

Community led convergence model to prevent vertical transmission of HIV: results from Global Fund supported Ahana project in 14 states of India

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Background: India has one of the largest public health infrastructure, offering primary health care at the last mile till the village level. However, HIV service access never gone beyond district headquarters apart from few historically HIV high prevalent states. Ahana project funded by The Global Fund launched during October, 2015 and phase –II initiated during January 2018 to complement the Govt. of India Initiative to attain EMTCT through a community bases service delivery approach in 357 districts of 14 states of India with an estimated 16 million annual pregnancy load.

Description: Four pronged strategy adopted to converge service access at a very large scale and with a peripheral access of HIV testing and services for pregnant women, three tier policy level convergence for community engagement, capacity building convergence through building capacities of 40 thousand community care provider, community based single window service delivery through community volunteers, information system convergence to streamline and to facilitate one national data reporting for EMTCT.

Lessons learned: Community based single window service delivery mechanism implemented across 14 states resulted in rapid increase in HIV testing among pregnant women from 18% in 2014-15 to 74% during 2018-19 against estimated pregnancy. Early identification has been made possible with early HIV testing and resulted in identification of additional 2 thousand HIV positive pregnant women annually a 225% increase in positive identification in 2018-19 compared to 2015-16. Altogether, 13 thousand HIV positive pregnant women were linked with ART and provided with care and support services. Eleven thousand HIV exposed babies were linked with EID testing and followed up till 18 months for confirmatory testing. HIV transmission could be prevented successfully among 2,207 babies out of the 2,282 received confirmatory testing during 2017-19.

Conclusions/Next steps: The above results suggest that large scale successful outreach is only possible through a community based intervention. As the knowledge and the capacity remains at the community it also positively contributes to ensure the sustainability. With communities across 357 districts in 14 states empowered and started providing the services at the village level, Ahana project demonstrate the roadmap for the EMTCT by 2020 in India.

Living with HIV and co-infections and/or co-morbidities

PED573

Pathways from childhood abuse to adulthood mental health challenges: applying theories of accumulating health risks with a longitudinal cohort of women living with HIV in Canada

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Background: Research has identified a continuum of risk stemming from childhood abuse among women with HIV that may result in adulthood violence and substance use. There are calls for longitudinal assessment of pathways from childhood abuse to later mental health among women with HIV. Informed by life course epidemiology theories of accumulating health risks, we examined longitudinal pathways from childhood abuse to adult mental health via poverty, injection drug use and violence.

Methods: We conducted a five-year, three-wave longitudinal study with women with HIV in Canada (Ontario, British Columbia, Quebec). We used longitudinal path analysis to identify pathways from a latent construct of childhood abuse (indicators: physical, verbal, sexual abuse) to a latent construct of mental health (indicators: depression, post-traumatic stress disorder, well-being) via a latent construct of poverty (low income, food insecurity, housing insecurity), injection drug use, and violence, controlling for participant age, sexual orientation, and ethnicity.

Results: Of the 1417 study participants, 56% had experienced childhood physical abuse, 60% had experienced childhood verbal abuse, and 40% had experienced childhood sexual abuse. Having experienced childhood abuse was directly associated with being at increased risk of poverty at Wave 1 (β = 0.18, p <0.001), experiencing adulthood violence (but not using injection drugs) at Wave 2 (β = 0.30, p <0.001), and having poorer mental health outcomes at Wave 3 (β = 0.13, p = 0.01). Significant indirect pathways via poverty and violence experienced in adulthood accounted for 48% of the total association between childhood abuse and adult poorer mental health.

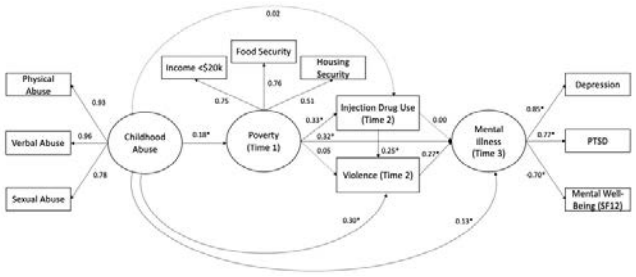

Figure.

Conclusions: More than half of this cohort of women with HIV in Canada experienced childhood abuse, which was associated with poorer adult mental health directly and via mediators of poverty and violence in adulthood. Trauma-informed care and poverty reduction are key to addressing comorbid mental health challenges among women with HIV.

PED574

Factors associated with impaired self-reported quality of life in males and females living with HIV in south-western France (QuAliV - ANRS CO3 Aquitaine cohort)

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Background: Ensuring people living with HIV (PLWH) maintain good quality of life (QoL) is the ultimate goal of HIV care. We assessed QoL in PLWH in Nouvelle Aquitaine, France and examined whether impaired QoL was associated with socio-demographic and/or disease-related factors.

Methods: We conducted a multi-centric cross-sectional study (QuAliV) within an open, prospective hospital-based cohort study of HIV-1-infected adults in care in 13 hospitals in Nouvelle Aquitaine, France, with participants completing the WHOQOL-HIV BREF assessment following their HIV consultation (23/07/2018 - 31/12/2019). The item "How would you evaluate your quality of life?" was treated as an ordinal variable in univariable and multivariable ordinal regression analyses, stratified by sex and adjusted for age, level of education, income, geographic origin, transmission category, CD4 cell count, viral load, CDC clinical category, and number of comorbidities.

Results: 965 participants completed the first item of the WHOQOL-HIV BREF by 31/3/2020, prior to COVID-19 lockdown measures. 726 (75.2%) were men, of whom 481 were MSM, 832 (86.2%) were of French descent, 337 (34.9%) were university educated and 510 (52.8%) had income of £2000€/month. Participants had been diagnosed for 19.7 (11.9, 28.0) years and 98.4% [950/965] were on ART. 94.7%, on ART, had achieved viral suppression. Excellent/good, neutral, or impaired QoL was reported by 63.5% [613/965], 29.8% [288/965], and 6.6% [64/965] respectively. In univariable analyses, lower education and income, having contracted HIV via IV drug use, a history of AIDS, and having >3 comorbidities were associated with higher proportional odds of impaired QoL in males, whereas, lower education and income, place of origin, CD4 cell counts <200 cells/ul, a detectable viral load measure, and a history of AIDS were associated with higher proportional odds of impaired QoL in females. They remained significantly higher only in lower income brackets in males, whereas they remained significantly higher in those with secondary education, of European descent, and with >3 comorbidities in females, holding other variables constant.

Conclusions: Factors associated with perceived impaired QoL appear to differ according to sex, perhaps given the relative positions of males and females living with HIV. Further exploration of factors affecting QoL warrants a gender-conscious lens.

PED576

COVID-19 vaccine hesitancy and associated factors among people with HIV in the United States: findings from a national survey

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Background: The rollout of vaccines against COVID-19 has been framed as an effective strategy for slowing the spread of COVID-19 transmission. However, the novelty of the vaccines and concerns over safety and efficacy have stirred a significant amount of distrust resulting in vaccine hesitancy. This is particularly concerning among people with HIV (PWH) who may be at elevated risk of COVID-19 disease due to overlapping co-morbidities.

Here, we aimed to identify and understand COVID-19 vaccine hesitancy in a nationally representative sample of PWH in the U.S.

Methods: A cross-sectional online survey of 1,030 PWH in the U.S. was conducted between December 6, 2020 and January 8, 2021. Participants were recruited online through targeted social media advertising. Survey items assessed demographics, participants' HIV and health-related attributes, COVID-19 history and experiences, COVID-19 vaccine-related concerns, and attitudes towards COVID-19 vaccines (using the Vaccination Confidence Scale, with higher scores indicating a greater hesitancy: range 1-5). Multivariate linear regression was used to identify factors associated with vaccine hesitancy in this sample.

Results: A total of 1,030 respondents completed the survey, the majority being male (89.7%), white/Caucasian (66.0%), and gay or lesbian (84.5%). Mean time living with HIV 17.0 years (SD=11.1). The mean score for vaccine hesitancy was 1.58 (SD=0.56); 401 participants (38.9%) had a score greater than 1.58, indicating some level of vaccine hesitancy.

The final multivariate linear regression showed being male (b=-0.105, p=0.019), Whites (b=-0.069, p=0.037), politically conservative (b=-0.144, p<0.001), and those living with HIV for a longer time (b=-0.069, p<0.001) were associated with greater vaccine hesitancy.

Participants who were Black (b=0.158, p<0.001), HIV virally suppressed (b=0.158, p=0.019), previously hospitalized with COVID-19 (b=0.558, p=0.003), "anti-vaxxer" (b=1.876, p<0.001), expressed concerns about efficacy (b=0.128,p=0.036) and safety (b=0.234,p<0.001) related to the vaccines, and thought they were being experimented on (b=0.264, p<0.001) were less hesitant to receive vaccination.

Conclusions: Our findings provide important insights regarding COVID-19 vaccine hesitancy among PWH. The degree of vaccine hesitancy is alarming and represents a significant barrier to the successful implementation of the nationwide vaccination campaign. Further efforts are required to understand various social, political, and psychological factors contributing to COVID-19 vaccine hesitancy among key populations.

HIV cure representations and perceptions

PED577

Ethical and practical considerations for scaling up cell and gene therapy towards an HIV-1 cure

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Background: Over 250 biomedical studies have been dedicated to finding a cure for HIV, an increasing number of which involve cell and gene therapy (CGT). We conducted a qualitative research study with key stakeholders to elicit ethical and practical considerations for scaling up HIV cure-related CGT approaches.

Methods: From September – November 2020, we conducted in-depth interviews of 12 biomedical HIV cure researchers, 5 community advocates, and 1 bioethicist working on CGT. Informants worked in the field of HIV for a mean of 24.2 years (SD = 10.8 years) and in the field of HIV cure research for a mean of 14.5 years (SD=9.9 years). We transcribed all interviews verbatim and employed grounded theory for thematic data analysis.

Results: All informants described CGT as a promising platform for curing HIV, but noted that it requires technological development. Ethical and practical considerations for scaling up CGT included strong investments in pre-clinical work, ensuring favorable benefit/risk ratios, augmented safety monitoring that includes long-term follow-up of trial participants, and robust informed consent.

Two CGT approaches were considered too risky: stem cell transplants in otherwise healthy volunteers with HIV, and any CGT intervention involving the germline. Informants detailed various ways to potentially reduce off target effects, balance immune activation profiles, and control the duration of CGT interventions.

For resource-limited settings, considerations included regulatory oversight, clinical/laboratory capacity, portability, decentralized manufacturing, safety monitoring (including self-monitoring), the ability to detect relapse, cost, and post-trial access. Informants also expressed the need to involve younger people with HIV in CGT research towards an HIV-1 cure. Use of mRNA vaccines to combat COVID-19 may increase acceptability of CGT approaches.

Conclusions: Ensuring HIV cure trials reach those areas that are most highly burdened by HIV remains a fundamental matter of equity and justice. As such, the ethics, feasibility, and implementation of CGT will be key considerations as these trials towards an HIV cure are scaled up globally. Robust engagement of stakeholders and affected communities will be necessary to manage expectations around the increasing number of CGT trials being implemented worldwide.

Conceptualizing social and structural factors and their impacts

PED578

High provider trust is associated with high HIV medication adherence among women living with HIV in metropolitan Washington, DC

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Background: Trust in providers and healthcare systems (HCS) has associated with higher HIV medication adherence. However, most previous studies primarily enrolled men and did not concurrently assess provider trust, HCS distrust, and clinical/biological outcomes. We explore provider trust and HCS distrust in a cohort of women living with HIV (WLH).

Methods: We enrolled 239 Washington, DC area Women's Interagency HIV Study (WIHS) women: 167 WLH and 72 high-risk seronegative women. Between 2017-2018, women completed surveys on provider trust (1-item, dichotomized as high vs. low trust), HCS Distrust (10-item, continuous scale), HCS discrimination, and HIV myths (9-items, e.g., "HIV is man-made", dichotomized as any belief vs. none). Covariates were obtained from the concurrent WIHS visit. Descriptive analyses included chi square and Mann Whitney tests. "Best subsets" selection in R produced logistic (provider trust) and linear (HCS Distrust) models.

Results: Most women were African American/Black (76.9%), currently insured (99.6%), with a median age of 52 (IQR 47, 58). Most women (69.5%) believed at least one HIV myth. WLH reported higher provider trust vs. seronegative women (p=0.0007), which remained significant in modeling (adjusted odds ratio [aOR] 2.87, 95% CI 1.39, 6.06). WLH were also less distrustful of the HCS (p=0.03). Modeling only WLH, high provider trust associated with higher odds of ≥95% HIV medication adherence (aOR 3.52, 95% CI 1.16, 10.86), adjusting for covariates. In linear modeling, report of HCS discrimination (4.09-point increase), college education or above (2.24-point increase), any HIV myth beliefs (5.15-point increase) significantly associated with increased HCS Distrust scores. These variables were also significant in models with WLH only. Interestingly, HIV medication adherence ≥95% significantly associated with 3.18-point increase in HCS Distrust score (p=0.03). CD4 count and viral load did not associate with provider trust or HCS distrust.

Conclusions: WLH reported higher HCS and provider trust versus high-risk seronegative women, which may have implications for PrEP use. Self-reported HIV medication adherence among WLH, but not CD4 count or HIV viral load, associated with higher provider trust, yet also higher HCS Distrust scores, which deserves further study. Potential impact of belief in HIV myths on the health of WLH should be explored.

PED579

Examining food insecurity as structural factor associated with reduced safer sex efficacy among Northern and Indigenous adolescents in the Northwest Territories, Canada

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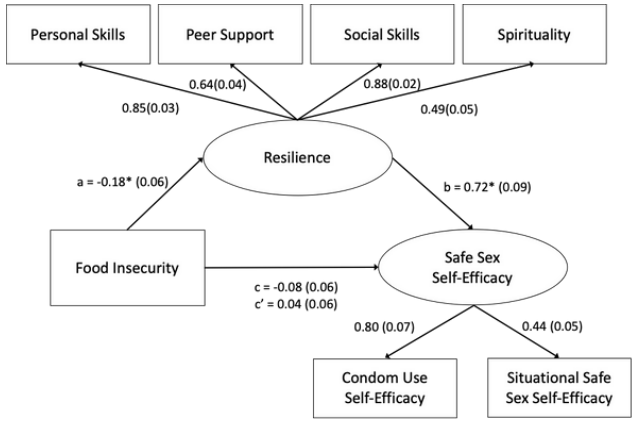
Background: Food insecurity is a structural HIV determinant that can increase feelings of disempowerment. It is important to understand food insecurity's potential role in shaping safer sex efficacy in Arctic contexts that experience heightened food insecurity. Safer sex efficacy comprises sexual agency, sexual decision-making, and condom negotiation.
We examined direct associations between food insecurity and safer sex efficacy (SSE), and indirect effects via resilience and relationship power, among adolescents in the Northwest Territories (NWT), Canada, where food insecurity is nearly double the national prevalence (16% vs. 9%).
Methods: We conducted cross-sectional surveys with adolescents aged 13-18 in 17 NWT communities. We assessed socio-demographics, food insecurity (frequency of going to bed hungry due to insufficient food, dichotomized: ever/never), SSE (scales: Safer Sex Negotiation, Situational Safer Sex Self-Efficacy), relationship power (Conflict Tactics Scale), and resilience (Child and Youth Resilience Measure subscales). We conducted descriptive statistics, bivariate analyses (chi-squared, Mann-Whitney U tests), and structural equation modelling using maximum likelihood estimation to assess whether resilience and relationship power mediated the association between food insecurity and SSE.
Results: Most participants (n=410; mean age: 14.3, SD: 1.26) identified as Indigenous (79%), heterosexual (85%), and 45% reported any food insecurity. The model demonstrated adequate fit (CFI=0.93, TLI=0.88, RMSEA=0.07, SRMR=0.04). Food insecurity was associated with lower resilience (β= -0.18, p=0.001, 95%CI = -0.83, -0.07), and resilience was positively associated with SSE (β=0.72, p< 0.001, 95%CI=0.55, 0.89). While the direct path from food insecurity to SSE was not significant (β=0.04, p=0.46, 95%CI = -0.07, 0.15), the indirect effect from depression to SSE via resilience was significant (β= -0.13, p=0.004, 95%CI = -0.21, -0.04). Results demonstrate a mediated relationship between food insecurity and SSE via resilience.



Conclusions: HIV prevention strategies targeting resiliencies alone will be insufficient to address the larger structural contexts of food insecurity that constrain safer sex efficacy for Arctic adolescents.

PED580

COVID-19 related stressors and HIV status neutral care among black men who have sex with men and black transgender women in the U.S. during COVID-19 pandemic

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Background: COVID-19 has significantly impacted marginalized groups, including black men who have sex with men (BMSM) and black transgender women (BTW). Stress-related to financial hardships, intimate partner violence (IPV), COVID-19 infection, and reduced mobility could further exacerbate disparities in status neutral care.
The current study investigated associations of COVID-19 related stressors with pre-exposure prophylaxis (PrEP) and antiretroviral therapy (ART) outcomes under "shelter-in-place" orders and social distancing recommendations in the U.S.
Methods: As part of the ongoing Neighborhoods and Networks (N2) cohort study, we launched a COVID-19 survey among young BMSM and BTW in the Midwest between April and July 2020. The COVID-19 survey included virtual face-to-face, 60-minute video interviews. Survey questions included COVID-19 related stressors (e.g., economic hardship, housing and food insecurity, violence exposure, COVID-19 symptoms and infections) and PrEP and ART outcomes. Multivariable logistic regression models were conducted to examine relationships between COVID-19 related stressors with PrEP use/access and ART use/access.
Results: Among 222 participants, the mean age was 27.9 years. About 87% of the participants were male and 13% were female. More than half of study participants identified as gay, one fourth identified as bisexual, and 14% identified as straight or other. Sixty percent of participants were HIV-negative and those living with HIV made up 40% of the sample.
Among HIV-negative participants, having physical reactions (e.g., sweating, pounding heart) to worries or problems related to COVID-19 (aOR=2.61 [95%CI 1.20-5.81]), having friends or loved ones experiencing COVID-19 symptoms (aOR=2.52 [95%CI 1.10-5.90]), and personally knowing someone diagnosed with COVID-19 (aOR=2.53 [95%CI 1.07-6.30]) were significantly associated with current PrEP use.
Among HIV-positive participants, exposure to IPV since shelter-in-place (aOR=5.51 [95%CI 1.29-25.51]) and experiencing financial travel burden since shelter-in-place (aOR=7.65 [95%CI 2.21-30.55]) were associated with a greater perceived difficulty in accessing ART. No COVID-19-related stressors were significantly associated with PrEP access or ART use.
Conclusions: Multiple COVID-19 related stressors were found to interfere with access and use of HIV prevention and treatment access. To minimize disruption in HIV biomedical interventions among BMSM and BTW, healthcare and service providers should consider strategies to address individuals' emotional stress due to COVID-19.

PED581

Multi-level factors influencing PrEP adherence among young women in Kenya

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Background: Young women (YW) in Siaya County, Kenya, experience one of the highest HIV incidence rates among YW in east/southern Africa. We implemented photovoice with YW in Siaya who have access to PrEP through the DREAMS Initiative, and with members in their social ecology, to identify multi-level factors influencing YW's PrEP adherence and persistence. We describe here a sub-set of adherence findings.

Methods: Informed by the social ecological model, five groups representing various perspectives—YW taking PrEP (YWTP; n=20), female peers (n=15), male peers and partners (n=13), family members (n=15), and community members, including healthcare providers (n=14)—captured photographic images of factors that do/can support and inhibit YW's PrEP adherence. YWTP's images depicted their perspectives of influential factors from various social ecological levels. Other groups' images included observer perspectives (e.g., male partners' insights about factors influencing YW's adherence) and direct/indirect influences by their specific group (e.g., male partners' perspectives of how partners influence YW's adherence). Members in each group wrote captions describing their photographs' relevance and shared/discussed photographs with their group. Discussions were audio-recorded, simultaneously translated/transcribed, and analyzed using applied thematic analysis.

Results: Factors influencing YW's PrEP adherence relate primarily to interpersonal-, organizational/structural-, and community-level factors rather than intrapersonal-level factors. Having positive interactions about PrEP with others, such as partners, female peers, and elders, followed by receiving emotional and instrumental social support, such as reminders and transportation, were the most frequently-identified positive interpersonal and overall influential factors; conversely, lack of support and negative peer interactions were frequently-identified negative interpersonal factors. At the organizational/structural level, participants said safe spaces supported PrEP use; yet they expressed a need for additional PrEP distribution sites and better access to existing sites, noting lack of privacy and long queues as barriers to access. Participants highlighted poor living conditions as a challenge to adherence, describing secure and clean houses as more conducive to pill taking. PrEP-related stigma was the most frequently-identified negative community-level and overall factor. Participants stressed the need to normalize PrEP in their community.

Conclusions: Future interventions supporting PrEP adherence among YW in Kenya should include components focusing on broader social-ecological influences.

PED582

The mediating effects of resiliency, social support, and self-efficacy on the relationship between HIV stigma and self-rated overall health

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Background: HIV stigma remains high across Canada and continues to negatively impact the health and wellbeing of people living with HIV. There are different types of stigma (internalized, enacted, anticipated) and understanding how these affect health as well as which factor(s) may buffer these effects is key to reducing their negative impact.
This study aims to examine whether social support, resiliency, and self-efficacy mediate the relationship between enacted, internalized, and anticipated stigma and self-rated health.

Methods: We recruited 724 participants across Ontario to complete the People Living with HIV Stigma Index, a survey tool designed by and for people living with HIV to measure nuanced changes in stigma and discrimination. The survey included measures for determinants of health, stigma, and protective factors which were the primary focus of this analysis. Separate parallel mediation models were created with each dimension of stigma as the antecedent and self-rated health as the outcome. Resiliency, social support, and self-efficacy were entered as mediators in all three models. Age, years since HIV diagnosis, gender, ethnicity, sexual orientation, geographic region, education, and employment were added into each model as covariates.

Results: With internalized stigma as the predictor, resiliency [b = -0.13, 95% CI (-0.19, -0.07)], social support [b = -0.06, 95% CI (-0.09, -0.02)], and self-efficacy [b = -0.03, 95% CI (-0.06, -0.01)] were all significant mediators for overall health.
For enacted stigma, resiliency [b = -0.07, 95% CI (-0.11, -0.03)] and social support [b = -0.05, 95% CI (-0.08, -0.02)] were significant mediators; anticipated stigma showed the same pattern.

Conclusions: We found that increased internalized, enacted, and anticipated stigma lead to worse self-rated overall health through the reduction of resiliency and social support. This suggests that interventions that focus on bolstering an individual's internal (i.e., resiliency) and external (i.e., social support) resources may be key to overcoming the negative impacts of various types of stigma and maintaining good health and wellbeing.

PED583

Examining the relationship between inequitable gender norms and HIV stigma in Eswatini, Uganda, and Zimbabwe

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Background: Stigma and inequitable gender norms are social and structural drivers of the global HIV epidemic in that they can affect preventive behaviors (such as HIV testing) as well as perpetuate risk behaviors. We examined the relationships between HIV testing, stigma, and inequitable gender norms among male and female participants who were part of the Project ACCLAIM study in Eswatini, Uganda, and Zimbabwe.

Methods: Project ACCLAIM was a three-arm, multi-country, multi-component cluster randomized trial that sampled women and men aged 18-60 years in randomly selected households. Data pertaining to participants' demographic information, HIV testing behavior, HIV stigma, and gender norms were used for this analysis. We examined differences in testing behavior, stigma, and gender normative beliefs across countries and between sexes, as well as conducted linear regression modeling to examine predictors of inequitable gender norms.

Results: Our data showed several demographic variables (married status, lower educational attainment, and lack of formal employment) and several HIV stigma variables predicted stronger endorsement of inequitable gender norms but having received HIV testing was inversely related to holding inequitable gender norms.

These findings were consistent across all three countries, despite the levels of inequitable gender norms being different in each country. Linear regression modeling found several significant predictors of inequitable gender norms, including sex (with men demonstrating lower inequitable gender norms scores compared to women), married or polygamous status, lower educational status, and lack of employment.

Receipt of HIV testing was associated with lower inequitable gender norms scores (compared to never testing: β=-0.66, p=0.0009), and several HIV stigma items were positively and significantly associated with higher inequitable gender norms.

Conclusions: These results reinforce the importance of addressing structural factors that continue to drive HIV risk practices in both resource-rich and resource poor countries and that function as barriers to the uptake of proven effective biomedical and behavioral interventions to prevent HIV transmission.

PED584

Socioeconomic and structural influences on psychological distress and HIV prevention and care continuum engagement among young Black sexual and gender minorities

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Background: Black sexual and gender minorities (SGM) are disproportionately impacted by socio-structural stressors such as housing instability, incarceration, and violence that may lead to psychological distress and impact engagement in HIV prevention and care continuums.

Methods: From 2013-2015, respondent driven sampling was used to recruit Black SGM ages 16-29 from the South Side of Chicago over 3 waves of data collection. Psychological distress was assessed using the Brief Symptom Inventory 18-item scale (BSI-18). Scores on the global symptom inventory and on depression, anxiety, and somatic symptom subscales were calculated; t-scores >62 indicated past week presence of clinically significant symptoms.

Mixed effects logistic regression was used to examine associations between structural factors (housing instability, financial hardship, incarceration, violence), psychological distress, past 12 month substance use (other than marijuana) and HIV prevention and care continuum outcomes (among HIV positive, viral suppression defined as HIV RNA <2000 copies/mL and among HIV negative, ever use of PrEP).

Results: Of 618 participants, at baseline, 92% identified as male and 8% as transgender. 226 (36.6%) were HIV positive by testing or self-report. The mean age was 22.8 (SD 3.2). In the overall sample, housing instability, economic hardship, and violence were significantly associated with higher odds of psychological distress (overall symptom score and all subscales) and substance use. In longitudinal mixed effects regression, among HIV positive participants (diagnosed ≥6m prior to baseline) current homelessness (aOR 0.12; 95% CI 0.02-0.68), lack of healthcare coverage (0.20; 95% CI 0.07-0.62), depressive symptoms (aOR 0.13; 95% CI 0.03-0.50), anxiety symptoms (aOR 0.22; 95% CI 0.05-0.92), general psychological distress (aOR 0.13; 95% CI 0.03-0.54), and substance use (aOR 0.22; 95% CI 0.06-0.74) were associated with lower odds of viral suppression over time. None of these factors were statistically associated with PrEP use among HIV negative participants, though PrEP uptake was low in the sample at the time of the study.

Conclusions: Given high rates of exposure to socioeconomic stressors and violence among Black SGM, integrating mental health interventions into HIV prevention and care may help to reduce health inequities.

Socio-economic differences: poverty, wealth, and income inequalities

PED585

Social exclusion and health-related quality of life of people living with HIV during COVID-19 pandemic

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Background: The challenges that COVID-19 has brought can lead to an increase in the PLHIV social exclusion risk, which could impair their health-related quality of life (HRQoL). This study aimed:

1. to know the degree of social exclusion that PLHIV suffered in Spain and the most impaired dimensions;
2. to analyze the effect of social exclusion on PLHIV's HRQoL;
3. to study the evolution of PLHIVs' social exclusion and HRQoL during COVID-19 times.

Methods: We conducted two nested studies. A total of 515 PLHIV participated in a cross-sectional study conducted between October-December. A short-longitudinal study was conducted in a sub-sample of 135 PLHIV who six months before filled the questionnaire measuring the study variables.

Eleven Spanish HIV centers (clinics and NGOs) recruited the participants and collected the data through an online self-administered survey. We used the Index of Social Exclusion for Health Surveys to measure social exclusion and the WHOQOL-HIV-BREF to measure HRQoL.

Results: Most of the participants of the overall sample were men (74%). Their mean age was of men composed the total sample. The mean age was 43.36±11.05 years. The cross-sectional study's results with the largest sample (n=515) showed that 35.1% suffered moderate-to-strong social exclusion. Material deprivation and social participation were the dimensions most affected (30.7 and 28.9% of PLHIV showing moderate-to-strong scores, respectively).

Compared with men, women presented a higher social exclusion score (p=.015), mainly in the material deprivation dimension (p<.001). Cross-sectional results showed high negative correlations between social exclusion and all HRQoL domains (p<.001). Longitudinal results showed an

increase in the percentage of PLHIV suffering social exclusion to some degree (p<.001). The dimension most impaired was material deprivation because we found 4% more of participants moved to the moderate-to-strong category.

The social exclusion dimension related to social participation predicted negatively the six month later Psychological health and Social relationships HRQoL dimensions (p=.021, p<.001).

Conclusions: The present study is the first to assess the social exclusion of PLHIV in Spain. It seems to be a relevant problem in Spain. In six months between COVID-19 outbreaks PLHIV's social exclusion evolved negatively and undermined PLHIV's HRQoL.

Intergenerational and/or transactional sex

PED586

Transactional sex and HIV viremia among men in rural Uganda: a population-based study

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Background: Transactional sex (TS) refers to non-marital, non-commercial relationships motivated by implicit exchange of sex for material support. TS is associated with greater odds of HIV among women, but little is known about heterosexual men engaged in TS. We examined sociodemographic and behavioral correlates of TS and viremia among men in a high HIV prevalence region of Uganda.

Methods: This analysis included 7,334 sexually active men aged 15-49 participating in the Rakai Community Cohort Study, a population-based open cohort of individuals residing in Rakai District, Uganda. To assess TS, men were asked if they had ever given money, gifts, or favors to any one of their four most recent past-year non-marital, non-commercial sexual partners. We used descriptive statistics to characterize men reporting TS and TS relationship characteristics. We used Poisson regression with robust standard errors to estimate adjusted prevalence ratios (adjPR) with 95% confidence intervals (CI) for bivariate and multivariable analyses for both TS and viremia (≥1,000copies/mL). Factors assessed for inclusion in models were identified a priori based on theory and extant literature.

Results: A total of 672 (9.2%) men reported 881 past-year TS relationships. Median TS relationship duration was shorter than non-TS relationships (TS:1.9 months;IQR:0,7 *vs.* non-TS:3.2 months;IQR:0,11.2;p<0.0001). Men reported that their TS partners were bar workers (15.3%), students (14.1%), or waitresses (13.3%). In multivariable analyses, TS was more common among men who were aged 15-24 (adjPR:1.45,CI:1.21-1.72), unmarried (adjPR:2.36,CI:1.99-2.79), students (adjPR:1.70,CI:1.14-2.53), had ≥2 sex partners (adjPR:3.60,CI:2.96-4.38), reported that their partner consumed alcohol before sex (adjPR:1.62,CI:1.33-1.97), and perpetrated sexual abuse (adjPR:1.66,CI:1.18-2.35). Men in TS relationships were not more likely to be HIV-positive; however, in analyses stratified by viremic status, viremic men aged 25-34 (adjPR:1.87;CI:1.29-2.70) and viremic married men (adjPR:1.94,CI:1.26-3.00) were almost twice as likely to report TS than non-viremic men.

Conclusions: Men in TS relationships were more likely to report high-risk sexual behaviors such as sexual abuse and multiple past-year sexual partnerships. While these men were not more likely to be HIV+, viremic men aged 25-34 and viremic married men were almost twice as likely to report TS. These findings have important implications for interventions aimed at reducing transmission of HIV in TS relationships.

Migration and HIV

PED587

Distinct forms of population mobility are differentially associated with objectively measured antiretroviral treatment (ART) adherence

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Background: Population mobility may impact ART adherence by interrupting routines or access to care. We sought to examine the association between forms of mobility and adherence in Eastern Africa, using hair concentrations of antiretrovirals (ARV) as an objective adherence metric.

Methods: At baseline in a study of mobility in 12 rural communities in three regions of Uganda and Kenya, we measured hair ARV concentrations via validated assays in participants living with HIV on efavirenz or nevirapine-based regimens. We estimated the percent difference in ARV concentrations associated with mobility metrics e.g., overnight trips for work or other reasons, local moves, and migrations (changes of residence across district/county or national boundaries). Models were adjusted for age, sex, region, and time on ART. We also examined separate models by sex.

Results: Among 384 participants, 52% were female and the median age was 40 (IQR 33-48); 57 (15%) reported work-related mobility and 170 (44%) reported non-work mobility in the prior 6 months; 109 (28%) reported any migration in the past 5 years. Compared to participants reporting no work-related travel, those who typically spent 1-2 nights away for work averaged 72% higher hair ARV concentrations (95%CI: 7, 187) while those with longer duration stays averaged lower, but with wide uncertainty (-26%, 95%CI: -54, 20). Those who traveled for non-work reasons in the past 6 months averaged 25% lower hair ARV concentrations (95%CI: -44, 0) than those who did not. Compared to participants with no migration in the past 5 years, those who reported their most recent move was *intra*-district averaged 53% lower ARV concentrations (95%CI: -70, -27), while those reporting *inter*-district moves averaged higher, though with wide uncertainty (+22%, 95%CI: -13, 72). Results were qualitatively similar by sex.

Conclusions: We found varied associations between objectively measured ART adherence and different forms of mobility. Localized, intra-district moves and non-work travel were associated with lower adherence, possibly reflecting interruptions in care or staying with family/friends unaware of the participants' status. In contrast, short work-related trips were associated with higher adherence, perhaps reflecting the stability that income can bring. Adherence interventions for mobile persons may require tailoring by forms of mobility.

PED588

Migration, non-local partnerships, sexual concurrency, and gender influence longitudinal STI prevalence in rural eastern Africa

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Background: Mobility challenges HIV prevention through linking geographically separate epidemics and associated higher behavioral risks and STIs. We sought to better characterize relationships between forms of mobility, sexual risks, and gender using STIs as an objective proxy measure for HIV sexual risks.

Methods: Data are from a longitudinal cohort study embedded within an HIV test-and-treat trial in Kenya and Uganda (SEARCH, NCT# 01864603). From 2015-2019, survey data on mobility and sexual risk behaviors were collected every 6 months, with annual *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) testing in a sex-and HIV-stratified random sub-sample of 2,750 adults aged 16+ in 12 communities. Repeated measures mixed-effects logistic models were used to examine bivariate and multivariate relationships of prevalent STIs (CT, NG, & any STI) with recent migration (change of residence over geopolitical boundaries) and local mobility (overnight travel away from home), sexual concurrency (overlapping partnerships), sexual partner residence (local town vs. non-local), high-risk sex partners (casual partner, commercial sex worker/client, one night stand, inherited partner/inheritor, or stranger), and demographics.

Results: Annual STI testing was available on 2,665 persons with an annual prevalence of any STI 3.1% (95%CI:2.5-3.9) at baseline, 3.3% (95%CI:2.6-4.0) at year 1, 4.4% (95%CI: 3.0-5.2) at year 2, and 4.8% (95%CI:4.0-5.7) at year 3. Prevalence across all years was; CT:1.98%, NG:1.79%, CT+NG:0.15%). 85% tested in all years, with 94% having ≥3 years of STI testing. STI prevalence did not differ significantly by sex or HIV status across years. Significant bivariate associations with STIs were seen for mobility and sexual behavior measures (Figure). In multivariate analysis, significant independent associations with any STI were: number of migrations in past year, non-local partner residence, sexual concurrency, being married, high-risk sex partners, age<25, low household wealth, and being female.

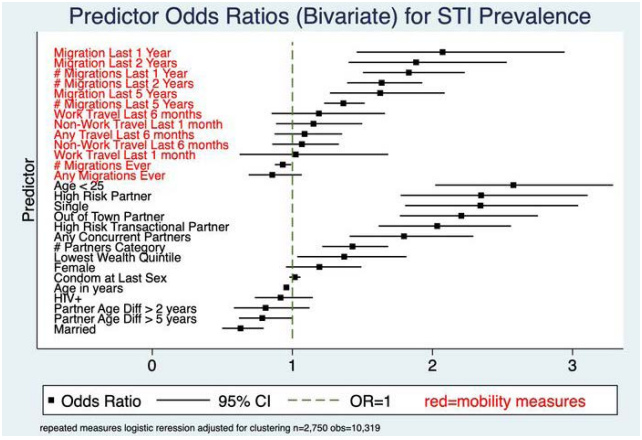

Figure. Predictor odds ratios (bivariate) for STI prevalence

Conclusions: Migration, non-local partnerships, sexual concurrency, high-risk partnerships, and female gender significantly influence longitudinal STI prevalence.

Violence and conflict: political, social, structural, interpersonal, and family-based

PED589

Prevalence and correlates of HIV status disclosure without consent among women living with HIV in Metro Vancouver, Canada

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Background: Involuntary HIV status disclosure (HIV status disclosure without consent) is a human rights issue and constitutes a form of gendered violence against cisgender (cis) and transgender (trans) women living with HIV (WLWH). Criminalization of HIV non-disclosure in Canada exacerbates risk of stigma and interpersonal violence for WLWH. This study aims to identify the prevalence and correlates of involuntary HIV status disclosure among WLWH.

Methods: Data were drawn from 4.5 years (September/14-February/19) of a longitudinal community-based open cohort of cis and trans WLWH who lived and/or accessed care in Metro Vancouver, Canada (Sexual Health and HIV/AIDS: Women's Longitudinal Needs Assessment "SHAWNA"). Participants completed baseline and bi-annual follow-up interviews. Bivariate and multivariable logistic regression with generalized estimating equations (GEE) were performed to identify correlates of recent (last six months) involuntary HIV status disclosure. Adjusted odds ratios (AOR) and 95% confidence intervals (95%CIs) are presented.

Results: The study sample included 1193 observations among 274 participants. Overall, 169 (61.7%) participants reported lifetime and 91 (33.2%) reported recent involuntary HIV status disclosure. In a sub-analysis among 80 participants who listed perpetrators of recent involuntary HIV status disclosure, most common were friends (36.3%;n=29), people in community (23.8%;n=19), neighbours (21.3%;n=17), family (18.8%;n=15), and health professionals (16.3%;n=13). Recent disclosure without consent was positively associated with, in the last six months: being unsheltered (AOR:1.75;95%CI:0.99-3.10 vs stable housing), sexual minority identity (LGBQ2S)(AOR:1.62;95%CI:1.03-2.55), being treated, monitored, or diagnosed with depression, anxiety, or post-traumatic stress disorder (1.60;95%CI:1.08-2.36), experiencing physical symptoms related to HIV diagnosis (1.58;95%CI:1.07-2.35); and negatively associated with living in HIV-specific housing in the last six months (AOR:0.24;95%CI:0.09-0.61).

Conclusions: Structural vulnerability correlates of involuntary disclosure of HIV status include unstable housing and mental health disorders, highlighting the need to integrate trauma- and violence-informed programs and policies that address involuntary HIV status disclosure in health services, housing, and outreach programs for WLWH. Programs and policies should acknowledge and address how other forms of stigma, interpersonal and structural violence intersect with involuntary disclosure and include a focus on autonomy, confidentiality, and safe disclosure practices. Criminal justice reform to protect the privacy and rights of WLWH, rather than focusing on criminalization of HIV non-disclosure, remains critical.

PED591

Conducting violence and mental health research during the COVID-19 pandemic: ethical considerations and lessons learned

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Background: Conducting research on violence and mental health requires careful consideration, to ensure that the research does no harm to either participants or researchers. Guidance from violence researchers warns against remote data collection. We describe the ethical challenges we had to overcome to complete research with Female Sex Workers (FSWs) in Nairobi, Kenya, during the covid-19 pandemic.

Description: The Maisha Fiti study is a mixed-methods longitudinal study with 1003 FSWs. Recent violence experience, depression and active suicidal ideation are assessed using validated tools; referrals are made to the study counsellor. By March 2020 – when Nairobi went into lockdown - follow-up data collection was underway.

After careful discussions including with community members, we decided where possible to conduct all remaining interviews (n=1003 quantitative and 47 qualitative) in-person, following Kenyan MOH COVID-19 guidelines. For a small number of participants who had left Nairobi, we developed strict guidelines and trained interviewers undertook remote phone interviews. Key to ensuring participant safety (with regards to partner violence or suicidal behaviours), was an initial call to discuss if a participant could safely participate, arranging a suitable time and agreeing a 'safe' word to immediately terminate an interview. All consent and qualitative interviews were recorded over the phone using a digital device; we did not use zoom or other platforms as such data cannot be stored securely.

Lessons learned: Lockdown in Nairobi bought extreme and sudden financial hardship to sex workers. Building on relationships created during the baseline interviews and creating a COVID-19 safe clinic environment enabled staff and participants to feel safe. Limiting remote interviews helped reduce risks to participants. Tele-medicine and tele-counselling by staff known to participants facilitated remote violence or mental health support.

Conclusions/Next steps: Relationships we had established with participants prior to the pandemic, the prioritisaion of in-person interviews, and the careful strategies we put in place for remote interviews enabled us to complete data collection without (to our knowledge) causing harm. Our research will enable us to understand how mental health and violence experiences changed during the pandemic and offer guidance for interventions to help with future economic shocks.

Criminalization

PED592

Characterizing the relationship between same sex policies and HIV testing history among gay men and other men who have sex with men across 10 countries in sub-Saharan Africa

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Background: Gay men other men who have sex with men (GMSM) are disproportionately affected by HIV across epidemic settings in Sub-Saharan Africa. Systematic reviews have evaluated the association of legislation and engagement in HIV testing services, however, there have been limited opportunities to assess these relationships using individual-level data across settings. In response, this study uses individual-data from GMSM in 10 countries across Sub-Saharan Africa to examine the relationship between HIV testing and the legal environment.

Methods: Respondent driven sampling was used to recruit 8049 GMSM between 2011-2018 in Burkina Faso, Cameroon, Côte d'Ivoire, Gambia, Guinea-Bissau, Nigeria, Senegal, eSwatini, Rwanda, and Togo. Interviewer-administered socio-behavioral questionnaires and biological testing for HIV were conducted. Same-sex policy categorization was based on ILGA defined legal approach: Not criminalized and not protected; criminalized (< 8 years imprisonment); and severely criminalized (>10 years imprisonment). Poisson regression with robust variance was used to measure the association between legal barriers and HIV testing history and awareness of HIV status among individuals living with HIV. Models adjusted for demographic characteristics and were clustered by country, site, and recruitment seed.

Results: Overall, 39.3% of individuals recruited were living in non-criminalized settings, 38.0% in criminalized settings, and 22.7% in severely criminalized settings. Individuals in criminalized (aPR:0.88:95%CI:0.82-0.95) and severely criminalized (aPR:0.63;95%CI:0.52-0.76) settings showed decreased history of HIV testing compared to non-criminalized settings (Table 1). GMSM in criminalized (aPR:0.68; 95%CI:0.48-0.96) and severely criminalized (aPR:0.16;95%CI:0.06-0.64) settings showed decreased awareness of HIV positive status compared to non-criminalized settings.

Conclusions: Consistently, legal barriers were associated with limited history of HIV testing, and limited awareness of HIV status among GMSM. The magnitude of these relationships was strongest in the most punitive settings. These results provide empiric data of how legal barriers impede HIV outcomes among GMSM across Sub-Saharan Africa.

Polices and Legal Barriers			Ever tested for HIV					Aware of HIV positive status among people living with HIV				
	%	N	%	n/N	aPR*	P value	95% CI	%	n/N	aPR*	P value	95% CI
Same sex policy												
Not criminalized and no protective laws	39.3	3163	75.4	2379/3156	Ref	Ref	Ref	38.8	102/263	Ref	Ref	Ref
Criminalized	38.0	3056	71.3	1943/2724	**0.88**	**0.001**	**0.82-0.95**	23.5	144/613	**0.68**	**0.029**	**0.48-0.96**
Criminalized Severe	22.7	1830	76.6	1396/1822	**0.63**	**<0.001**	**0.52-0.76**	81.7	183/224	**0.16**	**0.010**	**0.06-0.64**

Table 1. Legal barriers for gay men and other men who have sex with men and the association with HIV testing history and awarenee of HIV positive status.

Gay, bisexual, and other men who have sex with men

PED593

PrEP increases demand for HIV services among higher-risk key populations in Ghana

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Background: PrEP was implemented for the first time in Ghana through the PEPFAR- and USAID-funded project, Meeting Targets and Achieving Epidemic Control (EpiC) through the Key Population Investment Fund (KPIF). The purpose of the program was to initiate higher-risk men who have sex with men (MSM), female sex workers (FSWs), and transgender persons on PrEP to reduce HIV acquisition.

Description: PrEP was introduced in six health facilities in Greater Accra and Ashanti regions starting in August 2020. The program focused on higher-risk key populations (KPs) given the elevated HIV prevalence among these groups. PrEP screening was conducted at the facility and included a behavioral risk assessment, HIV test, possible acute infection, and/or recent exposure to HIV. If there was an exposure to HIV in the last 72 hours, post-exposure prophylaxis (PEP) was recommended for 28 days. Once the PEP cycle was completed, PrEP could be initiated. HIV Treatment was available for those who tested HIV positive.

Lessons learned: Availability of PrEP was found to create demand for HIV services among higher-risk MSM. About 27% of MSM were ineligible for PrEP since they tested HIV positive (28) during screening or were recently exposed to HIV and were initiated on PEP (7). National HIV prevalence among MSM is 18%; among FSWs, 4.6%. Case finding through PrEP services was 21.7% for MSM and 1.9% for FSWs, which could demonstrate that higher-risk MSM were coming for PrEP when they might not otherwise seek HIV services. (see Table 1).

	FSWs	MSM	Transgender People
Screened for PrEP	306	129	7
HIV positive	6	28	0
Case finding	1.9%	21.7%	
Referred/initiated on PEP	3	7	0
Total ineligible for PrEP (HIV positive or PEP)	9	35	
% Ineligible	2.94	27.13	
Eligible for PrEP	282	91	7
Initiated on PrEP	198	83	7

Table 1. PrEP Cascade, screening for PrEP initiation, August–November 2020

Conclusions/Next steps: A high demand for PrEP services was found among higher risk MSM. The addition of PrEP to an already established HIV program is an opportunity to reach MSM who may not otherwise seek services and initiate them on HIV treatment or PEP, facilitating prevention and achievement to the three 95 UNAIDS goals.

PED594

High risk sexual behavior, access to HIV prevention services and HIV incidence during the COVID-19 pandemic among men who have sex with men and transgender women in Brazil

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Background: Brazil has been severely affected by the COVID-19 pandemic. Changes in sexual practices and in health services use may impact HIV incidence rates. We investigated the association between COVID-19 control measures, sexual behavior, use of HIV prevention services, and the incidence of HIV infection among men who have sex with men (MSM) and transgender women in seven Brazilian cities.

Methods: A web-based survey on COVID-19 nested in two PrEP cohorts - one for adolescents and the other for adults - was carried out between May-November/2020. Information about HIV tests was obtained from follow-up records from the cohorts, after completing the survey. Logistic regression was used to analyze predictors of unprotected anal intercourse (absence of both PrEP and condom use) with a casual partner (UAI). A decision tree analysis was performed to determine the PrEP service demand profile. P-value <.05 and 95% confidence interval were considered as the significance threshold.

Results: Among 616 respondents (response rate 48,8%), most were MSM (89.4%), adolescents (15-19yo 47.5%), and black (55.1%). Prevalence of UAI was 15.9%. Resuming or starting sex work during the pandemic increased the chance of UAI in 3.09 times (1.05-9.13) and 1.61 times (1,03-2.51) for adults aged 30-62yo, when compared to 15-29yo. A total of 80.2% of people reporting UAI restricted sexual relations during the pandemic. Living with someone at increased risk for COVID-19 reduced the chance of UAI by 41% and greater adherence to quarantine measures reduced it by 12% (1-point increase on a scale of 1-10). One third did not access PrEP services, more frequently among those who abstained from sex (47.6%). Those reporting UAI had 1.99 times (1.14 – 3.46) higher chance of making a same-day appointment. Three new HIV infections occurred (incidence rate of 0.49%; 0.1-1.42) in individuals aged <19yo who interrupted or did not adhere to PrEP during the pandemic.

Conclusions: Despite the reduction of sexual activity among participants and the availability of PrEP services during the COVID-19 pandemic, a significant occurrence of UAI and new HIV infections was observed, highlighting the importance of retention in HIV prevention services and PrEP adherence to control the HIV epidemic during sanitary crises.

PED595

The effectiveness of a syndemic theory-based intervention to promote HIV testing, mental health and consistent condom use among MSM in Chandigarh: a quasi-experimental assessment of programme data

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Background: Psychosocial conditions such as depression, problematic alcohol use and internalised homonegativity have been shown to synergistically increase HIV risk among MSM in India. In 2020, our team published evidence for the efficacy of a syndemic theory-based intervention in reducing HIV risk among MSM. To assist in scale-up of that intervention in the national HIV programme, we integrated and assessed that intervention's components in targeted HIV interventions (**TIs**) among MSM in Chandigarh, North India. That intervention focused on promoting HIV testing and consistent condom use by addressing psychosocial syndemics.

Methods: Between October 2019 and April 2020, we conducted a pre-/post-test quasi-experimental trial to deliver a syndemic theory-based intervention among MSM enrolled in TIs of non-governmental organizations in Chandigarh. Trained peer educators administered a 12-item screening tool to assess HIV testing (past 3-months), past-month consistent condom use, depression (PHQ-2), internalised homonegativity and problematic alcohol use (AUDIT-C) as part of programme data from MSM in TIs (baseline=2046 MSM; endline=1812 MSM). Trained counsellors provided motivational interviewing (**MI**)-based counselling on mental health and safer sex. Z-tests for comparisons of proportions and logistic regression were used for analyses.

Results: The intervention significantly increased the proportion of those who underwent HIV testing in the previous three months (from 57.1% to 68.5% post-intervention, p<0.001), and reduced the proportion of those with problematic alcohol use (from 30.0% to 18.4%, p<.001) and internalized homonegativity (from 13.7% to 1.4%, p<.001).

Further, 66% of those who reported inconsistent condom use at baseline underwent HIV testing within the next 3 months, i.e., most potentially HIV-exposed persons underwent testing promptly. The intervention did not significantly change the proportion of those with consistent condom use (69.3% at baseline; 67.8% post-intervention, p=0.32) or depression (9.5% at baseline; 9.2% post-intervention, p=0.74).

Conclusions: The intervention was found to be effective in improving HIV testing and reducing HIV risk factors like alcohol use amid COVID-19 epidemic. The study also demonstrated the feasibility of implementing and intergrating an effective MI-based syndemic theory-based intervention in government-supported HIV projects. The tools used and lessons learnt from this intervention will help in scaling-up of interventions to reduce psychosocial syndemics and HIV risk in national HIV programme.

PED596

Results from two bio-behavioral surveillance surveys among older men who have sex with men in Eswatini

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Background: Surveillance data suggest new HIV infections are declining across much of sub-Saharan Africa, including Eswatini. However, in generalized HIV epidemics, there are limited data on HIV incidence among key populations (KPs). The World Health Organization recommends bio-behavioral surveillance surveys (BBSS) as integral components of national HIV strategies and surveillance systems. Some KPs such as older men who have sex with men (MSM) are difficult to reach through these surveys and, thus, less is known about their infection rates than other, more accessible MSM. We compared data from two BBSS in Eswatini to measure participation and HIV prevalence over time among older MSM.

Methods: We conducted two national BBSS in four regions (July--December 2011 and October 2020–January 2021). The first BBSS surveyed 319 MSM at one study site, while the second surveyed 450 MSM at five study sites. Both used respondent-driven sampling and identical inclusion criteria for MSM: age 18 or older and anal sex with a male partner in the past 12 months.

Results: The HIV case-finding rate among all MSM rose from 17% in the 2011 BBSS to 24% in the 2020–2021 BBSS and remained disproportionately high among older MSM (41% and 43%, respectively). In 2011, older MSM accounted for 7% of those tested and 17% of those found HIV positive, vs. 31% and 57%, respectively, in 2020–2021 (Table 1).

	Indicator	30+ Years	<30 Years	Total
2011 BBSS	Tested	22	297	319
	Distribution tested	7%	93%	100%
	HIV positive Distribution	17% (n=9)	83% (n=45)	100% (n=54)
	Case-finding rate	41%	15%	17%
2020–2021 BBSS	Tested	82	180	262
	Distribution tested	31%	69%	100%
	HIV positive Distribution	57% (n=35)	43% (n=26)	100% (n=61)
	Case-finding rate	43%	14%	24%

Table 1

Conclusions: BBSS participation among older MSM increased from 2011 to 2020, but their burden of HIV has not improved over time. HIV programs should develop strategies tailored to the needs and preferences of older MSM. While their participation in the BBSS was lower than younger MSM, HIV case finding among older MSM suggests that reaching this subgroup with prevention, testing, and treatment services will be critical to achieving epidemic control.

PED597

Factors associated with depressive symptoms among adolescent's men who have sex with men and transgender women enrolled in a PrEP cohort in Brazil

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Background: Mental health issues such as depressive symptoms (DS) are more prevalent among men who have sex with men and transgender women (MSM/TGW) than in the general population, and it can affect the adoption of HIV prevention methods. In recent years, the HIV epidemic has grown among MSM/TGW adolescents, but data on DS in this population is scarce. We aimed to investigate factors associated with DS among adolescents' key population (AKP) of MSM/TGW in Brazil.

Methods: Baseline data from the first demonstration PrEP cohort study among AKP 15-19 years old ongoing in three large Brazilian cities (PrEP1519). Participants were enrolled in the cohort between March/2019-December 2020. DS was defined according to the Center for Epidemiological Studies-Depression Scale (CES-D) score (range of possible scores: 0-60). A total score of 16 or greater on CES-D indicates a possible clinically significant DS condition. A socio-behavioral questionnaire was applied and multivariate analyses were performed using logistic regression with adjusted odds ratio (aOR) and 95% confidence intervals (95%CI) estimation.

Results: The prevalence of DS was 61.1% (95%CI: 57.2-64.9%) among the AKP. Factors associated with DS were lower educational level (aOR=2.12, 95%CI:1.05-4.40), worse self-perception of health (aOR=1.74, 95%CI=1.14-2.65), intimate partner psychological violence (aOR=1.98, 95%CI=1.12-3.51), the experience of sexual violence (aOR=3.77, 95%CI=2.34-6.09) and fear to walk in public spaces due to sexual orientation or gender identity (aOR=1.74, 95%CI=1.18-2.57).

Conclusions: Our findings report a high and worrisome prevalence of DS among AKP in PrEP cohort study, which points to the need for greater care for this population using PrEP.

Furthermore, DS were associated with vulnerability factors such as low education, violence and discrimination experience, and these are key elements to inform better policies, and interventions to improve the health of AKP, specifically mental health disorders.

PED598

Use of wheels as differentiated service delivery model to improve access and uptake of clinical services among Men who have Sex with Men (MSM) at MAAYGO in Kisumu, Kenya

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Background: Men against Aids Youth Group organization (MAAYGO) is a local Community based organization found in 2008 responding to health, human rights advocacy and development among men having sex with men within the Lake region of Kenya. MAAYGO provides both HIV prevention and treatment services, GBV services, security and safety literacy, economic empowerment, financial literacy and skill building, policy advocacy.

Description: In Kenya, men who have sex with men (MSM) are still not accessing services at the Dice optimally despite its availability. this is contributed by various issues including distance to the clinic, stigma related to identification and association with the organization, mobility status of the MSM and economic status of the MSM that contributes to financial constraints of the individuals therefore making it difficult for them to attend to all clinic appointments.

This poses risks especially the MSM who are HIV positive as they may fail to keep their clinic appointments which might in turn impact negatively on the adherence to ART. MAAYGO has been in the frontline in scaling up integrated clinical services such as HIV prevention and treatment, HIV testing, Sexually Transmitted Infections screening and treatment, PrEP and gender based violence identification and response.

Lessons learned: Within a period of 3 months, MAAYGO reached a total 149 (21.4%) MSM/MSWs with clinical services through the Van. A total of 76 (30.04%) MSM/MSWs received HIV Testing Services identifying 5 (33.3%) MSM/MSWs who tested HIV positive.

149 MSM/MSWs were screened for STIs out of which 6 (33.3%) were diagnosed and treated .

A total 19 (25%) MSM/MSWs with known HIV positive status were reached with ART refills and other HIV related services.

103 (47.5) MSM/MSWs were reached with PrEP refill services contributing positively to continuation rates.

Conclusions/Next steps: This highlights that application of different strategies that are workable for the organization matched with continuous advocacy bear marvelous results to improve access to service uptake. Further, engagement of peer educators and peer-to-peer approach was incorporated that led to a significant increase in service uptake.

Continuous clinical services build up activities, peer-to-peer and targeted outreach approaches to help reach out to the MSM population amidst challenges.

PED599

Applying system dynamics mModeling to characterize intersectional stigma and its impact on prevention access and uptake among gay, bisexual and same gender-loving men of color in New York City

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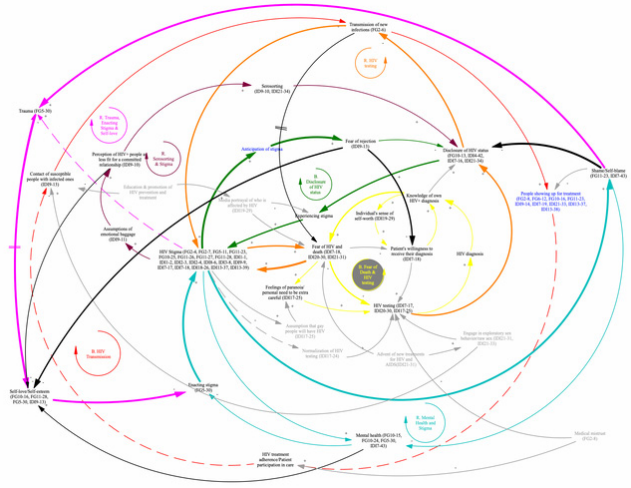
Background: HIV stigma has adverse effects on access to/uptake of HIV prevention and treatment in the United States; intersectional stigmas, including PEP/PrEP and testing stigmas, internalized stigmas, and anti-Black racism, combine with HIV stigma to create a powerful web of barriers to health and well-being among gay, bisexual and other same gender-loving men who have sex with men (MSM), particularly Black or African-American men. System dynamics modeling reveals the complexity and durability of intersectional stigma/discrimination, defining feedback structures that reinforce it and informing preventive interventions.

Methods: We conducted focus groups/in-depth interviews with 80 Black/African-American MSM and/or HIV service professionals, exploring intersectional stigma and discrimination (HIV stigma, homophobia

and racism) and access to and uptake of HIV treatment/prevention (HIV testing and PEP/PrEP). All interviews/groups were digitally recorded, professionally transcribed and coded with broad codes (stigma, racism, homophobia, PrEP/PEP and COVID-19) and emergent "causes" (intersectional stigma/discrimination, PrEP/PEP education and marketing, and medical mistrust/racism) in an AirTable designed for use in causal loop diagramming (CLD). The first and second author read and coded all transcripts and used the "stigma" code data to create the CLD in Vensim. We validated the CLD via study team (read all transcripts/queries) discussions.

Results: The resultant CLD identified numerous reinforcing and balancing loops including ones related to mental health and stigma, self-love, serosorting (within group stigmas) and fear of testing/infection and death, and disclosure stigma, which act to maintain the system of HIV stigma.



Conclusions: The CLD we identified offers insights into how HIV stigma works along specific interactional pathways and interrelates to experiences of trauma, HIV treatment and prevention, and within-community experiences. These complexes of factors and interactions can have adverse impacts on prevention uptake and well-being more generally.
Our study team is currently using the model to develop novel intervention components for a multi-level HIV testing and PEP/PrEP uptake intervention.

PED600

Characteristics of men who have sex with men and transgender women who seek male sexual partners online in Kigali, Rwanda

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Background: Men who have sex with men (MSM) and transgender women (TGW) are at high risk for HIV and other sexually transmitted infections (STI), but they have limited access to clinic-based prevention and treatment services. Especially in the context of social stigmas, online sexual partner seeking has become increasingly popular among MSM and TGW across Sub-Saharan Africa and may represent opportunities for HIV/STI intervention delivery. The aim of this study was to assess the prevalence and determinants of online sexual partner seeking among MSM and TGW in Kigali.

Methods: From March-August 2018, MSM/TGW ≥ 18 years were recruited using respondent-driven-sampling in Kigali. Participants underwent a structured interview in which avenues for male sexual partner seeking were assessed. Chi-square comparisons were used to compare MSM and TGW who report seeking male sexual partners online to those who do not on key sociodemographic, behavioral and other health-related factors.

Results: Of the 738 participants, 14% identified as TGW. Most participants(60.8%; 95% CI:57.3-64.4) reported using social media applications or websites to meet male sexual partners. Generic social media apps or websites including Facebook (79.3%), WhatsApp (48.8%) and Instagram (19.2%) were the most popular. Gay-specific apps or websites were less widely used, with only 6.7% of app users reporting use.
Seeking male sexual partners online was more common among: participants aged 18-24 compared to participants over the age of 35 (75.9% vs 15.1%; p<0.001), students compared to employed participants (91% vs 52.7%; p<0.001), participants who had a secondary education or higher compared to those who had a primary education or less (89.0% vs. 13.8%; p<0.001), and those who made over 50,000 Frw compared to those who made less (68.9% vs. 56.6%; p=0.002). HIV-infection (14.3% vs. 7.3%; p=0.003) and syphilis positivity (11.5% vs. 2%; p<0.001) were higher among MSM and TGW not reporting online male partner seeking compared to those who did.

Conclusions: These data reveal that online male partner seeking is common among MSM and TGW in Kigali, suggesting the potential utility of employing online platforms for HIV/STI intervention delivery to reach key populations. Moving forward necessitates implementation research to evaluate optimal delivery for digital health interventions for key populations in Rwanda and across sub-Saharan Africa.

People who use drugs (including by injection)

PED601

Association of dual partnership and sexual and injecting behaviors among persons who inject drugs from 20 cities in the United States, 2015

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Background: Persons who inject drugs (PWID) may be at higher risk for HIV through their injection and sex practices. PWID engaging in receptive syringe sharing and sex with the same partner (dual partnership) may have different behavior patterns that could affect their risk for HIV infection, but data on this population remain sparse. Using data from the 2015 National HIV Behavioral Surveillance (NHBS), we explore which injecting and sexual behaviors are associated with engagement in dual partnership.

Methods: PWID from 20 U.S. cities were recruited by respondent-driven sampling (RDS), interviewed, and tested for HIV. This analysis includes PWID who reported injecting non-prescribed drugs in the past 12 months, were 18 years or older, tested negative for HIV, and reported receptive syringe sharing in the past 12 months. We used descriptive analyses to explore the characteristics of PWID and log-linked Poisson regression to examine the associations between injecting and sexual behaviors and dual partnership. We adjusted all models for RDS design and reported adjusted prevalence ratios (aPR) and 95% confidence intervals (CI).

Results: Among 3,303 PWID with receptive syringe sharing, 41% reported engaging in dual partnership with their last sharing injecting partner, 69% were male, 73% were 30 years of age or older, and 51% were non-Hispanic, White.

Among PWID included, PWID who reported condomless sex at last sex were more likely to engage in dual partnership (aPR = 2.39, 95% CI = 2.06 - 2.77). PWID who reported having two or more sex partners (aPR = 0.68, 95% CI = 0.62 - 0.73), or two or more sharing injecting partners (aPR = 0.56, 95% CI = 0.49 - 0.63) were less likely to engage in dual partnership.

Conclusions: PWID reporting condomless sex at last sex were more likely to engage in dual relationship. PWID with two or more sex or injecting partners were less likely to engage in dual relationship. Interventions such as couple-based HIV testing and counseling, pre-exposure prophylaxis, and access to syringe services programs could help reduce HIV risk for PWID who engage in dual partnership.

PED602

Characterizing pain self-management among people living with HIV who use unregulated drugs

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Background: Despite the high prevalence of pain among people who use unregulated drugs (PWUD) and people living with HIV (PLWH), pain is frequently undertreated among both groups and has been linked to self-management. Preliminary studies have raised concerns about risks associated with pain self management but this has not been fully investigated among PLWH who use drugs. Thus, we sought to quantify the prevalence of pain self-management and its links to substance use patterns, socio-structural exposures, and HIV clinical measures among a cohort of PLWH who use drugs living with pain.

Methods: Data were derived from the AIDS Care Cohort to evaluate Exposure to Survival Services (ACCESS) study, an ongoing prospective cohort of community recruited PLWH who use unregulated drugs in Vancouver, Canada. Associations of pain self-management strategies were identified using multivariable generalized linear mixed-effects modelling (GLMM) logistic regression.

Results: Between June 2014 and November 2017, 486 participants were included in the study. At baseline, 342 (70.4%) participants self-managed their pain in the six months prior. In the multivariable GLMM model, pain self management was positively associated with homelessness (Adjusted Odds Ratio [AOR] = 1.72, 95% confidence interval [CI]: 1.06–2.79), daily injection heroin use (AOR = 2.30, 95% CI: 1.42–3.71) and daily non-medical prescription opioid injection (AOR = 2.70, 95% CI: 1.28–5.71), while older age (AOR = 0.98, 95% CI: 0.96–1.00) was negatively associated. Among the clinical factors, self-managed pain was negatively associated with never being diagnosed with a chronic pain condition (AOR = 0.70, 95% CI: 0.51–0.95) and positively associated with a higher average CD4+ cell count in the previous 6-month period (AOR = 1.08 per 100 cells/mL, 95% CI: 1.02–1.14).

Conclusions: Pain self-management is highly prevalent, reported by almost three quarters of our study population. Participants who self-managed pain were more likely to be exposed to higher-risk structural and drug-use factors. Higher CD4+ cell counts among participants suggests that adequate pain relief may play a role in achieving optimal HIV clinical outcomes. Together, these findings highlight the need for integrated substance use and HIV-related pain management interventions designed to minimize high-risk self-management methods among this population.

PED603

Periods of homelessness linked to higher VACS Index among people living with HIV who use unregulated drugs

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Background: Homelessness is a prevalent risk factor for sub-optimal engagement in HIV treatment and care among people living with HIV, especially those who use unregulated drugs (PWUD.) We sought to evaluate the impact of homelessness on HIV disease progression among PWUD living with HIV and test if this association was mediated by adherence to antiretroviral therapy (ART).

Methods: We analyzed data from PWUD living with HIV in Vancouver, Canada, with linked comprehensive HIV clinical data. We applied general linear mixed-effects modelling to estimate the longitudinal relationship between homelessness and the Veterans Aging Cohort Study (VACS) Index, a validated measure of HIV disease progression that predicts all-cause mortality. We also performed a sensitivity analysis applying inverse probability of censoring weights to account for differential loss to follow-up.

Results: Between 2005 and 2017, 805 ART-exposed PWUD living with HIV were enrolled in this study. Among 805 participants, 224 (27.9%) were experiencing homelessness at baseline. In a longitudinal model adjusted for ART adherence, homelessness was significantly associated with increased VACS Index scores (ß=1.20, 95% confidence interval: 0.55–1.84). A mediation analysis indicated that 16% of the association between homelessness and the VACS Index was mediated by ART adherence (P<0.001).

Characteristic	Unadjusted		Final Adjusted	
	β (95% CI)	*p* - value	β (95% CI)	*p* - value
Homelessness (yes vs. no)	0.65 (0.01, 1.31)	0.051	1.20 (0.55, 1.84)	**<0.001**
Age (OR per year older)	0.59 (0.53, 0.64)	**<0.001**		
Gender (male vs. female)	0.87 (-1.03, 2.77)	0.372		
White ethnicity (yes vs. no)	2.44 (0.66, 4.22)	0.007		
Employment[a] (yes vs. no)	-0.47 (-1.06, 0.11)	0.112		
Crack use[a] (≥daily vs. <daily)	0.05 (-0.56, 0.65)	0.880		
Cocaine use[a] (≥daily vs. <daily)	-0.27 (-1.21, 0.67)	0.571		
Heroin use[a] (≥daily vs. <daily)	0.17 (-0.61, 0.94)	0.677		
Methamphetamine use[a] (≥daily vs. <daily)	-1.01 (-2.08, 0.05)	0.062		
Prescription opioid use[a] (≥daily vs. <daily)	-0.37 (-1.47, 0.74)	0.514		
Alcohol use[a] (≥daily vs. <daily)	0.94 (-0.05, 1.93)	0.063		
Cannabis use[a] (≥daily vs. <daily)	-0.09 (-0.75, 0.58)	0.800		
Injection drug use[a] (≥daily vs. <daily)	-0.44 (-0.99, 0.12)	0.122		
Mental illness[a] (yes vs. no)	1.55 (0.57, 2.52)	**0.002**		
Opioid agonist therapy[a] (yes vs. no)	-0.14 (-0.86, 0.59)	0.714		
Drug or alcohol treatment[a] (yes vs. no)	-0.46 (-1.26, 0.35)	0.268		
Incarceration[a] (yes vs. no)	-0.51 (-1.48, 0.45)	0.298		
Community supervision[a] (yes vs. no)	-1.00 (-1.76, -0.23)	**0.011**		
ART adherence (≥95% vs. < 95%)	-2.76 (-3.21, -2.31)	**<0.001**	-3.13 (-3.58, -2.68)	**<0.001**
Time since baseline (per year longer)	0.53 (0.46, 0.60)	**<0.001**	0.60 (0.53, 0.67)	**<0.001**

Notes: CI= confidence interval, [a]Refers to activities in the 6 months prior to the follow-up interview, bold text refers to *P*-values <0.05, ART= antiretroviral therapy.

Table 1. Bivariable and multivariable generalized mixed effects analysis of factors associated with the VACS Index among 805 participants.

Conclusions: We found that homelessness was a significant risk factor for HIV disease progression and this association was marginally mediated by ART adherence.

Future studies are needed to quantify the other mechanisms (e.g., food insecurity, mental health) by which homelessness increases mortality risk among PWUD living with HIV.

PED604

Developing a cognitive dysfunction risk score for people who inject drugs in drug treatment

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Background: Cognitive dysfunction has been associated with increased HIV risk behaviors and poor clinical outcomes in various patient populations. The extent of cognitive dysfunction in people who inject drugs (PWID) is limited either due to its under-recognition in these group and/or underuse of screening methods that can be incorporated into clinical practice.

There is a need for a brief but accurate screening measures to efficiently assess cognitive dysfunction in these resource-limited settings. We therefore sought to develop a brief predictive risk score tailored for use among PWID enrolled in common addiction treatment settings (e.g., methadone).

Methods: The present study examined predictors of mild cognitive impairment (MCI), objectively assessed via the NIH Toolbox, among 173 patients receiving medication for opioid use disorder (MOUD) at an urban New England drug treatment facility. Predictors of MCI were identified in one subsample using demographic characteristics, medical chart data, and selected items from the Brief Inventory of Neuro-Cognitive Impairment (BINI). Predictors were cross-validated in a second subsample using logistic regression. Receiver operating curve (ROC) analyses determined an optimal cut-off score for detecting MCI.

Results: We calculated a cognitive dysfunction risk score (CDRS) from patient demographics (age 50+, non-White ethnicity, less than high school education), medical and substance use chart data (history of head injury, overdose, psychiatric diagnosis, past year polysubstance use), and selected self-report items (BINI). The CDRS discriminated acceptability was good, with a ROC curve area of 70.6%, and correctly identified 78% of MCI cases (sensitivity = 87.5%; specificity = 55.6%).

Conclusions: The CDRS identified patients with cognitive challenges at a level likely to impede HIV treatment engagement and/or key outcomes. The CDRS may assist in efficiently identifying patients with cognitive dysfunction while requiring minimal training and resources. As cognitive dysfunction limits treatment outcomes, the CDRS and specific risk characteristics highlighted among this sample population of PWID may identify key attributes of at-risk subgroups in treatment.

With knowledge of individual CDRS among patients, HIV prevention treatment efforts can be personalized and tailored to maximize engagement in treatment, adherence to HIV prevention medications, and reduce the transmission of HIV. Larger validation studies are needed in similar settings.

Sex workers

PED605

"I achieved, have you?" A surge campaign to close viral load testing gaps among key populations in Zambia

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Background: USAID Open Doors (ODP) is an HIV prevention project implemented in Zambia targeting sex workers (SWs), men who have sex with men (MSM), and transgender people. The project is implemented by FHI 360 and funded by USAID and PEPFAR. The project, focused in eight high-traffic districts, refers individuals diagnosed HIV positive to public clinics for antiretroviral therapy (ART) initiation and management. Due to access challenges, only 37% of key population (KP) members eligible for viral load (VL) testing had received the test by the end of July 2020, well below the 75% project target. ODP implemented a VL testing campaign to review program processes and close coverage gaps by September 2020.

Description: A surge campaign, entitled "I achieved, have you?", was implemented August 17 to September 30, 2020, to address the identified gaps. The surge included virtual technical assistance (TA) from FHI

360, and online meetings with all sites to conduct root cause analyses and targeted quality improvement interventions. In each site, clients overdue for VL testing from October 2019–September 2020 were line listed. Clients with accurate phone numbers and addresses were tracked through phone calls and home visits. Site teams made appointments to collect samples at convenient locations. Site staff were given transport vouchers to ensure all samples collected were promptly delivered for processing.

Lessons learned: Out of 3,985 clients due for VL testing in 2020, 960 (24%) were eligible during the surge period. Of these, 713 (74%) [(511 SWs, 181 MSM, and 21 transgender individuals)] were tracked, and 592 (62%) gave blood samples. Project VL coverage increased from 37% to 53%. Inaccurate contact details (19.5%), lost to follow-up (16.8%), and increased KP displacement during COVID-19 (5.8%) were the main reasons for those not tested. At the facility level, a limited number of PCR machines and long turnaround time for results of up to 6 weeks (IQR=2–6 weeks) impeded achievement of program targets. As of December 2020, VL coverage stood at 69.2%.

Conclusions/Next steps: The surge helped the program identify bottlenecks and improve VL testing. However, access to VL testing will remain suboptimal until testing capacity and efficiency are also addressed.

PED606

Younger initiation of selling sex and drug use among female sex workers in 7 African countries

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Background: Youth who sell sex likely face behavioral health issues that may persist into adulthood and potentiate HIV acquisition and transmission risks. Research in Mexico and Iran has documented associations between drug use and selling sex as a minor, but additional research is needed on this understudied topic in Africa.

Methods: Female sex workers (FSW) aged 18+ recruited from 2013-2016 through respondent-driven sampling in Burkina Faso, Cameroon, Cote D'Ivoire, Lesotho, Senegal, South Africa, and Togo completed interviewer-administered surveys including questions about their age of entry into selling sex and lifetime and recent (past 6-12 months) illicit drug use. Younger initiators were defined as those who sold sex before age 18. Bivariate and multivariable logistic regression analyses were conducted to assess associations.

Results: 26.1%(1094/5846) of FSW started selling sex as minors. Younger initiators were more likely to have used non-injection drugs in their lifetime and recently compared to older initiators (Table 1). Injection drug use was uncommon (~1%) and not significantly related to age of initiation of selling sex. The lifetime prevalence of any drug use was 17.6%(192/1094) among younger initiators and 11.4%(543/4752) among older initiators (p<0.001). After controlling for current age, HIV status, and experiences of lifetime physical assault and forced sex as a minor, younger initiators were more likely to have ever used drugs than older initiators (Table 2;aOR 1.6;95% CI1.38-1.97;p=0.013). Experiencing physical assault and forced sex as a minor were positively and significantly associated with both drug use and selling sex as a minor.

	Any drug use		Non-injection drug use[a]		Injection drug use[a]	
	Ever*	Recent[b]*	Ever*	Recent[b]*	Ever	Recent[b]
Started selling sex <18	17.6% (192/1094)	15.8% (133/842)	16.7% (160/961)	15.0% (106/708)	1.1% (11/963)	0.7% (5/709)
Started selling sex 18+	11.4% (543/4752)	11.3% (317/2795)	11.0% (48/4420)	11.0% (271/2460)	1.1% (49/4426)	0.5% (12/2458)

Table 1
[a]Excludes Cote d'Ivoire
[b]Excludes Cote d'Ivoire, Cameroon, and South Africa
*p<0.05

Dependent variables ↓	Independent variables →	Selling sex <18	Drug use	Current age	HIV status	Was forced to have sex <18	Was ever physically assaulted
Selling sex <18	Odds ratio (95% Confidence Interval)	-	1.65 (1.38, 1.97)*	0.84 (0.83, 0.86)*	0.64 (0.55, 0.75)*	4.19 (3.54, 4.96)*	1.56 (1.36, 1.78)*
	Adjusted odds ratio (95% Confidence Interval)		1.30 (1.06, 1.60)*	0.85 (0.84, 0.86)*	1.02 (0.85, 1.22)	3.42 (2.83, 4.14)*	1.26 (1.08, 1.47)*
Drug use	Odds ratio (95% Confidence Interval)	1.65 (1.38, 1.98)*	-	0.98 (0.97, 0.99)*	1.10 (0.93, 1.31)	2.06 (1.68, 2.52)*	3.09 (2.65, 3.63)*
	Adjusted odds ratio (95% Confidence Interval)	1.29 (1.06, 1.59)*		0.99 (0.98, 1.01)	1.05 (0.88, 1.26)	1.60 (1.28, 1.98)*	2.88 (2.45, 3.39)*

Table 2

Conclusions: Early experiences of selling sex and forced sex as a minor may exacerbate risks during adulthood, including drug use. These findings underscore the need to prevent violence and underage entry into selling sex as well as scale up substance use treatment programs for this key population.

PED607

Multi-level factors driving cyclical use of pre-exposure prophylaxis among female sex workers in Durban, South Africa

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Background: While not intended as a lifelong treatment, the effectiveness of pre-exposure prophylaxis (PrEP) for women requires consistent usage across extended periods of risk. Although safe PrEP cycling is possible, cycling appears to require distinct "seasons of risk", rather than intermittent interruptions over short periods.
The objective of these analyses is to understand the motivators for stopping and restarting PrEP and the multi-level factors influencing these decisions among HIV-negative female sex workers (FSW) in South Africa.

Methods: Semi-structured, in-depth interviews were conducted with 36 HIV-negative FSW and 12 key informants including nurses, counselors, and peer educators in Durban, South Africa from January-October 2020. Criterion-based sampling was used: recruited FSW included PrEP-naïve women, those discontinuing PrEP within one month post-initiation, and long-term users. Interviews were conducted in English or isiZulu, transcribed and translated. Data were analyzed using a thematic coding approach in ATLAS.ti.8.

Results: Several key factors at the individual, interpersonal, and organizational socioecological levels were identified by FSW as reasons for temporary PrEP discontinuation, including temporary relocation, substance use, lack of information on or difficulty coping with side effects, and delays in accessing medication. Women who re-started PrEP were motivated to do so once these barriers were overcome. These accounts of temporary discontinuation being driven by external factors were at odds with perspectives from key informant service providers, who emphasized the importance of individual adherence to PrEP and reliance on personal risk assessments when counseling FSW on cycling decisions.

Socioecological Level	Female Sex Worker (FSW) Perspective	Key Informant Perspective
Individual	"I didn't take it long. I won't lie…I was on and off with it. But now seeing all the girls on the road getting sick and getting infected, I don't want to be that. So I would rather continue to come here every month, collect my medication, make sure that they finish and come back, you know. To keep myself safe because I've got a long way to go, I don't want to die." **FSW on PrEP** "I stopped taking it maybe for about 6 months because I was still caught up by other things and I was smoking [crack], you see? You don't take care of yourself during that time when you do those things." **FSW on PrEP** "PrEP, I started taking it now because in the beginning I did take it and it made me sick, I was vomiting and lost appetite…Then I stopped a bit, then these ladies [from the mobile clinic] came yesterday and I told them my story about what happened. Then they said maybe there was a problem with me that led to me vomiting. Then they said I should try again to take them and see if there is any difference." **FSW who initiated PrEP & discontinued**	"Taking PrEP doesn't mean that you don't use a condom, some would be taking PrEP but when they take a break they would think that it's still in their blood and it's still protecting them. She would continue and engage in unsafe sex, when she can see that there's more problems now she would come back and say 'my sister I want to continue with PrEP' when you test her you find that she is already positive." **Nurse working with FSW**
Interpersonal	"At home they won't understand because they don't know these pills. So that's why I quit in Zimbabwe because my boyfriend won't understand, because they are the same with the HIV…Pills, the bottles are the same and so they won't understand. That's why I quit but I'll start very soon." **FSW who initiated PrEP & discontinued** "Last month…they [were] stealing my PrEP so I didn't take PrEP for 1 week because I had no tablets. Then mobile [clinic] came and they gave me, I had to re-test again because I didn't take for 1 week. So they had to test me before giving me." **FSW on PrEP**	"Our clients don't stay. They move and there's a time here she would visit home and when she visits home she would stop. When they come back to business they start again…One would be afraid to explain to the family, then one would leave behind the pills and say 'I have left the pills I was not in business but now I am back' and others would call you and say 'I am back, I was not around I was home'. One would say 'I left the pills, I am not taking them because they will ask me at home why I am taking the pills, then it would be difficult to explain why I am taking these pills.'" **FSW peer educator**
Organizational & Policy	"What led me to take it only for 1 month is because I come here [to the mobile clinic], they gave me then I left. Then I didn't know that if I were to go to the clinic and ask for it whether I'll get it or not because I registered here. That is why, then I thought I will wait for you to come back then I'll take it again." **FSW who initiated PrEP & discontinued** "The police just said 'listen here, we don't even want to see you because you are going to spread Corona' we said no we have to get our things so that we can drink [PrEP], they said 'no you can't'. That's how we stopped and then we waited to hear from the nurses when they are available because they said 'even your nurses are not available' then we said we'll hear from the nurses when they are back to help us." **FSW who initiated PrEP & discontinued**	"Some understand but there are some who-, you find a person-, because there are some who would take it and then stop it. But when you follow-up and continue talking to them then they restart again." **FSW peer educator** "I think you have to be deep when you explain that it's optional because when they stop you find that it's painful when one comes back and find that she's already positive. I think health education about the seasonal option should be deep. So that you stop it when you really see that you are not at risk." **Nurse working with FSW**

Table 1. Quotes illustrating drivers of temporary PrEP discontinuation and cycling at multiple socioecological levels

Conclusions: These data highlight a disconnect between providers' recommendations on the potential for cyclical use of PrEP during periods of minimal risk and actual drivers among FSW causing temporary PrEP discontinuation. FSW experience numerous challenges to sustained, daily use of PrEP and these multi-level barriers must be addressed to ensure FSW are able to make safe, risk-informed decisions when it comes to PrEP cycling.

PED608

Exploring the barriers and facilitators to PrEP uptake and PrEP adherence among female sex workers: implications for intervention design

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Background: Female sex workers (FSW) in South Africa face a disproportionally high burden of HIV, indicating an unmet need for appropriate prevention measures. Pre-exposure prophylaxis (PrEP) has proven to be a successful HIV prevention intervention, but barriers to uptake and sustained use are pervasive among FSW. The objective of these analyses is to characterize overlaps and differences in barriers and facilitators to PrEP uptake and sustained use among FSW in Durban, South Africa.

Methods: Semi-structured in-depth interviews were conducted with 36 HIV-negative, PrEP-eligible FSW and 12 key informants in Durban, South Africa from January-October 2020. FSW participants were recruited using purposive sampling methods and represented a variety of PrEP use experience. Key informants included PrEP care providers and sex work venue managers. Qualitative data were double coded iteratively in Atlas.ti.8 and analyzed using a grounded theory approach.

Results: Multiple barriers common to PrEP uptake and adherence arose, notably concerns around side effects, challenges with daily pill-taking, and PrEP stigma from sexual partners or peers (Figure 1).

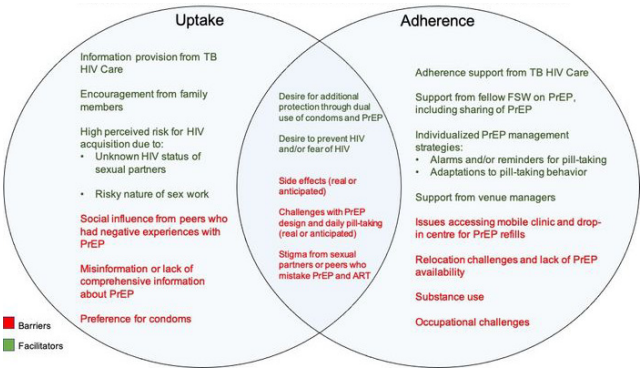

Figure 1. Similarities and differences in barriers and facilitators to PrEP uptake and adherence

Common facilitators included a fear of HIV fueled by experiences of family members or friends living with HIV as well as a desire for added protection. Negative social influence from peers and a lack of information about PrEP acted as unique barriers to uptake, even among FSW who had a high perceived risk of acquiring HIV.

Conversely, FSW on PrEP faced more tangible barriers to adherence, including issues continuously accessing PrEP and challenges balancing PrEP use and sex work.

Conclusions: While similarities exist in barriers and facilitators to PrEP uptake and adherence, tailored support interventions are needed to address key differences between FSW who are starting and continuing PrEP. Given the similarities in barriers between anti-retroviral therapy (ART) and PrEP adherence, ART interventions can be adapted for PrEP users and strengthened by the facilitators highlighted in these data.

PED609

Challenges with tracing women who do not revisit targeted health services for female sex workers in Zimbabwe, and recommendations for future practice

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Background: Zimbabwe's National Sex Worker programme, "Sisters," offers HIV-related services. Many female sex workers (FSWs) accessing these services do so only once. As reasons for non-return are not known, we developed a pragmatic approach to tracing FSWs to support continuity of care.

Description: We identified FSWs who had visited "Sisters" January 2018 to June 2019 and had not returned before September 2020. We piloted an approach where locator information (physical addresses and phone numbers) collected by the programme was used to trace women and ascertain reasons for non-return.

Lessons learned: Programme staff spent 106 person-days tracing 134 eligible FSWs. Figure 1 shows 60 (44.8%) women were successfully traced, of whom 31 (51.7%) reported being active in sex-work and still in need of "Sisters services". Reasons for non-return to the programme included migration within and outside Zimbabwe, familial influences, and conflicting (non-sex) work and clinic schedules. Of the 74 (55.2%) women not traced, 54 could not be located and 20 had no contact information. Challenges to effective tracing included perceptions of breach of anonymity through discursive engagement among FSWs making women distrustful of Tracers, shame associated with transitions into and out of sex-work, clinic-level barriers including service disruptions due to Covid travel restrictions, suboptimal clinic record-keeping (e.g. a woman having duplicate IDs), extensive travel-time for tracers to visit FSWs, and poor communication between the tracing team and clinic staff resulting in referred FSWs experiencing long clinic waiting times following successful tracing.

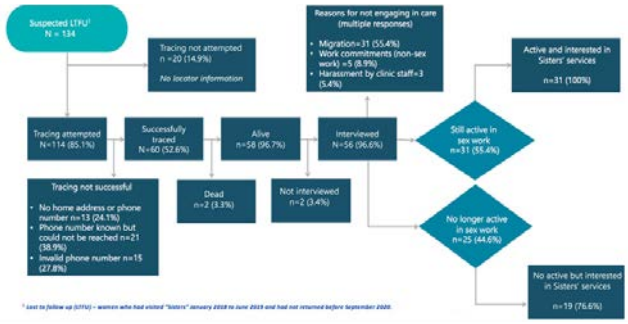

Figure 1. Outcomes of women lost to follow up (LTFU) - women who had visited "Sisters" January 2018 to June 2019 but not returned before September 2020.

Conclusions/Next steps: We identified reasons for FSWs not returning to the programme, and challenges in tracing those women who do not revisit. Peer-led interventions, such as microplanning, that enhance contact between FSWs and trained peer educators can increase the likelihood women will be retained in the programme, whereas enhanced record-keeping and communication can improve ability to trace women lost to the programme.

PED611

Experiences in the implementation of a pre-exposure prophylaxis programme amongst sex workers in South Africa

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Background: Sex workers (SW) are thirteen times more likely to acquire HIV infections compared to other women of reproductive age. Additionally, SW living with HIV have inadequate antiretroviral therapy (ART) coverage globally. Oral pre-exposure prophylaxis (PrEP) has the potential to significantly reduce new infections among populations considered at highest risk of HIV acquisition such as FSW. The Global Fund (GF) programme is currently implementing a SW HIV prevention programme for SW in fourteen districts in South Africa (SA). We evaluated the uptake, obstacles, and barriers to the successful implementation of PrEP in two of the GF districts, Mopani (Limpopo) and Bojanala (North West).

Methods: A mixed method approach was used to gather data on the implementation and uptake of the PrEP programme in the two provinces. Univariate analysis of programme monitoring data was conducted, and is to be supplemented by qualitative key informant interviews targeting PrEP health providers and SW in two provinces (Mopani &Bojanala). The analysis covered programme data for the first year of implementation (April to December 2019).

Results: A total of 10 930 SW were reached with HIV prevention services. The majority of the SW reached in the districts were in the age category of 25-35 years. The HIV positivity rate amongst these SW was 34% (N= 3676). A total of 661 of the 1 684 SW (39%) who tested HIV-negative were offered PrEP in accordance with the National PrEP guidelines (2016). The PrEP uptake rate was 34% N= 224 (65% N=136 in Mopani and N=88 20% in Bojanala).

Conclusions: Findings show a low PrEP uptake by SW. Further the PrEP retention rate after 3 months is poor in both districts. The next steps will involve a qualitative component consisting of key informant interviews with health providers and SW to establish the barriers and enablers to PrEP uptake and retention.

Transgender people

PED612

Comprehensive care for transgender men in Rio de Janeiro, Brazil: a pilot project

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Background: In Brazil, surveys have demonstrated that most health professionals are unaware of male transsexuality. The fear of embarrassment by trans men most often results in not seeking medical attention and guidance. Thus, transgender men have difficulty accessing health services, particularly gynecological care and hormone therapy.
The goal of this study is to describe the main social and structural barriers faced by trans men living in Rio de Janeiro to access public health services, in particular gynecological care.

Description: Tirésias is a prospective cohort study of transgender men aged 18 and older who were previously using hormones being conducted in Rio de Janeiro, Brazil. This pilot project provides free comprehensive psychological, gynecological, and clinical care. Here we present data on the first study visit.

Lessons learned: One hundred trans men were enrolled between September and December 2020. The median age was 26. Most (67%) identified as non-white and 50% had an income equal or below the minimum wage (≤200 US dollars per month). History of suicide attempts and transphobic-related violence were common, 56% and 77%, respectively. Thirty-five percent reported transphobic physical violence, of which 49% were victims of domestic physical violence; 12% reported sexual violence. Among those reporting sexual violence in relation to their gender identity, 92% were victims of domestic violence.
Regarding access to medical care, 83% reported fear of gender identity-related discrimination as a barrier to seeking care. Seventeen percent reported mental health disorders; 34%, 46%, and 7% reported tobacco, cannabis, and cocaine use; respectively. Ninety-eight participants were seen by the study gynecologist, 60 (51%) of which had ≥1 gynecological health concern; 93/98 (95%) consented to a gynecological exam (100% to a breast exam and 43% to a specular exam).

A patient-centric clinic can provide comprehensive care for transgender men in a middle-income country with a high prevalence of transphobic violence and discrimination.

Conclusions/Next steps: In depth analysis of an extensive questionnaire on perceptions of psychosocial barriers experienced by trans men in accessing health care services in Brazil will allow the development of guidelines to expand patient-centric care for transgender men in Brazil.

PED614

Transphobic violence, stigma and structural barriers in healthcare services: the experience of transgender women in Lima, Peru

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Background: Currently, transgender women are one of the most stigmatized and vulnerable populations in Latin America; representing a large percentage of those affected by the HIV epidemic in Peru. In some situations, healthcare services can act as spaces where violent social conditions are replicated. This study aimed to explore the stigma and violence that transgender women are subjected to when attending healthcare centers of Lima and Callao, Peru.

Methods: In accordance with a phenomenological design, in-depth interviews (IDI) were conducted with 12 trans women who'd attended private or public healthcare centers in Lima and Callao between August and November of 2018. The interviews were transcribed and analyzed for recurring themes in the data.

Results: Three main themes relating to the research objective were identified: the types of stigma and violence reported to which trans women were victims of in healthcare centers, which included sexual harassment, psychological violence, and medical negligence. We found that misgendering and calling the participants by their legal name were some of the most recalled incidents.

The second theme included the ways in which these women responded to said instances, including their emotional reactions, such as frustration, sadness and insecurity; and behavioral reactions, expressed as confronting their aggressor or feeling paralyzed.

The final theme involved the consequences brought on by those situations, both at a cognitive and emotional level, which included a severe lack of confidence of healthcare service providers, as well as the coping strategies they employed and developed in order to navigate these conditions, mostly expressed as avoiding these services.

Conclusions: Our findings suggest that healthcare institutions in the Lima and Callao regions are not safe, welcoming environments for transwomen, leading to avoidance and self-medication as coping mechanisms, as well as a lack of trust in medical professionals and healthcare services. A comprehensive, effective HIV treatment and prevention strategy would require healthcare personnel and centers to be accessible and validating for vulnerable populations.

We suggest that further research be conducted with healthcare officials and personnel, as well as other key populations, in order to develop policies and interventions that ensure transgender women can obtain the services they need.

Adolescent girls and young women

PED615

The consequences of adolescent motherhood for key HIV-related risk behaviours: a propensity score analysis comparing adolescent mothers and non-mothers in South Africa's Eastern Cape Province

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Background: Evidence from South Africa indicates that adolescent mothers experience up to three times higher risk of HIV infection than non-mothers, marking this group as a key risk population. It is critical to differentiate among different HIV risk behaviours to inform effective targeting of HIV prevention interventions to this group. Consequently, we evaluated the relationship between adolescent motherhood and seven key HIV-related risk behaviours in South Africa.

Methods: We surveyed 1302 sexually active adolescent girls (12-25 years old, 78.2% mothers, 36.5% living with HIV) participating in the HEY BABY and Mzantsi Wakho studies in 180 communities in the Eastern Cape province of South Africa, between April 2017 and July 2019.

Questionnaires measured seven self-reported HIV-related risk behaviours: Multiple sexual partners, transactional sex, age-disparate sex, unprotected sex, sex on substances, alcohol, and school non-enrolment. In statistical analysis, first we balanced the distribution of covariates between adolescent mothers and non-mothers using propensity scores.

Second, we evaluated the association between adolescent motherhood and HIV risk behaviours weighting on estimated propensity scores. Third, we controlled for multiple hypothesis testing using the Benjamini-Hochberg procedure. All relevant ethical approvals were obtained.

Results: Adolescent mothers were more likely than sexually active non-mothers to be older, HIV –ve, maternally orphaned, live in informal housing, and receive social grants. They reported poorer parental monitoring, reduced access to basic necessities, and more sexual abuse. Propensity score weighting yielded good balance for all covariates except age (standardised mean difference: 0.14). In the ensuing regression, adolescent motherhood was associated with appreciably higher risk of unprotected sex (adjusted probability 65.3% versus 49.3%, $p<0.001$), and school non-enrolment (48.1% versus 33.3%, $p<0.001$); but lower risk of sex on substances (8.0% versus 21.2%, $p<.001$), and alcohol use (6.6% versus 15.5%, $p<0.002$). Limitations include use of cross-sectional data and risk of unmeasured confounding.

Conclusions: Adolescent mothers are more likely to engage in particular HIV-related risk behaviours, such as unprotected sex and school non-enrolment. Further research should focus on understanding reasons for these behavioural differences amongst young mothers. Culturally relevant communication about "safe sex" practices and negotiation skills, improved access to condoms, and supporting return to school may be effective prevention strategies.

PED616

Association between prenatal depression, disclosure and intimate partner violence among pregnant women living with HIV in the Democratic Republic of Congo

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Background: Depression among women living with HIV (WLWH) is high, but less is known about prenatal depression in high-prevalence settings in Central Africa, as well as the association between prenatal depression, disclosure, and intimate partner violence. To the best of our knowledge, there has been no study examining associations between depression, status disclosure, and intimate partner violence (IPV) in pregnant WLWH. This study fills this gap as provides with a better understanding of depression among this key population.

Methods: This cross-sectional study analyzed baseline characteristics of 1,392 pregnant WLWH enrolled in an ongoing cluster randomized trial evaluating the effect of continuous quality interventions on long-term therapy outcomes in Kinshasa, DR Congo. The Patient Health Questionnaire-9 (PHQ-9) was used to assess depressive symptoms, the primary outcome of interest, while IPV and disclosure status were assessed through questionnaires. Multivariate logistic regression models were used to estimate associations between prenatal depression, disclosure, and IPV.

Results: Most women (78%) reported no symptoms of depression (PHQ-9 score 0-4); 16% had symptoms of mild depression (PHQ-9 score 5-9), and 6% had symptoms of moderate to severe depression (PHQ-9 score ≥10). 35% experienced any type of lifetime IPV. About half of women had disclosed to anyone while only one-third disclosed to a partner. HIV disclosure to anyone was associated with lower moderate/severe depression symptoms (adjusted OR 0.74, 95% CI 0.31, 1.76), when compared to those who had not disclosed. Any form of IPV (aOR 1.16, 95% CI 0.34, 3.98), physical (1.82, 95% CI 0.53, 6.33) and sexual violence (aOR 1.16, 95% CI 0.32, 4.27) along with being in a serodiscordant relationship (aOR 3.3, 95% CI 1.07, 10.11) were associated with moderate/severe depression symptoms. The association between psychological violence and depression was not statistically significant.

Conclusions: The high prevalence of IPV and low disclosure among pregnant WLWH suggest the need of adding mental health services for pregnant women and their partners as part of comprehensive HIV care. Along with interventions to prevent IPV and to promote HIV status disclosure and testing in men, these measures can be useful within the PMTCT programing in DR Congo and other high-HIV burden settings.

PED617

Contrasting needs and vulnerabilities of adolescent females aged 15-19 years living with HIV according to likely mode of transmission in Mozambique

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Background: The population of adolescents living with HIV (ALHIV) includes those with vertically acquired HIV (AVH) and behaviorally acquired HIV (ABH). There have been few studies examining differences among ALHIV based on mode of transmission (MOT) in high prevalence settings.

Methods: We conducted a survey of Mozambican ALHIV to measure sociodemographic characteristics, health history, and antiretroviral therapy (ART) adherence. The survey was conducted in 2019 at three health facilities in Nampula, Mozambique among a convenience sample of ALHIV 15-19 years (yrs), including females attending antenatal care. Classification of ALHIV by MOT was based on medical charts and survey data: those who initiated ART at <15yrs or reported no sexual history were considered AVH; all others were ABH. We compared female participants according to MOT, frequencies compared using Chi-square, Fishers exact and Wilcoxon rank-sum tests.

Results: There were 208 ALHIV participants including 143 females, 50 (35%) AVH and 93 (65%) ABH. Female ABH were older at ART initiation compared to AVH, 18yrs (IQR: 17-19) vs 12yrs (IQR: 9-16) (p<0.001). Socioeconomic indicators were worse for ABH compared to AVH: lower proportions had an inside toilet (11% vs. 28%, p=0.008), running water (5% vs. 26%, p=0.001), ever accessed the internet (19% vs. 48%, p<0.001); more ABH vs AVH were not in school (67% vs 16%, p<0.001). Among ABH not in school, 49% reported no or incomplete primary school. Only 61% of ABH knew they should not miss any doses of ARVs compared to 78% of AVH (p=0.04).

Only half of ABH (51%) and AVH (58%) had viral suppression <50 copies/mL. ABH were more likely to be in a relationship compared to AVH (85% vs. 36%; p<0.0001) and a higher proportion of ABH (75%) had disclosed to partners compared to AVH (44%) (p=0.01). Among ABH, 56 (60%) were pregnant or breastfeeding at the survey compared to 3 (6%) AVH (p<0.0001).

Conclusions: Our novel findings demonstrate diversity within the population of ALHIV by mode of transmission and highlight high levels of health, economic and social vulnerability and need especially among young women with ABH.

PED618

Poor concordance between objective and reported measures of pre-exposure prophylaxis (PrEP) adherence and factors associated with over-reported adherence among adolescent girls and young women (AGYW) in Kenya

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Background: Adherence is crucial for PrEP effectiveness but challenging to determine in real-world PrEP programs and resource-limited settings. We investigated concordance between an objective measure of adherence based on tenofovir-diphosphate (TFV-DP) concentrations within dried blood spot (DBS) samples and self-reported adherence, and identified cofactors of over-reported adherence among AGYW in Kenya.

Methods: We enrolled participants, randomly selected among AGYW, aged 18-24 years, who were participating in the PEPFAR DREAMS-PrEP program in Kisumu and Homa Bay counties. Participants underwent interviews and provided DBS samples at two timepoints approximately three months apart between June 2019 and January 2020. We assessed adequate adherence, defined as TFV-DP ≥700 fmol/punch or reporting 4+ doses in past week. We used Cohen's Kappa statistic and McNemar's test to assess agreement and discrepancy between adequate DBS-based and self-reported adherence by timepoint. We used bivariate mixed effects logistic regression models to explore cofactors of over-reported adherence, defined as reporting 4+ doses in past week with TFV-DP <700 fmol/punch.

Results: Among 359 AGYW, 93.6% and 62.8% reported current PrEP use at Timepoint1 and Timepoint2, respectively. Among those reporting current PrEP use, 88.7% reported 4+ doses in past week and 6.3% had adequate DBS-based adherence at Timepoint1. At Timepoint2, 83.3% reported 4+ doses in past week and 4.4% had adequate DBS-based adherence. Adequate DBS-based and self-reported adherence differed markedly (p-value <0.001); agreements between the two measures was only slightly better than chance (Kappa <0.1) at both timepoints. The proportion of AGYW who over-reported adherence was 82.7% at Timepoint1 and 78.8% at Timepoint2.

Over-reported adherence was positively associated with reporting partner aware of PrEP use (OR=1.70, 95%CI: 1.05-2.74), preference for safe space over clinic for PrEP service (OR=1.74, 95%CI: 1.02-2.99) and moderate/severe depression as measured by PHQ-9 scale (OR=1.97, 95%CI: 1.05-3.69), and negatively associated with reporting moderate/high perceived chance of getting HIV (OR=0.41, 95%CI: 0.21-0.82) and partner with positive/unknown HIV status (OR=0.48, 95%CI: 0.29-0.78).

Conclusions: AGYW in this study had very low adherence to daily oral PrEP and considerably over-estimated their PrEP adherence in self-reports. AGYW at high risk of HIV need more assistance to achieve adequate levels for effective PrEP.

PED619

The impacts of COVID-19 on health and human rights among women living with HIV in Nepal: a community-led, rapid, participatory study

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Background: There is a critical lack of data about the impacts of the COVID-19 pandemic on the health and human rights of people living with HIV, particularly within resource-constrained settings. In June 2020, the International Treatment Preparedness Coalition (ITPC) launched a project with Dristi Nepal (an advocacy organisation for women living with HIV (WLHIV), who use drugs, and sell sex), to source, analyse and disseminate first-hand accounts of the effects of COVID-19 on these women.

Methods: A participatory research tool was developed to capture and assess the impacts of COVID-19 on WLHIV, combining formats of a 'citizen's report card', 'community assessment', and qualitative survey. Images and emoticons encouraged participants, regardless of literacy, to relate their experiences. Every component of the tool's development and implementation was collaborative, from the formulation of indicators, to its inclusive design and analysis.

A total of 18 participants were recruited through purposive, convenience sampling, with the rapid assessment conducted in Nepalese, and results co-analysed inductively.

Results: Nepal's COVID-19 lockdown restricted people's movements, with profound consequences for each component of the '90-90-90' cascade. WLHIV were afraid to seek ART and other healthcare services. They worried that transferral to ART facilities closer to where they were living during lockdown threatened their confidentiality. They were also concerned that their families and neighbours would discover that they were HIV-positive, and that they would face stigma or even expulsion from their homes.

Data revealed the difficulties that WLHIV faced in monitoring their ART regimens, including through accessing biomarker tests. Data also revealed the real-world economic toll of the COVID-19-pandemic on an already marginalised and precarious population. Most of the women in Dristi's community of care had lost their jobs during the lockdown.

Conclusions: The research tool was designed, adapted and implemented by community-based activists to provide direct support to WLHIV, including sessions on ART literacy, and awareness about COVID-19 prevention, psychosocial support, and food security.

This project has demonstrated the vast potential for grassroots HIV advocacy organisations to gather and analyse detailed, context-specific data about the impacts of the COVID-19 pandemic on their communities of care.

PED620

Delivering a virtual modular education session intervention to antenatal and postnatal adolescent girls and young women (AGYW) in South Africa through a teleconferencing platform

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Background: Adolescent pregnancies, frequently unplanned, are more likely in poorer and marginalised communities. Adolescent girls and young women (AGYW) are often mentally and physically ill-equipped for pregnancy and motherhood and at greater risk for adverse maternal and perinatal outcomes; and their infants, for adverse developmental outcomes. A significant contributor to adolescent pregnancies is poor access to sexual and reproductive health (SRH) information and services.

In response mothers2mothers (m2m) designed a modular education session intervention to pilot with AGYW, aimed at providing information in a group setting, to enable informed choices regarding SRH, pregnancy and motherhood.

Description: Two courses of five modular group education sessions were designed for antenatal and postnatal AGYW respectively to cover pregnancy and infant care, SRH, self-esteem and mental health, decision-making and future-planning, to be delivered face to face in biweekly sessions with up to 10 AGYW over 10 weeks. With the advent of the COVID-19 pandemic, the intervention was modified for virtual delivery via phone, at no cost to clients.

Lessons learned: 143 clients have thus far enrolled in the programme, with 10 groups currently underway. Virtual delivery of a pilot programme originally designed for face to face group implementation has resulted in several challenges and lessons learnt. Virtual delivery via telephonic voice calls impacted facilitator ability to engage clients, gauge their understanding of content, and deliver group and hands-on activities. Biweekly sessions, originally intended to promote reflection, were found to further hamper engagement and contribute to reduced retention. Creating a 'safe space' virtually for dispersed clients who may have limited privacy in their homes is a further barrier to engagement.

Conclusions/Next steps: In order to deepen engagement and attentiveness, facilitators have adapted their language and the technical language and content of the curriculum to be more appropriate for and used by their audience. Further modifications to volume of curriculum content will be considered. Changes in scheduling of sessions to hold sessions more frequently, are underway in order to optimize retention. Methods of building rapport and engagement between the clients in each group to assist in building group coherence despite geographical disbursement will also be explored.

PED621

Partnership dynamics and dual method use among adolescent girls and young women in South Africa: a longitudinal analysis of HIV Prevention Trials Network 068 data

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Background: In South Africa, adolescent girls and young women (AGYW) account for nearly 28% of all new HIV infections and 65% report an unintended pregnancy before age 25. Dual method use is known as the most reliable protection against pregnancy and sexually transmitted infections, including HIV. However, uptake of dual method use remains low. Understanding how partner characteristics and dynamics impact AGYW dual method use might explain low uptake beyond individual and environmental factors.

Methods: Data are from HIV Prevention Trials Network (HPTN) 068, a longitudinal study of AGYW (age 13-23) in South Africa. We used GEE log-binomial regression models to calculate adjusted risk ratios for the association between partner characteristics, partnership dynamics and dual method use. Partner characteristics included being $\geq$ 5 years older, concurrent partnerships, HIV status, and provision of financial support. Partnership dynamics included relationship power, gender equitable norms, intimate partner violence (IPV), and condom use communication. Dual method use was defined as concurrent hormonal method and condom use.

Results: Our sample included 2,452 HIV-negative AGYW who were followed for up to five years. At baseline, most participants reported that it was very important to not be pregnant (N = 1520, 62%) and that they had no chance of getting HIV in their lifetime (N = 1795, 73%). Among sexually active participants (N=650, 27%), 10% (N = 64) were using only condoms, 20% (N= 133) only hormonal methods, and 13% (N = 87) both methods. At endline, 1439 (90%) participants were sexually active and 5% (N = 70) were using only condoms, 17% (N= 247) only hormonal methods, and 10% (N = 144) both methods. After controlling for pregnancy intention and covariates, we found knowing a partner's HIV-positive status (aRR: 1.48, 95% CI: 1.13, 1.93), high relationship power (aRR: 1.48, 95% CI: 1.08, 2.19), and experiencing no IPV in the past year (aRR: 1.22, 95% CI: 1.03, 2.44) to predict dual method use.

Conclusions: Partner characteristics and dynamics are important for dual method use among AGYW. Interventions to help AGYW navigate partnership dynamics and safely engage partners in HIV status disclosure could be beneficial for both HIV and pregnancy prevention.

PED622

Stakeholder experiences of an intervention for provision of HIV self-testing kits and contraception to adolescent girl and young women in privately-owned drug shops in sub-Saharan Africa

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Background: Adolescent girls and young women (AGYW; ages 15-24) in sub-Saharan Africa face dual burdens of 25% of new adult HIV infections and 44% of unintended births. Accredited drug dispensing outlets (ADDO) are found throughout local communities and may be a resource to provide sexual reproductive health (SRH) products to AGYW.

Methods: The Malkia Klabu ("Queen Club") intervention is a loyalty program facilitating access to HIV self-testing (HIVST) and contraception developed with stakeholders through a human centered design process to overcome stigma associated with AGYW accessing SRH resources. AGYW present a loyalty card to secure prizes, receive free HIVST, pregnancy tests, and use a symbol card to request SRH products without having to request them verbally. ADDOs in the control arm received HIVST kits to distribute to AGYW for free.

Following a 4-month randomized cluster trial of 20 ADDOs in Shinyanga, Tanzania, AGYW (n=11), shopkeepers (n=26), and counselors (n=3) participated in in-depth interviews. Using modified grounded theory, translated transcripts were reviewed by a team of four data analysts not otherwise associated with the program to identify key ideas and develop a codebook. The analysis team reviewed coding clusters to identify emergent themes.

Results: AGYW reported a relative advantage to safely and easily access HIVST. The HIVST was popular among AGYW, because it offered privacy to test in one's own home. AGYW who had previous experience of testing in health centers (blood test) preferred the HIVST because it is less painful, yields fast results, and affords greater privacy.

The primary motivation of AGYW to test was to "know one's status." Confirming that they were HIV negative was a relief, but AGYW also expressed that finding out that one was HIV positive enabled them to take control of their health.

Conclusions: AGYW valued knowing their status and equated it with control and power. Stigma associated with sexual activity of AGYW continues to surround the act of testing for HIV, but provision of HIVST by ADDOs is one way to promote knowing one's status without incurring stigma. Privately owned ADDOs are an adequate way to deliver AGYW-friendly HIVST and other SRH products.

Migrants and displaced persons

PED623

Provision of antiretroviral therapy during flexible clinic hours and an enhanced package of services increases treatment initiation in Dominican Republic

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Background: Since October 2019, USAID-funded HIV System Strengthening (HS3) project, implemented by FHI 360, has supported HIV prevention and treatment services to focus clients (FCs) — Haitian migrants and their descendants— at the community and facility level in Dominican Republic. FCs are mobilized through their peer network, offered HIV testing and navigated to 18 facilities in six provinces, where they can access antiretroviral therapy (ART).

Description: From April 2020, HS3 project began offering flexible ART clinic hours and an enhanced ART package to HIV-positive FCs to increase ART initiation. The intervention targeted newly diagnosed FCs as well as individuals known HIV positive who were lost and returned to treatment. Twelve clinics initiated ART after working hours and at community hot spots that were easily accessible by the FCs and where HIV testing and treatment services were integrated. The enhanced ART package given at ART initiation included: six months of a pre-paid SIM card, airtime voucher, and food vouchers; 12 months transportation allowance; voucher to cover baseline investigations. The items included in the package were based on the outcome of consultations with HIV-positive FCs. We present trends from October 2019 to December 2020 showing the effect of the intervention on ART initiation.

Lessons learned: Between October 2019 and December 2020, the project identified 2,073 HIV-positive FCs and started 1,512 (73%) on treatment. Among 705 HIV-positive FCs identified during six months pre-intervention, 44% (307) were initiated on ART, compared to 85% (485/568) during the six months post-intervention ($p < .00001$). Furthermore, when comparing the second quarter of the post-intervention period (July–September 2020) to the following quarter (October–December 2020), ART initiation was sustained at a high rate (Table 1).

Time period	HIV positive	Initiated on ART	ART initiation rate
October-December 2019	321	115	36%
January-March 2020	384	192	50%
Pre-intervention (October 2019-March 2020)	705	307	44%
April-June 2020	185	143	77%
July-September 2020	383	342	89%
Post-intervention (April-September 2020)	568	485	85%
October-December 2020	800	720	90%
October 2019-December 2020 (Total)	2,073	1,512	73%

Table 1

Conclusions/Next steps: Providing ART during flexible hours and venues, together with an enhanced ART package was successful in increasing and sustaining high treatment initiation among FCs over a period of nine months following rollout.

PED624

Results of HIV testing strategies to increase case detection among Haitian migrants and their descendants in Dominican Republic

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Background: The USAID-funded HIV System Strengthening (HS3) project supports HIV prevention and treatment services for focus clients (FCs) at the community and facility levels in the Dominican Republic. FCs, defined as Haitian migrants and their descendants, are mobilized through the peer network and offered HIV testing service (HTS) at the community and facility levels.

Description: HTS is offered to FCs through the enhanced peer outreach approach (EPOA), index testing, and walk-in testing. EPOA uses performance-based incentives and works through social and sexual networks, whereby peer mobilizers reach out to their social and sexual networks to encourage peers to get tested. Index testing refers to offering HTS to the partners and biological children of HIV-positive clients. These three testing modalities were concurrently rolled out in January 2020. We describe the contributions of EPOA and index testing and compare baseline (January–March 2020; Q2 FY20) to endline data (October–December 2020; Q1 FY21).

Lessons learned: From January to December 2020, the project tested 41,875 FCs and diagnosed 1,752 as HIV positive. Over three quarters, the number of FCs tested and those found to be positive increased. HIV positivity higher from index (14%) than from EPOA (6%) overall and at every quarter (14% vs. 7% in Q3 FY20; 11% vs. 5% in Q4 FY20 and 17% vs. 7% in Q1 FY21 respectively). Despite a low positivity, EPOA contributed more positives (37%) than index testing (16%) overall and for every quarter (32% vs. 14% in Q3 FY20; 38% vs. 25% in Q4 FY20 and 50% vs. 16% in Q1 FY21 respectively). EPOA and index testing were more efficient strategies, than other testing modalities (positivity 3%) and contributed to 53% of positives (Table 1).

Conclusions/Next steps: EPOA is an effective testing approach and increased the number of HIV-positive FCs identified. More effort is needed to scale up index testing and ensure that it is rolled out with fidelity to maximize its potential in the DR.

People in prisons and and other closed settings

PED625

Advancing efficient HIV case-finding through expansion of index case testing (ICT) and partner notification services (PNS) among people in penal and probation settings in Ukraine

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Background: Ukraine has the second largest HIV epidemic in Eastern Europe, concentrated among key populations. The HIV prevalence in the Ukrainian penal system is 8.9% (IBBS 2019). To improve HIV case finding, the PATH-led, USAID-funded Serving Life (SL) project scaled ICT and PNS among index partners of people in penal and probation settings.

Description: Index testing was implemented by the SL trained medical and social providers to notify sexual and injecting partners and children of HIV-positive detainees, prisoners and people on probation (index clients) about their increased risk of HIV; offering them testing; and immediately linking them to prevention services, if negative, or treatment, if positive.

Providers followed the guidance for implementing safe and ethical ICT and WHO 5 Cs. In 2020, ICT services were extended to all pretrial detention centers, prisons, correction and probation centers in 12 regions of Ukraine through offering ICT for 100% of HIV-positive cases identified, both current and new, in penal and probation settings.

We used descriptive statistics to analyze data gathered from October 2019 through September 2020 across 60 penal and 24 probation settings.

Lessons learned: Of 3,779 index clients in penal settings offered ICT, 2,287 people (61%) accepted ICT and provided partner/contacts; 1,227 (32%) accepted but did not have partner/contacts; and 265 (7%) refused. 6,029 partners (88% needle-sharing partners and 12% sexual partners) were elicited from index clients, of whom 5,724 were not HIV-positive and eligible for testing. 3,922 (69%) among those eligible were tested, and 297 were newly diagnosed with HIV (7.8% yield); 238 (80%) initiated on treatment.

Time period	EPOA		Index Testing		Other Testing		Total		EPOA Contribution		Index Testing Contribution		Other Testing Contribution		Positivity Rate(Yield)			
	Tested	HIV Positive	Tested	HIV Positive	Tested	HIV Positive	Tested	HIV Positive	Tested	HIV Positive	Tested	HIV Positive	Tested	HIV Positive	EPOA	Index Testing	Other Testing	Total
January–March 2020 (Q2 FY20)	1,510	45	183	38	11,113	301	12,806	384	12%	12%	1%	10%	87%	78%	3%	21%	3%	3%
April–June 2020 (Q3 FY20)	845	59	186	26	4,686	100	5,717	185	15%	32%	3%	14%	82%	54%	7%	14%	2%	3%
July–September 2020 (Q4 FY20)	3,181	146	872	95	5,403	142	9,456	383	34%	38%	9%	25%	57%	37%	5%	11%	3%	4%
October–December 2020 (Q1 FY21)	5,399	400	732	125	7,765	275	13,896	800	39%	50%	5%	16%	56%	34%	7%	17%	4%	6%
Total	10,935	650	1,973	284	28,967	818	41,875	1,752	26%	37%	18%	16%	69%	47%	6%	14%	3%	4%

PED624 Table 1

Of 3,922 index partners tested, 1,906 were in penal settings, of whom 243 (12.7% yield) were newly diagnosed HIV-positive. 2,016 partners tested resided outside of the penal settings, of whom 54 were newly diagnosed HIV-positive (2.7% yield).

Conclusions/Next steps: Results of ICT expansion showcase the effectiveness of ICT and PNS in accelerating HIV case identification, particularly identifying HIV-positive individuals unaware of their HIV status, and improving testing efficiency across penal population. Based on these results, SL is supporting the government of Ukraine to institutionalize ICT across all penal and probation settings, in support of 2030 epidemic control targets.

PED626

Implementation of innovative HIV case finding approaches among communities of people who inject drugs (PWID) in Ukraine

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Background: Ukraine has the second largest HIV epidemic in Eastern Europe and Central Asia. According to the integrated bio-behavioral survey (IBBS, 2020), Ukraine has a prevalence of HIV among PWID of 22.6%, but only 58% of PWID are aware of their HIV-positive status. From February to September 2020, the PATH-led, USAID-funded Serving Life (SL) project piloted an innovation to reach PWID communities with HIV testing and index case testing (ICT) in six project regions of Ukraine.

Description: SL implements an innovative approach to HIV case finding among PWID communities by continuously sourcing new networks of PWID and offering them HIV testing through community outreach. SL partner NGOs enroll ex-prisoners, former or current PWID who know the locations and needs of PWID communities as peer HIV case finders. HIV case finders suggest PWID to be tested, provide assisted rapid or self-testing, and refer HIV-positive PWID for further diagnosis and linkage services. All peer case finders follow the WHO 5 C's. Recruitment of new peer case finders was also done through this community outreach effort ensuring their frequent rotation. HIV-positive PWID were offered ICT for their sexual and injecting partners. Clients with HIV negative test results were provided with referrals to prevention services.

Lessons learned: 1,754 HIV tests were conducted by PWID peer case-finders, of them 20 were newly diagnosed HIV-positive (1.1% yield), 19 people initiated ART (95%). ICT were offered to 20 new positives and 220 PWID who knew their HIV-positive status, of which 216 agreed (90%) and provided contacts for 684 verified index partners, of them 666 index partners (97.4%) were tested for HIV, 7 partners knew about their HIV-positive status, 9 refused and 2 were lost for follow-up. 34 people were newly identified as HIV-positive (5.1% yield).

Conclusions/Next steps: The results of the pilot intervention demonstrate the effectiveness of providing ICT services to HIV-positive PWID and their partners. The percentage of newly diagnosed HIV-positive people among index partners of HIV-positive PWID was almost five times higher than the percentage of newly diagnosed HIV-positive people in the general PWID community, indicating the need to scale up this targeted approach to accelerate HIV case finding nationally.

Awareness, information, and risk perception regarding HIV transmission and prevention

PED628

Messaging focused on "Taking Control" may increase uptake of HIV prevention among South African adolescent girls and young women

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Background: HIV infection incidence among South African Adolescent Girls and Young Women (AGYW) remains a significant public health concern, as researchers increasingly seek more effective messaging for prevention. We conducted a two-stage qualitative study of South African AGYW to investigate their response to different messages and images (i.e., "creative content"), with the goal of developing tailored influence campaign strategies that could increase motivation for and HIV prevention uptake.

Methods: Data were collected in 2020 through in-depth interaction with Black and Colored AGYW, ages 16-25, in two stages: a moderated online community (n=30) and online focus groups (n=38). Participants were recruited by telephone from three metropolitan areas. Online community participation was completed asynchronously over the course of three days, during which participants shared information about themselves, responded to creative content related to HIV prevention, and reported their expectations of how others might perceive the content. Online focus group participants discussed similar information synchronously, reacting to messaging content covering eight factors (Figure 1). Two independent analysts performed content analysis.

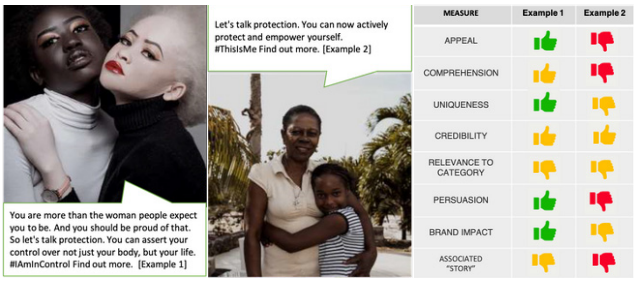

Figure 1. AGYW responses to creative content (sample)

Results: Gender-based violence represented a more salient topic for the AGYW than HIV. HIV information is not actively sought, and AGYW perceive limited control over their infection prevention. Analysis of participant responses to different creative content suggested two distinct visual and messaging routes, one focused on "Protection" and a second on "Taking control." Participants expressed greater understanding, enjoyment, and involvement with creative messaging about empowering women to take control and stand up for themselves.

Conclusions: Findings show that targeted marketing campaigns built on a foundation of AGYW "Taking control," of their health, overall life and future trajectories, have the potential to improve HIV prevention uptake. Future studies should comprehensively assess the messages' effectiveness, including how they can be aligned with salient themes (e.g. GBV), on changing attitudes toward HIV prevention and motivating behavior change.

PED629

HIV risk behaviors among those with and without viral load suppression: findings from population surveys from four African countries

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Background: Individual viral load suppression (VLS) is critical to achieving individual health and population-level prevention of HIV transmission. Yet, the population-level association between successfully controlled viremia and sexual risk behaviors is poorly understood. We assessed behavioral factors associated with unsuppressed viral load (UVL) in Population Based HIV Impact Assessments (PHIA) surveys conducted in four sub-Saharan African countries.

Methods: We analyzed cross-sectional data from nationally representative, general population surveys conducted in Eswatini, Malawi, Tanzania, and Zambia (2015-2017). Among people living with HIV (PLWH) aged 15-59 years, we focused on four higher risk behaviors during the prior year: multiple sexual partners, unprotected non-marital sex, hazardous drinking (using AUDIT-C), and commercial or transactional sex. We evaluated the correlation between UVL (≥1,000 copies/ml) and each risk behavior using logistic regression on weighted data, adjusting for age, household wealth quintile, urban residence, and country, stratified by sex. A risk score was developed by summing the total number of reported risk factors. The score was dichotomized as 0 to 1 versus 2 or more risk behaviors.

Results: Among 73,726 participants, 9,062 were PLWH with available viral load data. UVL varied across countries: Tanzania (48.0%, 814/1,708); Zambia (40.8%, 948/2,413), Malawi (32.0%, 682/2150) and Eswatini (27.7%, 735/2,788). UVL was more common in men (47.8%) than women (37.0%, p<0.0001). Among women, UVL was independently associated with having multiple sexual partners (aOR=1.41, 95% CI 1.05-1.91) and unprotected non-marital sex (aOR 1.64, 95% CI 1.18-2.30). Among men, UVL was independently associated only with hazardous drinking (aOR 2.01, 95% CI 1.48-2.72). Women with UVL were more likely to engage in two or more risk behaviors (aOR 1.47, 95% CI 1.11-1.96), whereas men were not (aOR 1.27, 95% CI 0.86-1.86).

Conclusions: Study findings suggest that UVL among PLWH remains a substantial challenge. PLWH with UVL in contrast to those with viral load suppression (VLS) are more likely to engage in higher risk behaviors associated with HIV transmission, particularly women. Efforts are needed to disseminate information regarding the importance of VLS for individual benefit and regarding U=U.

PED630

HIV and STI testing among sex parties visitors in Moscow

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Background: Heterosexual contacts and intravenous drug using are declared as the main risk factors for most newly registered HIV cases in Russia. But the risk of HIV acquisition for heterosexual person besides sex with intravenous drug user is not determined.

The aim of this study was to assess the prevalence and risk of HIV and STI among participants of heterosexual sex parties "Kinky Party" in Moscow Russia.

Methods: From August to October 2020, at three "Kinky Party", were conducted anonymously voluntarily survey, HIV and STIs testing. OraQuick RAPID saliva rapid tests for HIV 1/2 antibodies were used. For STIs test women underwent self-sampling of a vaginal swab; DNA determination of N.Gonorrhoeae, C.Trachomatis, M.Genitalium, T.Vaginalis by real-time multiplex PCR was carried out in the laboratory. The questionnaire contained 15 questions about socio-demographic characteristics and sexual behavior.

Results: 158 people (100 women and 58 men) surveyed, 62 men and 101 women were tested for HIV, and 95 women were tested for STIs. The average age of participants was 27.9 (median 27, range 18 to 46) years, comparable for men and women. The median age of sexual debut was 17.2 (from 12 to 30) years.

Based on the results of the survey: more than 5 sexual partners in 6 months – 24.2% respondents (31% men, 20.9% women); use of condoms for all types of contacts – 15.3% (22.4% men, 11.1% women), only for vaginal – 40.8% (36.2% men, 43.4% women), for vaginal and anal – 24.2% (22.4% men, 25.3% women), do not use condoms – 14% (17.2% men, 12.1% women); bisexual contacts practiced 36.5% respondents (8.8% men, 52.5% women); commercial sex – 10.2%; using non-intravenous drugs for/during sex – 28.2%; never got STIs test – 11.5%. Testing revealed 2 (1.2%) HIV positive persons and 3 (3.2%) cases of STIs, for one case – N.Gonorrhoeae, M.Genitalium, C.Trachomatis.

Conclusions: The prevalence of HIV/STIs in the sexually active group was not higher than in the same age general population. But significant risks for HIV/STIs such as many sexual partners, irregular use of condoms and chemsex were found. Further spreading of HIV in this group is predictable and special prevention interventions are needed.

PED631

Safer sexual health awareness, attitudes and practices among HIV key populations in the early months of the COVID-19 pandemic in the Philippines

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Background: Awareness and accessibility of sexual health services are influenced by cognitive, psychosocial and geographical factors (Thongmixay et al., 2019). During the enhanced community quarantine (ECQ) enforced in March-May 2020 in the Philippines in response to COVID,

these geographical factors were heightened. This study sought to describe safer sexual health awareness, attitudes and practices of HIV key populations (KP) during the ECQ.

Methods: The study utilized a phenomenological design to characterize safer sexual health practices of KP during the ECQ. It employed a mixed method approach, including a nationwide online survey and a series of virtual small group discussions. PLHIV participants were invited to key informant interviews to ensure confidentiality of status. Descriptive data analysis was done on survey results while thematic analysis was employed for multimedia recordings.

Results: The April 2020 survey yielded 1,001 respondents, with 798 belonging to MSM, TGW and young KP. 19% reported having anal sex during the ECQ, down from 52% who engaged in it within the three months preceding ECQ. Oral sex likewise dropped from 73% to 26%. Awareness on condom use (67%) and PrEP (51%) were more common than ARV adherence (47%) and PEP (44%). PrEP use decreased among MSM and TGW, and access to HIV, CD4 and viral load testing were impeded. ECQ restrictions notwithstanding, PLHIVs were able to maintain ARV adherence, abstinence and condom use, with only 16.5% reporting perceived risk of increased viral load. Meanwhile, majority of non-PLHIV practiced abstinence and self-pleasure, with only 4.4% perceiving that they were at risk of contracting HIV.

Conclusions: While the ECQ may have reduced sexual activity and number of sexual partners among KPs, the minority who still engage in high-risk sexual behavior face the risk of contracting HIV because ECQ restrictions also decreased access to HIV prevention measures. There too remains an awareness gap on PrEP, PEP and ARV adherence across regions and KPs, magnified by the ECQ limiting information and access to these methods. The value arises for COVID-responsive innovations in the delivery of HIV prevention and testing services and for a comprehensive HIV prevention, testing and awareness campaign with differentiated messaging per region and KP.

PED632

Gender differences in perceived and actual HIV Risk in rural high school learners in KwaZulu-Natal, South Africa

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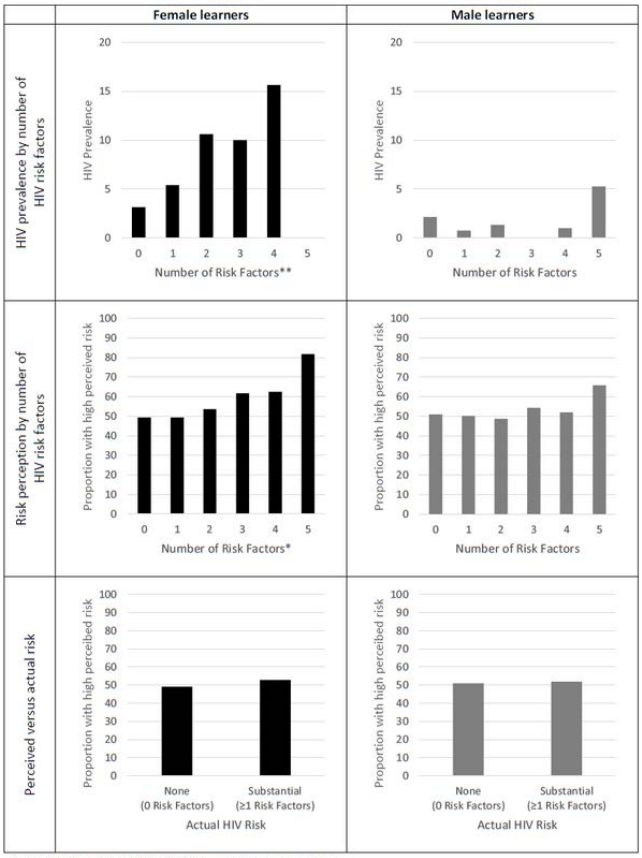
Background: In generalized HIV epidemic settings, transitioning from adolescence to adulthood is associated with increased HIV acquisition risk. HIV risk perception influences motivation to access HIV prevention services. We examined perceived and actual HIV risk among grade 9 and 10 learners in rural KwaZulu-Natal, South Africa.

Methods: Using baseline self-reported and serologic data collected from a clustered randomized controlled trial (2010), we used univariable and multivariable (age, grade) gender-stratified generalized estimating equations (logit link) to identify correlates of high perceived risk. We also used risk factors included in the South African Ministry of Health's (SAMOH) definition of "substantial risk" (STI experience, condomless sex, multiple sex partners, not knowing a partner's HIV status, and alcohol/drug use) to create a risk continuum (range: 0-5) and classification (None [0 factors] vs. Substantial [≥1 factor]).

Results: Among female learners, high perceived risk was associated with financial dependency (ref:financially vulnerable, aOR:1.35 [1.06-1.71]), knowledge of adolescent girls' and young women's heightened risk (aOR:1.32 [1.06-1.66]), greater condom knowledge (aOR:0.84 [0.74-0.95]), endorsement of negative HIV attitudes (aOR:1.14 [1.07-1.21]), sexual experience (aOR:1.36 [1.02-1.81]), and consistent condom use (aOR:0.44 [0.20-0.97]). For male learners, high risk perception was associated with number of social welfare grants (aOR:1.18 [1.02-1.36]), knowing an older sexual partner increases risk (aOR:1.29 [1.01-1.63]), greater condom knowledge (aOR:0.80 [0.69-0.92]), endorsement of negative HIV attitudes (aOR:1.11 [1.05-1.19]), and sexual violence survivorship (aOR:1.41 [1.04-1.90]). In the SAMOH risk continuum, females' HIV prevalence (aOR:1.22 [1.06-1.41]) and risk perception (aOR:1.10 [1.01-1.20]) increased as risk factors increased (Figure 1); however, the association between perceived and actual risk was null. Among males, all SAMOH-related associations were null.



*p<0.05, **p<0.01, ***p<0.001 in multivariable analyses

Figure 1. Exploration of SAMOH risk factors characterizing "substantial risk" in Grade 9 and 10 learners

Conclusions: In both genders, perceived risk belied actual risk, indicating a disconnect between knowledge of HIV risk factors and actual risk. Gender-differentiated approaches are needed to fill this gap and facilitate appropriate and timely access to prevention services and activities.

PED633

Barriers and facilitators of risk disclosure among women at high risk for HIV acquisition and onward transmission in Uganda

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Background: Underreporting of HIV-associated sexual risk behaviors is common, including among African women, who have among the highest HIV burdens globally. A deeper understanding of the barriers and facilitators of female risk disclosure in African healthcare settings may help facilitate delivery of high impact HIV prevention interventions, such as long-acting injectable PrEP.

Methods: We used HIV phylogenetic and epidemiological data from the Rakai Community Cohort Study (RCCS), a population-based study of HIV incidence in Uganda to identify women ≥18 years at high risk of HIV acquisition and onward transmission. In-depth interviews (IDIs) were conducted among a purposive sample of women (n=31), including 9 HIV seroconverters with an HIV-negative sexual partner and no other reported partnerships, 5 HIV-negative women with ≥5 partners in the last year, and 17 HIV-positive women with evidence of onward transmission to ≥1 partner as determined from phylogenies. IDIs were conducted between August 2019-March 2020, and a team-based coding approach using framework analysis was used to identify salient themes.

Results: Individual, cultural, and health systems barriers were identified as deterrents to female risk behavior disclosure. Women said being married, having strong religious beliefs, working as a sex worker, holding high status in the community, having multiple partners, and shyness discussing sex were barriers to talking about their risk. Women frequently reported anticipated stigma from health care workers (HCWs) and feared HCWs would breach confidentiality, in some cases potentially leading to intimate partner violence. Facilitators of disclosure included being unmarried and having one partner. Informants also consistently reported strong preferences for older, female HCWs, whom they felt had more expertise and maturity.

Feeling that disclosure would lead to health improvements, such as receiving treatment for sexually transmitted infections, and HCW demeanor, which included not shouting, attentiveness, active listening, and ensuring confidentiality, also arose as facilitators to risk disclosure.

Conclusions: Women face significant barriers to disclosure of HIV risk behavior likely impacting HCW ability to identify women at high risk of HIV acquisition and onward transmission. Prioritization of HCW trainings on patient-centered care and confidentiality as well as integrated healthcare services is critical for effective delivery of HIV prevention interventions to African women.

HIV services in healthcare settings

PED634

Performance of an HIV risk screening tool to identify people living with HIV aged 15 years and above in primary care facilities in Uganda: a secondary program data analysis

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Background: Uganda is nearing its 1st 90 target. 89% of people living with HIV (PLHIV) are aware of their status, but approximately 215,000 PLHIV are not yet on treatment. As Uganda and other countries scale treatment coverage, it is increasingly difficult and resource-intensive to identify remaining PLHIV, particularly as resources for HIV testing services (HTS) decline. To reduce testing volumes while increasing positivity, many countries are implementing risk-based screening tools, but there is very limited evidence on their impact. Uganda is screening for HTS eligibility among adults in outpatient departments (OPD) of public facilities. This abstract describes secondary analysis of programmatic data on the impact of risk-based screening tools in OPD settings in Uganda.

Methods: We conducted a retrospective secondary data analysis of routinely collected program data from October to November 2019 in 24 facilities implementing HIV risk screening. Participants were clients over the age of 15 in OPD who were screened and then tested for HIV, regardless of eligibility. De-identified data was analyzed to calculate HIV positivity rates with and without screening, and sensitivity and specificity of the tool.

Results: Of 19,704 patients screened, 12,971 (66%) were female and the median age was 27 (IQR: 21-35). Overall, 732 (yield 3.71% (95% CI: 3.06-4.50)) patients were positive. Based on risk screening, 14,879 (76%) patients were eligible for testing and 664 (yield 4.5% (95% CI: 4.1%-4.8%)) of these patients were positive. Overall sensitivity of the screening tool was 90.7% (95% CI: 88.4%, 92.7%) and specificity was 25.1% (95% CI: 24.5%-25.7%). With screening, the number needed to test (NTT) to identify one PLHIV fell from 32 to 22.

Conclusions: Implemented in OPD, the screening tool in Uganda reduced testing volumes 24.5%, but did not result in a statistically significant increase in yield. The tool identified 9.3% of PLHIV as ineligible for testing; these PLHIV would have been screened out and not offered HTS. Given the increasing difficulty and costs of identifying remaining PLHIV, it is critical that ministries of health carefully consider potential risks and tradeoffs in implementing risk-based screening tools which may miss PLHIV at facilities.

Sero-adaptive behaviours: preference, practice, and impact

PED635

Sexual network models of HIV serosorting and PrEP sorting among men who have sex with men in the United States

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Background: Nonrandom sexual partnering among men who have sex with men (MSM) with respect to diagnosed HIV status (serosorting) and preexposure prophylaxis use (PrEP-sorting) may decrease the population-level impact of PrEP by concentrating PrEP in fewer partnerships.

Methods: We used behavioral data from a 2017–2019 egocentric study of MSM in the US to fit exponential random graph models of cross-sectional anal-sexual networks in a simulated population of 10,000 MSM. To elucidate mechanisms generating the observed network data, we compared models fully-specified to the observed serosorting and PrEP-sorting to counterfactual models based on preferential partnering within demographic groups (age and race/ethnicity) only. Models were stratified by partnership type and accounted for degree (count of momentary persistent or cumulative one-time partners) heterogeneity by demographics, diagnosed HIV status, and PrEP use.

Results: Among men with diagnosed HIV, half of their partnerships were with men of the same HIV diagnosis status, in models fully-specified to the observed data – double the fraction expected based on demographic mixing only. Similarly, we found greater concordance of PrEP use in fully-specified models, compared to demographic mixing models, with 15.8% and 8.0% higher (absolute) PrEP use among the persistent and one-time partners, respectively, of men also using PrEP. Among men without current PrEP use (including those at risk for HIV or with undiagnosed HIV) most of their partners were also not using PrEP – an absolute increase of 14.3% (persistent partnerships) and 12.7% (one-time partnerships) concordance in fully-specified models compared to demographic mixing models.

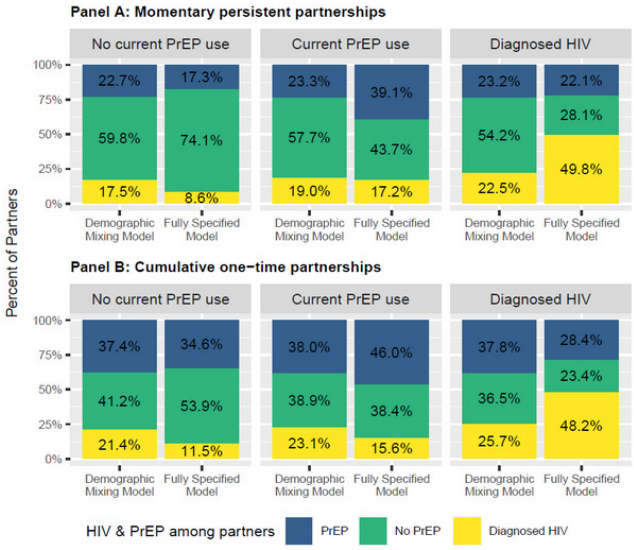

Figure. Serosorting and PrEP-sorting among N = 10,000 simulated MSM in the US in cross-sectional anal-sexual network models

Conclusions: We found evidence of preferential partnering by diagnosed HIV and PrEP use in sexual networks beyond levels expected by demographic mixing. This high clustering of HIV and PrEP may be the primary reason for gaps between actual and predicted population-level impact of PrEP, due to excess HIV transmission in population subgroups with higher undiagnosed HIV and PrEP non-use.

Voluntary medical male circumcision

PED636

Evaluation of factors influencing uptake of voluntary medical male circumcision amongst males in the pivot age group (15-29 years) in East Central Uganda

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Background: The World Health Organization recommends Voluntary Medical Male Circumcision (VMMC) as a key HIV prevention approach. Mathematical modeling suggests that circumcising 80% of males aged 15–49 in sub-Saharan Africa could avert 3.36 million HIV infections by 2025. With respect to Uganda, the focal demographic for HIV prevention was 15–29 years. However, little is documented in Uganda about factors influencing VMMC uptake in this pivot age group. We sought to determine the level of uptake, and factors influencing uptake of VMMC amongst males aged 15-29 years in East-Central Uganda.

Methods: This was a cross-sectional study. Eligible participants were males aged 15-29 years mobilized for VMMC by the thirty health facilities accredited for VMMC in East-Central Uganda. Following ethical approval and participant informed consent, data was collected in September 2020. Participants were randomly sampled from a line-list of mobilized individuals using systematic sampling. Participants were categorized as circumcised or not circumcised. Logistic regression was used to identify factors associated with the uptake of VMMC.

Results: Overall 1,230 males aged 15-29 years were enrolled in the study of whom 937 (76%) were circumcised. Motivators to VMMC uptake included: Parental encouragement: [aOR = 1.76 ,95%CI:1.26-2.44];knowledge about benefits: reduces risk of STIs and HIV [aOR = 2.04,95% CI:1.13-3.68], reduces risk of cervical cancer in female partners [aOR =1.51,95% CI:1.09-2.10];knowledge about where VMMC services are offered [aOR = 3.18,95% CI:1.99-5.09]; health worker confidentiality [aOR= 2.89,95% CI:1.63-5.10];affordable transport costs [aOR=1.57,95% CI:1.06-2.31].

Barriers to VMMC uptake included: female partners involvement in decision making to take up VMMC [aOR = 0.37,95% CI: 0.26-0.52]; Fear of complications [aOR=0.67,95% CI:0.49-0.93]; Fear of pain [aOR=0.46,95%CI:0.30-0.70].

Conclusions: The study showed that an estimated 76% of males aged 15-29 years in East-Central Uganda have been circumcised. The factors associated with VMMC uptake included: parental encouragement; belief in health worker confidentiality; affordable transport costs; knowledge about where VMMC is offered, and VMMC benefits i.e. decreases risk of HIV, STI's and cervical cancer for female partners. Barriers included: fear of pain and post VMMC complications; and involvement of female partners in decision making to take up VMMC. We recommend that mobilization messaging be refined to address these findings.

Antiretroviral therapy, including treatment as prevention

PED637

Robust progress in ARV optimization for older adolescents and adults despite COVID-19

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Background: PEPFAR prioritizes the WHO-recommended uptake of DTG-based regimens for PLHIV. In October 2019, PEPFAR began semi-annual monitoring of ARV volumes dispensed. We sought to understand the trend in ARV optimization for PLHIV ≥ 15 yo (PLHIV15) during the COVID-19 pandemic.

Description: PEPFAR, through USAID, supports 5.8 million PLHIV15 in > 40 countries. Programs adapted to continue transition to TLD during COVID-19. Clinical partners adjusted HCW training platforms to promote rapid transition to DTG-based regimens. To mitigate commodity disruption, staff developed tools and processes to expedite delivery of products with higher shelf life and optimize cargo and storage space.

Lessons learned:

Despite tremendous COVID-19 related challenges, substantial gains in TLD uptake were made. From March to September 2020, PLHIV15 on ART in USAID-supported programs increased in 16 of 18 countries. More than 85% of all TLD orders affected by COVID-19 arrived on-time.

ARV dispensing data reveal that all countries except Zambia and DRC increased the percentage of USAID-supported PLHIV15 receiving TLD (Figure 1).

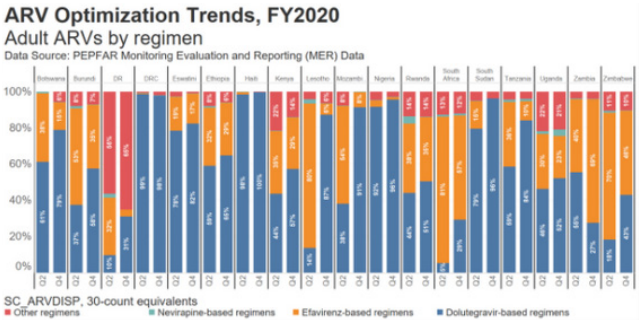

Figure 1. TLD dispensing to PEPFAR-supported, through USAID, PLHIV ≥ 15 years of age at the end of March 2020 (USG FY20 Q2) and the end of September 2020 (USG FY20 Q4), excluding Asia, West Africa, and Western Hemisphere regional programs.

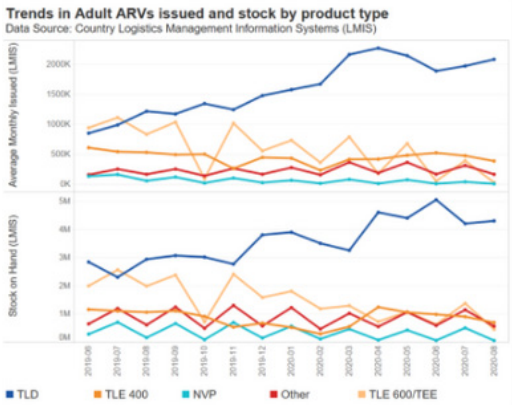

Figure 2. Trend in increased stock availability of TLD as NNRTI-based products declined for eight countries (Botswana, Haiti, Lesotho, Mozambique, Namibia, Nigeria, Uganda and Zambia

To decongest facilities in Zambia, individuals were temporarily provided a six month supply of TLE400 before being transitioned back to TLD by late 2020. TLD coverage in DRC declined slightly but remained extraordinarily high (98%); TLD coverage in four other countries (Haiti, Mozambique, Nigeria, South Sudan) exceeded 90% by the end of September 2020. TLD coverage more than doubled in the Dominican Republic, Lesotho, Mozambique, South Africa and Zimbabwe. Product stocking level analysis from eight countries revealed fewer NNRTI products and more DTG, reflecting increased dispensing of optimal regimens (Fig. 2). Inventory status for these countries was sufficient for continued ART optimization.

Conclusions/Next steps: Program adaptation, including monitoring and preserving ARV stocks, allowed millions of PLHIV15 to receive TLD despite COVID-19 disruptions. Continued, proactive implementation and strategic supply chain adjustments are needed to ensure all PLHIV can access the benefits of DTG.

PED638

Impact of rapid antiretroviral therapy initiation on treatment response in men who have sex with men in West Africa (CohMSM ANRS 12324 – Expertise France)

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Background: Data on rapid antiretroviral therapy (ART) initiation and its impact on treatment outcomes in men who have sex with men (MSM) living in West Africa is lacking. We assessed the time from HIV diagnosis to ART initiation and the impact of rapid ART initiation on attrition and virologic and immunologic responses among MSM in Burkina Faso, Côte d'Ivoire, Mali, and Togo.

Methods: We performed a prospective cohort study between June 2015 and December 2019 in four community-based clinics. MSM aged 18 years or older were eligible if they were newly diagnosed with HIV infection. ART initiation was proposed to participants at HIV diagnosis, irrespective of clinical stage and CD4 cell count. Participants attended quarterly follow-up visits. HIV viral load and CD4 cell count were measured every six months. Determinants of rapid ART initiation (i.e. within seven days of HIV diagnosis) and its impact on attrition, viral load suppression and gain in CD4 cell count were assessed using multivariate analyses.

Results: Of 350 MSM newly diagnosed with HIV infection, 335 (95.7%) initiated ART after a median time of 5 days (interquartile range [IQR] 1-13). Eighty participants (23.9%) initiated ART the same day, 216 (64.5%) within 7 days, 268 (80.0%) within 15 days, and 298 (89.0%) within 30 days. Participants were followed up for a median time of 24.1 months (IQR 12.7-39.6). One hundred and eleven participants (33.1%) were not retained in care. Rapid ART initiation was lower in participants who had a CD4 cell count ≥ 200 cells/µL (adjusted odds ratio [aOR] 0.37, 95% confidence interval [CI] 0.15-0.88, p=0.025). Rapid ART initiation was associated with more frequent suppression of viral load (aOR 5.54, 95% CI 1.71-17.9, p=0.004). By contrast, rapid ART initiation was not associated with attrition (aOR 0.87, 95% CI 0.57-1.33, p=0.525) nor with the gain in CD4 cell count (adjusted coefficient 28.2, 95% CI -17.0; 73.4, p=0.221).

Conclusions: Our study in MSM newly diagnosed with HIV infection in West Africa supports the WHO recommendation for rapid ART initiation. Clinics need to set up context-specific strategies to minimize the delay before ART initiation and to retain MSM in care.

PED639

Pediatric ARV optimization in a real-world setting: Dolutegravir transition in Mozambique

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Background: Dolutegravir (DTG) is recommended for first and second line antiretroviral therapy for children and adolescents living with HIV and is being scaled up globally to optimize treatment. However, barriers to adoption and supply distribution can hinder sustainable uptake. We describe rollout of DTG 50mg tablets for children weighing ≥20kg in Gaza and Inhambane provinces, Mozambique following national guideline updates in September 2019.
Methods: Clinic records from children 0-14 years with an HIV clinic visit between September 2019 and February 2020 were extracted from clinical databases in 16 health facilities. Among children aged ≥5 years (proxy for weight ≥20kg), we described treatment switches, defined as change in anchor drug for any reason, ignoring changes only to NRTI backbones. Among those on DTG-based regimens during the 6-month study period, we described treatment changes and available viral load (VL) outcomes.
Results: Of 3,107 children aged ≥5 years, 2,488 (80%) switched ART regimens during this period; 950 (38%) children switched ≥ 2 times; 11 changed 5-6 times. Of those who switched, 2,009 (81%) switched to DTG-based ART per national guidelines: 336 (17%) switched from PI-based, 1,616 (80%) from NNRTI-based ART, 36 (2%) had both PI and NNRTI switches, and 21 (1%) switched from other regimens. However, 711/2488 (29%) on DTG switched to other regimens within 6 months: 317 to PI, 387 to NNRTI and 7 to both drug classes. At last visit, 75% (2,311/3,092) of children were on DTG, excluding 15 without any documented regimen during follow-up. Among children ever on DTG, 1,607/2,596 (62%) were on continuous DTG for ≥2 months (median [IQR] 4.2 [3.1-5.0] months). Of these, 85 children had VL results available at median 2.9 [1.1-4.7] months after DTG start; 68 (80%) had undetectable VL <50 copies/mL.
Conclusions: This study highlights progress towards DTG transition for eligible children. However, rollout should be accompanied by ongoing training and forecasting support to minimize stock-outs and avoid non-clinically justified switches that may contribute to multiple changes. More consistent VL testing is also needed to monitor effectiveness. Addressing these issues, particularly as introduction of additional pediatric formulations are imminent, will help ensure timely uptake and continuous treatment for children.

PED640

Access to antiretroviral therapy for people living with HIV and associated factors in Cameroon: a cross sectional study

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Background: Antiretroviral therapy (ART) is essential for improving the health of people living with HIV (PLHIV) and preventing onward transmission. Yet, as of June 2020, only 328,264 of Cameroon's 510,000 PLHIV were accessing life-saving ART. To support the country's catch-up plans, we sought to evaluate access to ART and analyze associated barriers and enablers.
Methods: From October to December 2017, we conducted a cross-sectional study among 4338 PLHIV (aged 15 years and older) on treatment at 60 high-volume sites across Cameroon's 10 regions. Gender balance among study participants was considered. Participants were enrolled after giving their inform consent. We measured access to ART by using multiple correspondence analysis followed by mixed classification. Factors associated with access to ART were investigated by using multinomial logistic regression.
Results: Out of 4338 PLHIV on ART enrolled, 65% (2820 /4338) were women and 63% (2733/4338) were living in urban area. Patients who lived less than 5 km from the hospital, walked or took bicycle to hospital, spent less than a dollar on transport, found the service to be fast and did not want to change their hospital, had a high access to ART and represented 45%. A proportion of 10% lived in another health district, found the reception unsatisfactory and not at all rapid, were classified as having affordable access. Those who lived in another region, who spent more than 3 dollars for transport and paid voluntary a part of their treatment was classified as having a poor access to ART and represented 45%. Despite having higher ART coverage, women were more likely to have a poor access to ART than men (RR = 1.76 and 95% CI: 1.109-2.803). The median age was 37 years (IQR: 29-45), with advanced age associated with reduced access to ART. Not receiving post-test counselling was also associated with a poor access to ART (RR = 2.451 95% CI: 1.397 - 4.302).
Conclusions: To improve ART coverage in Cameroon, decision-makers should focus on bringing services closer to patients, reducing wait times at the health facility, eliminating user fees and ensuring post-test counseling is done before linking patients to treatment.

PED641

TLD turnaround: increasing rates of Dolutegravir-based regimens among women of childbearing age in Zimbabwe

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Background: Zimbabwe has an HIV prevalence among women of childbearing age (WOCBA) of 15.3%. Initial public health messaging around Dolutegravir (DTG)-based Anti-retroviral medicines emphasized educating WOCBA on the possible increased risk of neural tube defects in

pregnant women. Zimbabwe Ministry of Health released new guidance emphasizing the safety and efficacy of DTG-based regimens among WOCBA in December 2019. The objective of this assessment was to evaluate the initiation rates of Tenofovir-Lamivudine-Dolutegravir (TLD) regimen among females newly identified as HIV positive, one year on from the release of the revised guidelines.

Methods: A retrospective cross-sectional assessment of routine program data for females 10 years and older testing HIV positive from 151 purposively sampled OPHID supported health facilities was conducted. The period under review was January– December 2020. Data was analyzed descriptively using MS-Excel.

Results: From January to December 2020, 8233 females >10years of age were newly identified as HIV positive, with 8024 (97.5%) newly initiated on Anti-Retroviral Therapy (ART). Overall, 6356 (79.2%) were initiated on TLD. There was a gradual month on month increase in the proportion of WOCBA initiated on TLD, from 51% in January 2020 to as high as 90% in November 2020). Older women had higher TLD initiation rates compared with younger age groups representing clients on ART being switched to TLD.

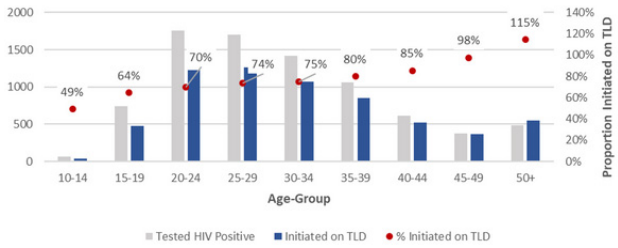

Figure. TLD initiation by age-group, Jan-Dec 2020

Conclusions: We demonstrate a gradual temporal shift in TLD initiation rates among WOCBA newly diagnosed HIV positive despite guidance on its safety. Targeted program remediation to increase TLD initiation rates among adolescent girls and young women is required. Revision of HIV treatment guidance should be accompanied by information, education, and communication material for recipients of care and health workers to dispel myths and misconceptions and prevent delays in policy to practice.

PED642

Stigma, survival, and social support: exploring lived experiences of antiretroviral therapy among young gay and bisexual men, sex workers, and transgender women living with HIV in Jamaica

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Background: Antiretroviral therapy (ART) engagement remains low in Jamaica, where an estimated 44% of people living with HIV (PLHIV) are taking ART, and 35% of PLHIV have an undetectable viral load. Social and structural contexts of stigma and criminalization of same-sex practices and sex work likely shape barriers to engaging in the HIV treatment cascade in Jamaica. Yet limited research has explored barriers and facilitators to ART engagement among young key populations in Jamaica.

Our study explored experiences with ART with young (aged 16-24) gay, bisexual and other men who have sex with men (gbMSM), transgender women, and sex workers living with HIV in Jamaica.

Methods: We conducted 9 focus groups between January 2020-January 2021 with young PLHIV aged 16-24. Three FG were held with sex workers, 3 with gbMSM, and 3 with transgender women; one FG was conducted per population in Kingston, Montego Bay, and Ocho Rios. FG were audio-transcribed and translated verbatim. We conducted thematic analysis to explore inductive and deductive findings regarding ART engagement.

Results: Focus groups included sex workers (n=20), gbMSM (21), and transgender women (n=26) living with HIV. ART adherence barriers fell into three broad and interconnected themes: stigma; survival; and unmet support needs. Stigma was associated with HIV, whereby low treatment literacy resulted in beliefs that HIV was a death sentence.

Community-level stigma toward PLHIV reinforced social exclusion and resulted in participants taking numerous precautions to hide ART usage at home and in workplaces; these precautions often resulted in skipping ART doses. Fear of being stigmatized due to becoming visibly sick, and wanting to appear physically healthy to avoid such stigma, was also a motivation for taking ART.

Structural stigma in health settings was another deterrent to ART engagement. Unmet survival needs, including pervasive food and housing insecurity, were significant barriers to ART adherence. Participants identified support needs: *mental health support* to address low self-worth; *financial support*, including transport to clinics; and *social support*, including peer support .

Conclusions: Young key populations living with HIV in Jamaica identified social and structural contexts key to improving ART adherence, including multi-level intersectional stigma reduction, poverty alleviation, and fostering peer support networks.

Pre-exposure prophylaxis

PED643

Perceived acceptability of broadly neutralizing antibodies (bnAbs) for HIV prevention among young men who have sex with men at risk for HIV infection in the United States

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Background: HIV incidence remains high among young men who have sex with men (YMSM) in the U.S. Broadly neutralizing antibodies (bnAbs) administered intravenously are being tested for HIV prevention in the AMP ongoing efficacy trial. We examined YMSM's understanding and beliefs about bnAbs and their perceived acceptability as an HIV prevention regimen.

Methods: Semi-structured interviews with 30 HIV-negative YMSM (ages 16-24) were conducted via videoconferencing between May and November 2020. Participants were recruited online in the U.S. Northeast. Interviewers offered a description of bnAbs and asked participants to reflect

on the product, and discuss the hypothetical acceptability of bnAbs as a prevention product. Data were coded inductively and deductively and analyzed for themes.

Results: Participants' median age was 22 (IQR=3.5) and most participants were YMSM of color (n=16, 53%). About half of the sample (n=13) were currently taking pre-exposure prophylaxis (PrEP) for HIV prevention, and awareness of bnAbs for HIV prevention was low. Once the description was offered, many YMSM perceived antibody-mediated prevention to be more effective to prevent HIV transmission in comparison to antiretroviral-based PrEP. Participants had mixed opinions about the perceived safety of bnAbs for HIV prevention.

While some participants were concerned that receiving products intravenously would be more "invasive" and result in higher toxicity and side effects, others perceived infusions of bnAbs to be more "natural" and thus less toxic than antiretrovirals. Lack of prior experiences with other medical products administered intravenously was also a barrier to the acceptability of bnAbs for HIV prevention.

Additional concerns included discomfort with placing the intravenous catheter and longer times at health clinics receiving the infusion. Some participants reported that shorter infusion times and lower costs would facilitate uptake of bnAbs for HIV prevention among YMSM.

Conclusions: Biobehavioral research has the potential to optimize the drug development process by identifying potential barriers to the acceptability of novel HIV prevention products among potential end-users.

Future research involving bnAbs should consider addressing target population's concerns about bnAbs in order to promote enrollment in clinical trials and accelerate dissemination of bnAbs among at-risk individuals if the product is found to be effective.

PED644

Acceptability of and preferences for next generation PrEP products among young men who have sex with men

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Background: HIV incidence is increasing most rapidly among young men who have sex with men (YMSM) in the United States. While daily oral pre-exposure prophylaxis (PrEP) is effective in preventing HIV transmission, barriers to uptake and suboptimal adherence diminish its capacity to protect YMSM against HIV. Research on and development of next-generation PrEP products such as long-acting injectables (LAIs), subdermal implants (SIs), and rectal douches (RDs), are currently underway to create new modalities that may be more effective. However, YMSM's recruitment in next-generation PrEP studies has been limited.

This study assessed the acceptability of and preferences for these next-generation PrEP products among YMSM.

Methods: We conducted virtual qualitative, semi-structured interviews with a diverse sample of 30 HIV-negative YMSM between 16-24 years old in the United States who self-reported at least one recent high-risk sexual encounter. Participants were asked about their beliefs and perspectives on LAIs, SIs, and RDs as next-generation PrEP products.

Results: About half of our sample (n=16) was PrEP-naïve and 13 participants were currently using PrEP. Participants showed great affinity towards LAIs and SIs as a form of PrEP due to their perceived effectiveness, convenience, infrequent dosage requirements and longer duration of protection compared to daily oral PrEP.

However, participants also voiced concerns over cost, the recurrent need to visit a clinic or hospital, and fear of needles/implants as potential barriers to the acceptance and use of LAIs and SIs for PrEP. While participants were equally accepting of LAIs and SIs, they were markedly less receptive to RDs for PrEP. The top reasons given were their concerns over incorrect use, indisposition towards douching in general, and skepticism over its effectiveness and duration of protection.

Many participants also perceived RDs as applicable and beneficial only to the receptive partner during anal intercourse, while SI and LAI could protect insertive persons.

Conclusions: Our findings demonstrate a strong preference and acceptability among YMSM towards next-generation PrEP products that are more passive yet provide a longer duration of protection than existing formulations. YMSM's perspectives on these products should be considered when developing next-generation PrEP products to ensure high penetration and uptake among this population.

PED645

Pre-exposure prophylaxis as an additional HIV prevention choice in Uganda - the role of a responsive supply chain system

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Background: WHO recommended the use of pre-exposure prophylaxis (PrEP) in 2015. MOH and PEPFAR rolled out PrEP as an additional prevention choice in a comprehensive package of HIV services to people at substantial risk of HIV in 2017. However, PrEP program implementation needed to be complemented with easy access to PrEP medication which in some cases is hampered by supply chain constraints ranging from forecasting and procurement of medicines to health facility readiness to support PrEP medicine logistics. We describe the supply chain role in ensuring access to PrEP medicines at PEPFAR/CDC-supported health facilities.

Description: We forecasted and quantified the need for the PrEP medicine, Tenofovir/Lamivudine 300mg/300mg (TDF/3TC) based on programmatic targets. Leveraging from our list of prequalified suppliers, we procured up to 6 months of stock of the product. A baseline assessment was conducted to determine the logistics capacity of health facilities to handle PrEP commodities. Supportive supervision was provided to health workers regarding storage, inventory management, forecasting, ordering, and reporting on PrEP medicine. Mechanisms were instituted to monitor utilisation of TDF/3TC and enrolment rates towards set targets during the period April 2017 to December 2019.

Lessons learned: Health facilities, having acquired knowledge and skills in forecasting PrEP medicines, operated a pull ordering system after the initial push of the maiden supply for these commodities. With an order fill rate of 100%, stock-in levels of 100% and zero stock outs of PrEP commodities, there was a gradual increase in uptake of PrEP services since the

program was piloted in 2017 reaching 6,664 patients (49%) of the target by December 2018 and 12,124 patients (90%) of the target by December 2019 across 65 health facilities.

There was an improvement in reporting rates and timeliness of reporting of Logistics Management Information Systems (LMIS) data from 60% and 45% in 2017 to 100% and 86% respectively by the end of 2019. Accuracy of reports gradually improved from 33% in 2017 to 89% in 2018 and 100% by December 2019.

Conclusions/Next steps: Introduction and up scaling of new programs should be complemented with responsive supply chain systems to ensure uninterrupted supply and access to medicines and other health commodities.

PED646

Challenges of recommencing HIV pre-exposure prophylaxis (PrEP) use during the COVID-19 pandemic

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Background: The use of HIV pre-exposure prophylaxis (PrEP) among gay and bisexual men (GBM) in Australia rapidly increased until 2019, however many men suspended PrEP in 2020 during COVID-19 restrictions. As Australia mostly avoided large-scale COVID-19 infections, from June 2020 restrictions in most states eased, with many men increasing their sexual activity.

However, little attention has been given to how men planned/anticipated these increases in sexual activity and how they recommenced PrEP.

Methods: From an existing cohort study, 705 GBM consented to participate in a study comprising weekly surveys about their experiences of COVID-19 restrictions, including sexual practices and drug consumption. Weekly surveys contained a small number of open-ended questions, including about sex and relationships every four weeks, which provided real-time reflections on anticipated and actual sexual practices during COVID-19 restrictions.

We undertook a thematic analysis of responses from 631 non-HIV positive GBM collected during a 36-week period of surveys (3-May-2020 – 10-Jan-2021) that focused on anticipated and actual recommencement of PrEP.

Results: 384 men provided responses to open-ended questions. 29 men highlighted PrEP across 48 entries, with ten men providing multiple entries. Three themes emerged from these responses.

1. Anticipation of future sexual encounters. Anticipation was central to men's considerations of recommencing PrEP. Men provided accounts of planning and recommencing PrEP over time, as well as re-suspending PrEP due to fluctuating local restrictions. Some men described unanticipated sexual encounters with casual partners where neither PrEP nor condoms were used.

2. Choice of PrEP strategy. Suspension of PrEP during the pandemic allowed for speculation about the most appropriate strategy upon recommencement (i.e., daily or on-demand dosing). Anticipating sexual encounters was noted as a challenge to adopting on-demand dosing.

3. Clinical procedures. Recommencing PrEP was also often articulated in relation to the steps required to obtain it (e.g., clinical consultations, sexual-health testing, or refilling prescriptions).

Conclusions: These findings highlight the fluctuating nature of PrEP during the COVID-19 pandemic and some challenges GBM face when recommencing PrEP as restrictions ease and sexual activity increases. Guidance should be provided to GBM on the effective use of non-daily PrEP dosing and periods of fluctuating PrEP use.

PED647

Assessing level of exposure and predictors of intention to use HIV pre-exposure prophylaxis among adolescent girls and young women exposed to *Jipende JiPrEP* campaign in Kisumu, Kenya

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Background: Pre-exposure Prophylaxis (PrEP) is an effective user-dependent HIV prevention method which can particularly benefit adolescent girls and young women (AGYW) who are often not only disadvantaged in negotiating for safer sex but also are considerably vulnerable to HIV infection. Mass media behavioral interventions designed to enhance uptake of and adherence to PrEP among AGYW are few and their effectiveness unclear. This cross sectional study sought to assess exposure to the national *Jipende JiPrEP* mass media campaign, which utilized both traditional and social media campaigns (e.g., newspapers, leaflets, internet), and predictors of intention to use PrEP among AGYW following the *Jipende JiPrEP* mass media campaign.

Methods: Between July 2019 and September 2019, 419 HIV negative AGYW aged 15-24 years who were previously exposed to the *Jipende JiPrEP* campaign were recruited as part of a cross sectional study at the household level in Kisumu County, Kenya. Parental consent and assent was obtained from minors while adults provided individual consent thereafter participants were interviewed through in-person interviews. Linear framework and *Poisson* regression analysis estimated prevalence ratios. *Chi-square* tested whether the proportion of intention to use PrEP increased or decreased across levels of exposure.

Results: Two-thirds (67.1%) of participants had low exposure to *Jipende JiPrEP* campaign messages. Among those with high exposure, urbanites and those with higher education were more prevalent (7.2% and 9.2% respectively). There was no change in intention to use PrEP with increased exposure to the campaign (Chi-trend p-value= 0.403). However, intention to use PrEP was higher among those exposed to leaflets (aPR=1.51, 95% CI 1.01, 2.26, p= 0.043) and using radio almost daily (aPR=1.81, 95% CI 1.22, 2.69, p= 0.003). Those exposed to newspapers were 55% less likely to report intention to use PrEP (aPR=0.45, 95% CI 0.25, 0.81, p= 0.008).

Conclusions: Low exposure to the *Jipende JiPrEP* campaign was demonstrated among AGYW with majority reporting low intent to use PrEP even after campaign exposure. Radio and leaflets were the most effective channels used by the campaign to nudge behavioral intentions among AGYW. Therefore, innovative messaging approaches are needed to improve campaign effectiveness and enhance behavioral intentions.

PED648

Health care system- and provider-level barriers to utilization of oral pre-exposure prophylaxis (PrEP) among young men who have sex with men and lessons for implementation of next generation modalities

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Background: PrEP uptake and adherence remain suboptimal among young men who have sex with men (YMSM). Barriers to daily oral PrEP among YMSM include challenges at the individual (e.g., adherence) and health care system (e.g., access, provider training and comfort) level. While next generation PrEP may address individual-level factors, implementation success will depend on addressing health system and provider-level barriers.

Methods: We conducted virtual semi-structured interviews with 30 HIV-negative YMSM (53% non-white; ages 16-24 years) who reported high-risk sexual encounter in the past 6 months. Interview transcripts were analyzed for themes regarding YMSM's experiences accessing care and interacting with providers, and how these influences preferences for and acceptability of oral and next generation PrEP.

Results: Most participants had health insurance (n=29, 97%) and a primary care provider (n=26, 87%). Half (n=14; 47%) had past or current experience with daily oral PrEP. Perceived challenges to oral PrEP included concerns about confidentiality, particularly when YMSM were on their parents' insurance, and discontinuities in access to care (e.g., transitioning from pediatric into adult care, or losing parents' insurance). Perceived low cultural and clinical competence among primary care providers led some participants to seek different providers to manage PrEP care. Cost and insurance coverage for next generation modalities may be a concern for YMSM who are uninsured/underinsured or unwilling to use their parents' insurance for PrEP. Fragmented access to care may present barriers to use of next generation modalities that require more frequent visits to health clinics (i.e. bimonthly). Given uncertainty about attributes of next generation PrEP among YMSM, effective communication with providers will be essential to clarify clinical indications and management.

Conclusions: YMSM highlighted gaps for improvement within the health system to ensure continuous, equitable access to oral and next generation PrEP. PrEP services targeting YMSM should take into account transient discontinuities in care and consider delivery models that do not rely on parents' insurance to avoid service interruptions. Future PrEP implementation should consider training generalist providers on PrEP clinical management and on initiating conversations about sexual health with younger patients.

PED649

Characteristics of gay and bisexual men who use event-based PrEP dosing regimens using national Australian data 2019-2020

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Background: While daily PrEP remains the most common dosing regimen in Australia, gay and bisexual men (GBM) are increasingly using event-based dosing regimens.

However, there is evidence that awareness of event-based dosing is low. As event-based PrEP becomes more prevalent, understanding characteristics of those using event-based PrEP is important for targeted health messaging.

Methods: Using data from Australia's national HIV behavioural surveillance system collected in 2019-2020, we compared the characteristics of GBM who reported daily and event-based PrEP use in the last six months using bivariate and multivariate logistic regression.

Results: Of 7,731 HIV-negative GBM, 2,746 (35.5%) reported PrEP use in the last 6 months. Of those 2,746, 285 (10.4%) reported event-based PrEP use. At the bivariate level, event-based PrEP users compared to daily PrEP users were less likely to identify as gay (86.9% versus 92.9%, odds ratio [OR]=0.51, p<0.001), be socially engaged with gay men (Mean=5.5 versus Mean=5.7, OR=0.89, p=0.004), or have had >10 male sexual partners in the last 6 months (25.2% versus 45.6%, OR=0.40, p<0.001), group sex in the last six months (49.1% versus 61.6%, OR=0.60, p<0.001), an STI diagnosis in the last 12 months (37.3% versus 51.2%, OR=0.57, p<0.001), or recent condomless anal intercourse with casual partners (64.6% versus 74.9%, OR=0.61, p<0.001) but were more likely to report recent injecting drug use in the last 6 months (6.0% versus 3.3%, OR=1.86, p=0.023).

In multivariate analysis, not identifying as gay, having fewer male partners, no STI diagnosis in the last 12 months, and recent injecting drug use were independently associated with event-based PrEP use.

Conclusions: Event-based PrEP users had a lower sexual risk profile, were less gay-identified and involved with gay men. Event-based PrEP users were more likely to report recent injecting drug use, but this should be interpreted with caution due its rarity in this sample. As awareness of alternative regimens increases, continued monitoring of event-based PrEP use is important.

Event-based dosing is highly appropriate for GBM with infrequent risk; such men need clear health promotion messaging about how to take it correctly.

PED650

Service providers' acceptability of the HIV PrEP program: current situation and associated factors

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Background: Service providers play crucial roles in the implementation of the HIV PrEP program but little is known about their attitude and concern about HIV PrEP. The study aims to evaluate the association between the acceptability of the PrEP program and concern about PrEP use among service providers in Vietnam, where PrEP was piloted in 2017 and scaled up since 2019.

Methods: A cross-sectional study was conducted in September 2020 in three metropolitan cities (Hanoi, Ho Chi Minh City, and Hai Phong) among service providers who were 18 years old or above, directly providing services to MSM, and working for at least three months in an ART clinic. PrEP acceptability was measured by a two-item scale and concern about PrEP use was evaluated by a 17-item scale.

Other variables included demographic characteristics, work experience, the awareness of PrEP-related information, comfort in performing clinical activities for MSM, stigma toward MSM, stigma toward PrEP users, and job satisfaction. The multi-level linear regression model was fitted to investigate the association between PrEP acceptability and concern about PrEP use.

Results: A total of 270 eligible service providers in 46 ART clinics participated the survey. The average age of the participants was 39 (SD: 9.4). The majority of the participants were female (66.7%), counsellor (48.5%), ever received addiction training (72.6%), and ever provide PrEP-related service (68.2%).

The average scores of PrEP acceptability and concern about PrEP use were 8.6 (SD: 1.41, maximum of 10) and 51.8 (SD: 10.06, maximum of 85), respectively. In the multi-level model, awareness of PrEP-related information (β = 0.04, 95% CL: 0.01; 0.07), stigma toward MSM (β = -0.04, 95% CL: -0.07; 0.0002), and job satisfaction (β = 0.02, 95% CL: 0.001; 0.04) were correlated with PrEP acceptability. However, no association between PrEP acceptability and concern about PrEP use were observed (β = 0.02, 95% CL: 0.001; 0.04).

Conclusions: PrEP acceptability was high among ART service providers and it was positively associated with PrEP awareness and job satisfaction but negatively associated with stigma toward MSM. Providing training related to PrEP and LGBT for service providers could improve the acceptability of the PrEP program.

PED651

The value and impact of PrEP expansion depends on underlying epidemiological conditions: an illustration and implications for the HIV epidemic response in the United States

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Background: HIV pre-exposure prophylaxis (PrEP) can greatly reduce the risk of HIV and is a cornerstone of the US's 'Ending the HIV Epidemic' initiative, alongside rapid diagnosis following infection and continuous antiretroviral therapy (ART) engagement. We aimed to determine the cost-effectiveness of PrEP expansion and impact on HIV incidence under different HIV diagnosis and treatment targets in six US cities.

Methods: We defined HIV diagnosis, treatment and PrEP expansion targets as:

1. 95% of persons living with HIV receiving a diagnosis;
2. 95% of persons with diagnosed HIV continuously engaged in ART; and,
3. 50% of high-risk men who have sex with men (MSM) receiving PrEP.

We assumed expansion targets were achieved for each racial/ethnic group (Black, Hispanic/Latinx, and white/other) over a 10-year period (2021-2031). Using a dynamic HIV transmission model calibrated for Atlanta, Baltimore, Los Angeles, Miami, New York City, and Seattle, we estimated averted HIV infections, quality-adjusted life-years (QALYs), total costs and incremental cost-effectiveness ratios (ICERs) for PrEP expansion compared to the status quo, the diagnosis target and both the diagnosis and treatment targets (healthcare perspective; 20-year time horizon; 3% annual discount rate, 2018$US).

Results: Expanded PrEP coverage reduced cumulative HIV infections by 7.2% in Seattle to 33.8% in Baltimore (Figure) between 2021-2031 compared to the status quo. Estimated reductions in HIV infections due to PrEP expansion decreased as subsequent targets were met and meeting all targets reduced cumulative infections from 30.9% in Seattle to 58.2% in Los Angeles. In all but Miami, ICERs for PrEP expansion increased, indicating decreasing incremental value, as subsequent targets were met (Figure).

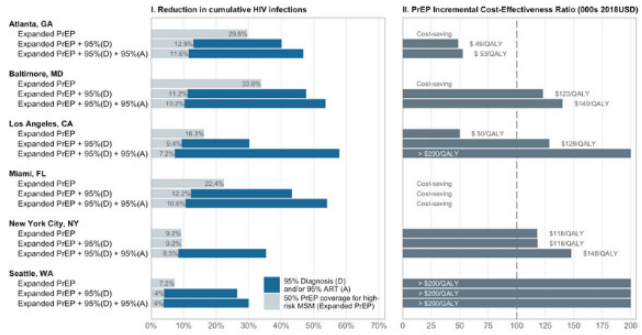

Figure. Estimated reductions in cumulative HIV infections (2021-2031) and incremental cost-effectiveness ratios (2021-2041) for expanded pre-exposure prophylaxs (PrEP) targeted to high-risk men who have sex with men.

Conclusions: The value provided by expanded PrEP coverage varied according to local context while the incremental impact and value provided by expanded PrEP in each city decreased as HIV diagnosis and treatment coverage targets were achieved.

PED652

Understanding barriers and challenges to PrEP adherence: experiences of PrEP discontinuation among MSM and Transwomen in Peru - The ImPrEP Demonstration Study

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Background: The ImPrEP Study is a Pre-Exposure Prophylaxis (PrEP) implementation study, which since 2018 has provided Daily-oral PrEP to over 2000 MSM and Transgender Women (TW) in Peru. However, various circumstances have led several participants to discontinue PrEP. This qualitative study sought to understand the reasons behind PrEP discontinuation.

Methods: Individual in-depth interviews (IDI) were conducted with 14 former ImPrEP participants (10 MSM and 4 TW) from 3 sites in Peru. We adapted a five-domain ecological model to theoretically explore the reasons for PrEP discontinuation: individual, sexual behavior and preventive practices, disclosure with the community, health care interactions, and structural barriers.

Results: PrEP discontinuers had multiple (including some serodiscordant) sexual partners; and many were sex workers, but their HIV risk perception was low. Most were offered PrEP when visiting the clinic for testing or condoms rather than seeking out PrEP. Some felt that PrEP could allow them to experiment sex without condoms. However, they found several issues with PrEP, such as: difficulties maintaining the daily regimen

and overcoming side effects; managing PrEP disclosure (e.g. to family, friends and partners, as PrEP-related stigma led to criticism about the effectiveness and utility of PrEP, their sexual identity and HIV status, and affected adherence); concerns about real PrEP effectiveness; health providers' indications about concomitant condom use; and preference for condoms given their capacity to prevent STIs (although their condom use was inconsistent). Their PrEP use was often circumstantial, based on their partnership situation, or sex perceived as risky.

While health providers played an important role in PrEP adherence, the limited capacity of health facilities to deliver PrEP was a structural barrier for participants, especially for those who required more tailored support (e.g. more frequent follow-ups, more permanent communication, or flexible visit schedules).

Conclusions: PrEP discontinuers in ImPrEP-Peru stopped using PrEP due to a combination of: low HIV-risk perception, lack of commitment to PrEP use, limited belief in PrEP effectiveness, and difficulties dealing with PrEP "demands". PrEP-related stigma poses uptake and adherence barriers that arise from their social environment, and Health services should adapt further to meet the needs of marginalized populations.

PED653

Sexual pleasure patterns among real life PrEP users and their characteristics in the ANRS Prevenir study

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Background: Pleasure seeking is at the core of individual's prevention choices. Among men having sex with men (MSM), it has been associated to a lower level of condom use, and seems to be a strong incentive for initiating PrEP, as demonstrated in the ANRS-Ipergay trial. We investigated whether different sexual pleasure patterns existed among MSM in the ANRS-Prevenir study.

Methods: ANRS-Prevenir is an ongoing study launched in May 2017, in the Ile-de-France region. Quarterly online self-questionnaires collected participants' sexual behavior. Analyses used data until June 2020. Sexual pleasure at the most recent sexual intercourse (MRSI) was assessed using a 5-point scale (1=very weak to 5=very high). Group-based trajectory modeling was implemented to identify the existing patterns. Baseline participants' characteristics were compared between patterns.

Results: Among 3067 participants enrolled in the study, 2631 had information about sexual pleasure representing 12528 questionnaires/visits up to 18-months follow-up.

Four sexual pleasure trajectories were identified: "systematic low-pleasure" (SLPL, 23.8% of participants); "systematic medium-pleasure" (SMPL, 62.9% of participants); "increasing-pleasure" (IPL, 6.3% of participants); "decreasing-pleasure" (DPL, 7.0% of participants).

At baseline, participants in "SLPL" and "SMPL" trajectories were younger (median[IQR] age was 36.7[29.4-43.9] and 36.1[29.4-43.6] years, p<0.001) than those in "IPL" and "DPL" (40.3[31.6-47.5] and 39.2[30.6-46.4] years). "SLPL" and "SMPL" had also lower proportion of participants (35% and 42%) not living alone than "IPL" and "DPL" (46% and 53%, p<0.001).

However, the "SLPL" and "SMPL" trajectories had the largest proportions of participants declaring not satisfying sexual life (44% and 22% respectively, compared to 17% or less in the other trajectories, p<0.001).

Finally, "DPL" trajectory had the largest proportion of participants perceiving a high sexual risk (21% vs 17% or less, p=0.018) and not using condoms at MRSI (84% vs 74% or less, p<0.001). No difference between trajectories was found according to PrEP status at enrolment (already on PrEP vs starting, p=0.292).

Conclusions: Unlike some other prevention strategies, PrEP seems to have no major impact on sexual pleasure, as the majority of PrEP users were in stable patterns during the whole follow up. However, further analysis is needed to understand the drop of pleasure experienced by some participants during the study.

PED655

Providing free PrEP to low income men having sex with men and trans individuals in a community setting in Berlin, Germany: the PrEP500 cohort

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Background: Pre-exposure prophylaxis (PrEP) is effective in preventing HIV transmission, but socio-economic differences impact the use of PrEP among MSM and trans populations. To improve PrEP uptake among socioeconomically disadvantaged MSM and trans individuals in Berlin the Prep500 program was implemented in Checkpoint BLN. Prep500 included free provision of PrEP, counselling and regular screenings for sexually transmitted infections (STI) in a community setting. The program started in 11.2018, last patient inclusion was 08.2019 because PrEP became generally available since it was covered by health insurance in Germany.

Methods: We included 224 individuals at baseline, 177 participants had at least one follow up STI examination and 160 answered the follow up questionnaire. Patients were followed up regularly for 48 weeks. We looked into sociodemographic characteristics and current STI prevalence at baseline, and for the follow up sample into bacterial STI incidence, and changes in sexual risk contacts, risk perceptions and sexual satisfaction.

Results: Cis-male MSM accounted for 87.6%, while 11.5% identified as trans or non-binary. Mean age was 34 years. Only 31.3% of participants were born in Germany, 23.5% were from Syria. Two third had a net income of <750 EUR. One third reported prior use of PrEP with 19.8% taking PrEP at study begin. At Baseline 11.1% tested positive for chlamydial and 4.5% for gonococcal infection, 2.2% had an active Syphilis. No HIV infections occurred during the observation period (132,67 py). 49% participants were diagnosed with at least one bacterial STI: 10 Syphilis infections, 72 chlamydial and 90 gonococcal infections. Among participants without current PrEP use at baseline high-risk contacts decreased by 91%, while number of sex partners and condomless intercourse did not increase. HIV risk perception and concern regarding HIV infection declined and sexual satisfaction increased in the group.

Conclusions: PREP500 demonstrated the feasibility of providing PrEP in a community setting in Germany. PREP500 helped increase PrEP uptake among low income MSM and trans individuals in Berlin before PrEP was covered by health insurance. It was effective in targeting economically disadvantaged and other hard-to-reach MSM and trans individuals and in reducing HIV transmission risks.

PED656

Oral PrEP consultations among adolescent girls and young women in Kisumu County, Kenya: insights from the DREAMS program

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Background: In May 2017, Kenya nationally scaled up oral pre-exposure prophylaxis (PrEP). However, PrEP utilization among adolescent girls (AG, aged 15-19 years) and young women (YW, aged 20-24 years) is suboptimal. To inform service delivery, we analyzed PrEP consultations—interactions with a health care provider about PrEP—among AGYW enrolled in DREAMS in Kisumu county, Kenya.

Methods: In April-June 2018, surveyors captured AGYW's self-reported knowledge, attitudes, and practices related to HIV risk and service access. Using an age-stratified sub-sample of HIV negative sexually active AG (n=154) and YW (n=289), we established the total target population (number with ≥1 Ministry of Health PrEP eligibility criteria [i.e., PrEP-eligible]), examined individual and cumulative PrEP eligibility criteria in relation to PrEP consultations, and used prevalence ratios (PR, adjusted: aPR) to measure associations.

Results: Most AG (139/154 [90.26%]) and YW (272/289 [94.12%]) were PrEP-eligible, primarily due to inconsistent/no condom use and experiences of violence or STIs. More PrEP-eligible (24.46%) than -ineligible AG reported high perceived HIV risk. Among PrEP-eligible YW, more were ever-married (54.41%), ever-pregnant (80.88%), and out-of-school (78.31%) compared with PrEP-ineligible YW. For PrEP-eligible AGYW, more AG were in-school (52.52%), while more YW were ever-orphaned (58.09%), ever-married, and ever-pregnant. More PrEP-eligible YW reported PrEP consultations than AG (41.18% vs. 24.46%, aPR=1.49 [1.04-2.15]).

YW engaged in transactional sex reported more consultations (58.62% vs. 39.09%, p<0.05), but only PEP use (aPR=2.80 [2.30-3.43]) and multiple partnerships (aPR=1.39 [1.06-1.18]) were independently associated with PrEP consultations. Among AG, PEP (post-exposure prophylaxis) users reported more consultations (93.75% vs. 15.45%, aPR=5.64 [3.54-9.01], controlling for travel outside the community).

Overall, consultations were low (i.e., <50%) across most criteria totals, especially among those with 1 criterion (AG=11.11%/YW=27.18%). Comparatively, consultations were higher among AG and YW with 2 (aPR=3.70 [1.64-8.34], PR=1.60 [1.07-2.38], respectively) or ≥3 (aPR=2.50 [1.09-5.72], PR=2.05 [1.42-2.97], respectively) criteria.

Conclusions: Almost all AGYW in our study were PrEP-eligible but few reported PrEP consultations, with significant differences by age and vulnerability. In high HIV-risk settings, PrEP consultations should be conducted with all AGYW. PrEP provision guidelines and their implementation need to be assessed and revised to accelerate PrEP access for at-risk AGYW.

PED657

"Our culture kills us." Effective community based communication of HIV pre-exposure prophylaxis (PrEP) in Eswatini

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Background: Community Leaders (CLs) play an important role in community acceptance of public health services in Eswatini. Despite CLs reach and intimate cultural knowledge, little is known about CLs experience or willingness to promote PrEP within their communities. Developing a better understanding of acceptance and promotion of PrEP by CLs is essential for future PrEP scale up and delivery.

Methods: We conducted in-depth-interviews with (n=26) purposefully selected CLs (n=11 female and n=15 male) from Hhohho region, Eswatini. Data were collected in 2019 as part of a formative research component of the Eswatini PrEP demonstration project where PrEP was made available to the general population in six primary-care, nurse-led clinics. Qualitative data analysis was informed by an inductive approach of Thematic Analysis and coded using NVivo Pro 12.

Results: Following the communication / persuasion matrix approach, we identified CLs, traditional healers and religious leaders as important communicators in culturally relevant PrEP messaging. CLs believe the leaders provide and access unique and effective communication channels as their communities identify with them personally and culturally.

Community meetings, religious services and church groups are considered effective and widely accessible channels to promote PrEP because communities trust and prefer their leader´s expertise more than health workers in clinic settings.

However, CLs said a persistent challenge is the misuse of these wide reaching channels to maintain false and stigmatizing messages about HIV. Finding methods to address this longstanding problem within the context of a novel HIV prevention approach was a priority for CLs. CLs are highly motivated to be involved in HIV prevention and would like to receive further training on PrEP.

Conclusions: CLs, religious leaders and traditional healers in Eswatini can play a significant role in the support of PrEP uptake and use. Active involvement in PrEP training and promotion alongside healthcare workers might not only increase the persuasive impact of the intervention on their audience but may also reduce the spread of false and stigmatising messaging.

With their cultural knowledge and influence, CLs can improve the design and dissemination of effective PrEP messages, tailored to the needs of each target audience.

PED658

"I had condomless sex, but I'm calm because I use PrEP": Experiences of adolescent's men who have sex with men and transgender women with daily oral PrEP in Brazil

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Background: Data on experiences of daily oral pre-exposure prophylaxis (PrEP) use among adolescent key populations (AKP) of men who have sex with men (MSM) and transgender women (TGW) have shown that adherence to PrEP and its continuation is still a challenge.
We aimed to analyze individual and social experiences related to the use of PrEP among AKP participants of the PrEP1519 Study.
Methods: PrEP1519 is the first PrEP demonstration cohort study, among AKP aged 15-19 y.o., ongoing in 3 Brazilian cities. Twenty semi-structured interviews were conducted, between June 2019 to June 2020 (17 MSM, 3 TGW), during their PrEP follow-up visit. Interviews were transcribed, coded and a thematic analysis was performed on NVivo software.
Results: The experiences related to the daily use of PrEP have highlighted the positive role of health service, such as friendly LGBTQI+ environment, young health team, accessible location, cash reimbursement to pay for lunch and transportation, and peer navigators to support adherence to PrEP and specific needs (eg hormone therapy doubts and listening family's problems). But individual and social issues related to the use of PrEP in the beginning were also noticed: pill size, handling of missed doses, lack of experience with sustained medication use, and possible mild side effects.
Besides, most of them reported the need to hide the PrEP pills from family and friends, in order to avoid stigmatization because it could be seen as a symbol of "promiscuity" or as a sign of a non-heteronormative sexual orientation, and also to avoid suspicions about being infected with HIV.
Nevertheless, these barriers did not prevent PrEP continuation. TGW reported initial concerns about possible interactions between PrEP and hormone therapy. The occurrence of missed doses was minimized by the use of an alarm clock and combined intake time for PrEP and hormone pills.
Conclusions: Friendly and non-judgmental environment were central to the positive experiences of daily PrEP use. It evidenced to be effective for PrEP retention and adherence as well.
Fear of stigmatization and difficulty in sustaining a disciplined intake practice of daily PrEP pointed to the need for permanent support for AKP users of PrEP.

PED659

Depressive symptoms and heavy alcohol use predict transmission risk behaviors among new oral PrEP clients in Kenya: results from a prospective cohort study

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Background: Risky sexual behaviors are key to oral PrEP eligibility determination. However, little is known about whether depressive symptoms and heavy alcohol use intersect with HIV transmission risk behaviors (TRB). The co-occurrence of these three issues has the potential to influence effective PrEP use. We examine the relationship between depressive symptoms, heavy alcohol use, and TRB among individuals initiating PrEP through the Jilinde project.
Methods: We enrolled 1,135 consenting individuals in a prospective cohort survey conducted in 16 facilities in ten counties in Kenya. Participants were newly initiated PrEP clients. Each completed an interviewer-administered questionnaire at baseline, and 3, 6, and 12 months thereafter. Sexual behavior (number and type of partners), condom and alcohol use were assessed on each day for two-weeks preceding each survey date using the timeline follow-back method. Depressive symptoms were assessed using the Patient Health Questionnaire (PHQ-9). A PHQ-9 score of 10 or more was suggestive of moderate to severe depression. TRB was defined as sex that involved either multiple or non-regular partners without consistent condom use. Bivariate and multivariate logistic regression models were used to measure the association between depressive symptoms, heavy alcohol use, and TRB.
Results: Complete baseline data were obtained for 877 participants and included in the analysis. The majority were female (91%) and younger than 30 years (76%). Overall, 47% reported TRB.
Further, 21% and 31% reported severe and mild depressive symptoms, respectively, while 32% reported heavy alcohol use using NIAAA classification. Moderate to severe depressive symptoms predicted a TRB (aOR: 1.66; 95%CI: 1.09, 2.53; p=0.018), as did heavy alcohol use (aOR: 2.83; 95%CI: 1.93, 4.14; p<0.001).
Additional predictors included moderate alcohol use (aOR: 1.74; 95%CI: 1.09, 2.77; p=0.020), being a female sex worker (aOR: 4.71; 95%CI: 2.98, 7.47; p<0.001) and being single (aOR: 0.58; 95%CI: 0.36, 0.93; p=0.025).
Conclusions: Depressive symptoms and heavy alcohol use were prevalent among new PrEP clients. Both are associated with HIV risk and thus PrEP candidacy but may compromise effective PrEP use.
PrEP programs should consider routine screening for depressive symptoms and alcohol use, alongside PrEP eligibility determination, and implement interventions to address these issues to optimize PrEP effectiveness.

PED660

Condomless sex and partner safe sex conflict: a latent class analysis among at-risk Black and Latinx sexual and gender minority youth (BLSGMY) assigned male sex at birth

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Background: Pre-exposure prophylaxis (PrEP) uptake in Black and Latinx sexual and gender minority youth (BLSGMY), assigned male sex at birth is sub-optimal. Individual and partner factors have been suggested as a reason for uptake, however little research explores individual, relationship, and partner conflict patterns associated with HIV risk perception, PrEP willingness, and PrEP use.

Methods: 306 BLSGMY age 15-24 years old from 4 urban U.S. cities, who reported behavioral risk for HIV and had HIV negative status, completed a self-administered, electronic survey focused on demographics, sexual health, and HIV risk perception. Latent Class Analysis was used to identify patterns of vulnerabilities for HIV using MPlus v.8. Indicators included:
Individual: lifetime - HIV testing, STI diagnosis, and exchange sex; and condomless sex in the past three months;
Partner: PrEP use; and,
Partner conflict: coerced sex, pressure to forgo condoms and arguments about using condoms.
Covariates of class membership included age, gender identity, ethnicity, degree of attractedness to women, education, employment, and insurance. Explored class characteristics associated with HIV risk perception (8-item perceived risk of HIV scale (PRHS-8; Napper et al., 2012)), PrEP willingness, and PrEP use.

Results: Three classes demonstrated the best balance of model fit and parsimony.

	Individual				Partner	Partner Conflict		
	Condomless Sex	HIV Testing	Positive STI Diagnosis	Sex Exchange	Partner PREP use	Forced Sex	Pressure to Forgo Condoms	Arguments about Condoms
Class 1	0.81	0.83	0.613	0.411	0.73	0.719	0.784	0.662
Class 2	0.706	0.838	0.529	0.211	0.493	0.007	0.353	0.246
Class 3	0.506	0.365	0	0.006	0.014	0.031	0.202	0

Age was associated with class membership with Class 2 and 3 more likely to be younger than Class 1. Class 3 had lower HIV risk perception, lower willingness, and higher PrEP use than both Class 1 and 2 (p-value <0.01). Class 2 had lower willingness to take PrEP than Class 1, but this only approached significance (p-value 0.059).

Table: Class Characteristics

Conclusions: Analyses suggest 3 patterns emerge that have different levels of condomless sex, partner conflict, and PrEP use among BLSGMY. These patterns of youth suggest those who could most benefit from PrEP are accessing PrEP, however, at sub-optimal levels; while younger youth may have used PrEP less, lower risk perception, and be less willing to use, despite moderate condom use and experiencing pressure to forgo condoms.
PrEP may provide one strategy for youth who experience partner conflict around condoms to prevent HIV acquisition as it relies less on partner involvement. In order to end the HIV epidemic, future research will need to develop different strategies to support different BLSGMY with these experiences in PrEP care.

PED661

"Reaching adolescents where they are": Innovative recruitment strategies for PrEP enrolment of adolescent´s key population in Brazil

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Background: In Brazil, HIV incidence has been growing in the past decade among adolescent´s key population (AKP), such as men who have sex with men and transgender women. PrEP1519 is a demonstration study that offers HIV combination prevention, including oral daily PrEP, to these groups in three Brazilian capitals, and uses culturally appropriate recruitment strategies.
We aimed to analyze the perceptions of AKP about the recruitment strategies implemented in the PrEP1519 study.

Methods: Qualitative study nested in the PrEP1519 study. Seventy-one semi-structured interviews were conducted with AKP from Salvador (SSA) and São Paulo (SP) between June 2019-June 2020 (54 MSM and 17 TGW; 46 oral PrEP users and 25 users of other prevention methods).
Participants were recruited by peer educators who engaged with MSM and TGW at social venues, in schools – PE (16); online platforms and apps – OP (15); direct referrals from health services – RHS (20); referrals from friends and partners – RFP (14); NGOs (06). Interviews were transcribed and coded by NVivo12.

Results: In SP, the majority of respondents were recruited by RHS (20), while in SSA by RFP (13) and OP (12) stood out. MSM participants were recruited by all strategies in both cities, and TGW were recruited mostly by RHS in SP and by RFP in SSA. Participants perceived these different strategies as friendly, informative and contributing to their awareness of HIV prevention methods. Being reached by PE (12) was perceived as good strategy to raise awareness and interest in oral PrEP. Being reached by OP (15) was perceived as an innovative strategy capable of reaching AKP at substantial risk of HIV. All participants reported that recruitment actions for PrEP or other prevention methods broadened their perceptions of risk and knowledge about HIV prevention.
The results show that adolescents feel more welcome, not judged, interested in care through these recruitment strategies.

Conclusions: Recruitment strategies implemented by PrEP1519 were perceived as friendly and informative, thus increasing adolescents' awareness of and interest on HIV prevention methods.
Studies including MSM and TGW need to consider the sociocultural contexts of these two groups since different recruitment strategies may work better to each of them.

Post-exposure prophylaxis

PED662

Findings from the Ngutulu Kagwero (agents of change) participatory comic intervention to increase post-exposure prophylaxis knowledge and acceptability among refugee youth and healthcare providers in a humanitarian setting in Uganda

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Background: Sexual and gender-based violence disproportionately impacts children and youth in humanitarian settings. Yet there is a dearth of evidence-based post-rape clinical care interventions, including those focused on post-exposure prophylaxis (PEP), tailored for refugee youth living in humanitarian contexts.
We developed and pilot-tested the Ngutulu Kagwero (agents of change) participatory comic intervention focused on sexual violence prevention and post-rape clinical care with youth and healthcare providers in Bidi Bidi refugee settlement, Uganda.
Methods: This sequential mixed-methods study involved a formative qualitative phase followed by a participatory workshop in Bidi Bidi. In-depth interviews and focus groups were conducted with refugee youth sexual violence survivors (n=58) (aged 16-24), elders (n=10), and healthcare providers (HCPs) (n=10) in Bidi Bidi.
Qualitative data were analyzed thematically to develop a participatory comic book about refugee youth sexual violence experiences [Figure 1].

Figure 1.

Refugee youth (aged 16-24) and HCPs participated in a 1-day peer-facilitated sexual violence and PEP workshop with comic-book discussions and activities. Surveys were conducted immediately before, after, and 2-months following workshops to assess PEP knowledge and acceptance, and differences were assessed using McNemar's Test with Fisher's exact correction.
Results: Among refugee youth (n=120), PEP knowledge significantly increased from 60.0% before to 99.2% following the workshop (p-value=<0.001). PEP acceptance was high among youth both before and after the workshop, 91.7% and 97.5% respectively (p-value=0.065). All HCPs (n=20) were knowledgeable and accepted PEP before and after the workshop.
Almost all HCPs reported having PEP guidelines at work (95.0%) and prescribing PEP to patients after experiencing sexual violence (80.0%). PEP practice was high: 23.3% of youth and 30.0% of HCPs reported every taking PEP.
Conclusions: In humanitarian settings, survivor-informed comics hold promise in increasing refugee youths' knowledge of HIV prevention strategies such as PEP, and informing health care providers of youth-friendly post-rape care clinical approaches for refugee sexual violence survivors.

Risk compensation: conceptualisation, assessment, and mitigation

PED663

Community- versus individual-level risk compensation with HIV preexposure prophylaxis among men who have sex with men

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Background: HIV preexposure prophylaxis (PrEP) has been shown to increase sexual risk behaviors after PrEP initiation (risk compensation) among men who have sex with men (MSM). However, risk compensation may also emerge among PrEP non-users in communities with high PrEP coverage.
Methods: We used demographic, behavioral, and sexual network data from ARTnet, a cross-sectional web-based study of US MSM conducted during 2017–2019. Multivariable regression models were used to estimate the association between community-level PrEP usage and six sexual behavior outcomes: total, main, and casual partnership network degree; rate of one-time partnerships; consistent condom usage in one-time partnerships; and coital frequency within persistent partnerships.
Community-level PrEP coverage was estimated from ARTnet and National HIV Behavioral Surveillance studies.
Results: PrEP coverage ranged from 38.9% (San Francisco) to 10.3% (Philadelphia). Total degree was highest in Miami (1.35) and lowest in Denver (0.78), while the rate of one-time partners was highest in San Francisco (11.7/year) and lowest in Detroit (1.54/year).
Adjusting for individual PrEP use, age, and race, ARTnet-based community-level PrEP coverage was associated with higher total degree (adjusted incidence rate ratio [aIRR]=1.57; 95% CI, 0.97–2.56), but lower coital frequency within persistent partnerships (aIRR=0.12; 95% CI, 0.07–0.23).
There was less evidence for association with main degree (aIRR=1.24; 95% CI, 0.57–2.69), casual degree (aIRR=1.80; 95% CI, 0.86–3.38), count of one-time partners (aIRR=1.56; 95% CI, 0.60–4.06), and consistent condom use in one-time partnerships (adjusted prevalence ratio [aPR]=1.08; 95% CI 0.85–1.38).

		Community-level Current PrEP Coverage Determined from ARTnet (n=3,259)				Community-level Current PrEP Coverage Determined from NHBS, 2017* (n=1,433)			
		Adjusted for Individual PrEP Status, Age, and Race		Adjusted for Age and Race		Adjusted for Individual PrEP Status, Age, and Race		Adjusted for Age and Race	
Outcome	Measure of Association	Adjusted Value	95% Confidence Interval	Adjusted Value	95% Confidence Interval	Adjusted Value	95% Confidence Interval	Adjusted Value	95% Confidence Interval
Total degree†	IRR	1.57	(0.97, 2.56)	2.84	(1.76, 4.58)	1.14	(0.73, 1.79)	1.66	(1.07, 2.58)
Main degree	IRR	1.24	(0.57, 2.69)	1.19	(0.56, 2.56)	1.14	(0.55, 2.34)	1.14	(0.56, 2.34)
Casual degree	IRR	1.80	(0.96, 3.38)	5.08	(2.75, 9.38)	1.10	(0.62, 1.95)	2.05	(1.17, 3.6)
Count of one-time partners	IRR‡	1.56	(0.6, 4.06)	23.48	(8.62, 63.93)	1.23	(0.54, 2.8)	6.97	(2.87, 16.97)
AI rate within persistent partnerships, per week	IRR	0.12	(0.07, 0.23)	0.13	(0.07, 0.24)	0.12	(0.07, 0.21)	0.12	(0.07, 0.22)
Always using condoms in one-time partnership(s)	PR§	1.08	(0.85, 1.38)	0.83	(0.64, 1.06)	0.69	(0.56, 0.87)	0.60	(0.48, 0.75)

PrEP, pre-exposure prophylaxis; AI, anal intercourse; NHBS, National HIV Behavioral Surveillance
*Includes individuals in the following cities, as NHBS estimates were not available for US census divisions: Atlanta, Boston, Chicago, Dallas, Denver, Detroit, Houston, Los Angeles, Miami, New York City, Philadelphia, San Diego, San Francisco, Seattle, Washington, DC.
†Degree is the number of persistent partners measured on the day of the survey completion. Total degree includes both main and casual persistent partners, main degree includes main partners only, and causal degree includes casual partners only.
‡Because of overdispersion, approximated using negative binomial regression.
§Approximated using Poisson regression with robust variance.

PED663 Table. Multivariable Associations of Community-Level PrEP Coverage and Various Outcomes of HIV-negative ARTnet Participants

Conclusions: Independent of individual-level PrEP use, community-level PrEP coverage was associated with greater sexual network connectivity among US MSM, but less certain impact on other sexual behaviors. Community-level risk compensation could generate new HIV outbreaks among PrEP non-users embedded within sexual networks of PrEP users in high PrEP coverage areas.

Combination HIV prevention

PED664

Interruption of HIV treatment and prevention services among key populations during the COVID-19 pandemic in Malaysia

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Background: In Malaysia, movement control orders (popularly known as lockdowns) were imposed to curb the transmission of COVID-19 in the community which could lead to interruption in essential HIV treatment and prevention services. However, there is very limited information on the extent to which key populations are impacted by COVID-19, especially in the context of restricted movements.
Methods: Between August and December 2020, study participants were recruited among key populations registered at HIV service organizations across Malaysia. Data on sociodemographic, illicit drug use, sexual behaviour and access to HIV services were collected and entered through a web application online survey. The outcome of interest was interruption of any HIV-related services during movement control orders, including needle and syringe exchange program, methadone treatment, condom and lubricant provision as well as antiretroviral therapy. A multivariate model was fit to assess factors associated with service interruption.
Results: Two-hundred ninety-two individuals were included in this analysis, of whom 77 (26%) were people who use drugs, out of which 51 (66%) were people who inject drugs; 73 (25%) transgender; 145 (50%) males; 126 (43%) sex workers and 71 (24%) men who have sex with men. Among study participants, 67 (23%) reported interruption of any HIV services. In the adjusted, multivariate model, participants who reported using drugs in the past one year were more likely to experience HIV service interruption, compared to those who did not report drug use ([AOR] = 2.46, 95% [95% CI]: 1.17 - 5.25, *p*-value = 0.019). Additionally, participants who reported living with family and friends were less likely to have their HIV service interrupted, compared to those living alone (AOR = 0.39, 95% CI: 0.15 - 1.18, *p*-value = 0.006).
Conclusions: Limited access to HIV-related treatment and prevention services is common among individuals reporting drug use, even before the pandemic. These results support the hypothesis that key populations who use drugs were more likely to continue to experience HIV service interruption, compared to other at-risk counterparts. Therefore, findings from our study warrant innovative strategies to engage key populations who use drugs to comprehensive HIV and ancillary health services, especially amidst the pandemic.

School-based sexual education, life skills and gender equality education

PED665

School-based interventions in the context of combination HIV prevention: Impact on adolescent girls' sexual risk behaviours in a rural area KwaZulu-Natal, South Africa

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Background: Adolescent girls and young women (AGYW) in South Africa remain disproportionately at risk of HIV (5% incidence between 2016-2018) and teenage pregnancy. Schools are an opportunity to provide health promotion. Between 2016-2018 school-based interventions (aimed at changing gender and or/risk norms, providing peer support/mentorship, or offering social protection) were rolled-out alongside the standard curriculum-based Life Orientation (LO), as part of a multi-level

package of interventions to reduce HIV incidence in AGYW. We investigated the impact of exposure to LO+school-based interventions in reducing HIV-related sexual risk and health outcomes among adolescents compared to LO alone.

Methods: We recruited and followed-up a representative cohort of AGYW (n=2184) aged 13-22 years in rural KZN over three-years (2017-2019). Logistic regression was applied to investigate the association between exposure to an enhanced intervention (LO+ up to 3 school-based interventions) and a range of sexual and reproductive health outcomes: early sexual debut, inconsistent condom use, and teenage pregnancy. Analyses was restricted to 1623(74.3%) school-going adolescents aged 13-19 at baseline who received different exposures to school-based interventions adjusting for confounders: age, socioeconomic status, and location.

Results: Over half (64.2%;1623) of the respondents were aged 13-19 and eligible for this analysis (2018 and 2019 follow-up rates were 84.8% and 78.4% respectively). Almost all (90%) were in school. 1099(67.7%) were exposed to at least one enhanced intervention. Of the 191(11.8%) adolescents that reported a teenage pregnancy: 68.6% received only LO and 31.4% received an enhanced intervention. Similarly, 16.4% of adolescents who received only LO reported inconsistent condom use, compared to 4.2% from enhanced intervention recipients. Among those reporting an early sexual debut (92/1623), 7.1% received only LO versus 5% enhanced intervention.

Exposure to LO+ three school-based interventions was significantly associated with lower: teenage pregnancy OR=0.27(95%CI 0.19-0.38, P<0.0001), inconsistent condom use OR=0.54 (95%CI 0.40-0.74 P<0.0001) and early sexual debut OR=0.47 (95%CI 0.28-0.78 P<0.002), compared to receiving only LO.

However, after adjusting for confounders, only teenage pregnancy remained significantly associated with enhanced interventions (aOR=0.66, 95%CI 0.45-0.96).

Conclusions: Providing school-based interventions alongside standard LO reduced the risk of teenage pregnancy and has the potential to reduce HIV-related sexual-risk among adolescents.

Community-based approaches, including empowerment, outreach, and service delivery

PED666

Experiences from clients and providers at community ART distribution sites and referring health facilities in Kinshasa, DRC

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Background: Differentiated service delivery models for HIV-positive, clinically stable clients has resulted in higher satisfaction for clients and reduced provider workload. We describe client and provider perceptions and experiences of the *poste de distribution communautaire* (PODI+) model, which provides multi-month dispensation (MMD) of ART plus limited other HIV, TB, nutrition and family planning services through lay cadre-run, community-based sites in DRC. Clients return to health facilities (HF) as needed for medical and laboratory services.

Methods: HIV-positive adults receiving MMD through PODI+ (n=30) participated in in-depth interviews (IDI). All providers at two PODI+ sites in Kinshasa (n=10) and purposively selected health workers (n=11) from seven HF that refer clients to the PODI+ sites also participated in IDI. IDI were conducted between March and June 2019. Topics included the PODI+ package of services and perceived quality, PODI+ referral process, effect on health facilities and recommendations for improvement. Interview recordings were transcribed and translated from French or Lingala into English and coded using MAXQDA 2020 software. Data were analyzed using thematic analysis by participant group.

Results: PODI+ clients reported high levels of satisfaction with PODI+ service delivery. The most commonly cited advantages of PODI+ over traditional care by PODI+ clients and staff included comprehensive counseling, welcoming reception, friendly provider interactions, privacy (e.g., primarily HIV-positive clients accessing clinic), and waiting times. Challenges included distance to PODI+, high transport costs and threats to privacy from other building tenants and neighbors. Some PODI+ clients advocated for expanding services (e.g., viral load testing, nutritional/ financial assistance). However, PODI+ staff felt this would change what clients like best, such as short wait times and in-depth counseling when needed. Most health workers experienced reduced workload following PODI+ introduction, though there was some resistance to referring clients, citing client objections to changing their care and poor follow-up communication on previously transferred clients.

Conclusions: Clients were highly satisfied with PODI+ services. Scale-up of the PODI+ model would bring services to more communities, closer to where clients live, addressing distance and cost challenges. Optimization of the model is also dependent on improved provider cooperation and orientation of potential clients.

PED667

Impact of social protection (combined cash transfer receipt and food security) on child cognition and education for children affected by HIV in South Africa and Malawi

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Background: Children affected by HIV may suffer from economic hardship as well as developmental challenges. Social protection interventions may be of benefit. These can take many forms. Both cash transfers and food security may have important contributions to child cognitive development.

This study examines the potential impact of combinations of cash transfers and food security status on child cognitive development and educational outcomes.

Methods: Cross-sectional data for 796 HIV-affected children was utilised for these analyses. Children and caregivers affected by HIV, attending community-based organisations completed interview schedules comprised of standardised items on socio-demographics, household data, cash grant receipt and food security status, school achievement, and cognition. A series of logistic and linear regression models inclusive of marginal effects analyses were undertaken to explore the impacts of differing levels of social protection (none; either cash grant receipt or food secure status or both in combination) on child educational and cognitive outcomes. Covariates controlled for in the models included child biological sex, child age, child HIV status, number of household assets.

Results: 13.8%(110/796) of children were living with HIV. 20%(157/796) of children did not receive a cash grant and did not report food security; 32.4%(258/796) reported either component of social protection and, 47.9%(381/796) received both measures of social protection in combination. Compared to no social protection, being in receipt of either component of social protection was found to be associated with being in the correct class for age, higher scores of non-verbal cognition, and higher memory scores. Receiving both social protection measures in combination was found to be associated with reduced educational risk scores, improved odds of being in the correct class for age, regular school attendance, missing less than a week of school in the previous two weeks, higher scores on measures of nonverbal cognition, higher memory scores, and learning new things more easily.
Conclusions: Educational and cognitive outcomes for children affected by HIV can be bolstered by social protection measures. Benefits are enhanced when social protection is received in combination. Such findings support the notion of synergistic social protection responses for children living in environments impacted by high levels of HIV burden and deprivation.

PED668

SelfCare: a community-based demonstration study on the acceptability and feasibility of HIV self-screening among men who have sex with men and transgender women in Metro Manila, Philippines during COVID-19 quarantine

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Background: Despite the accessibility of the testing and awareness about HIV in the Philippines, a portion of the population is still hesitant to visit facilities to get tested. The imposed community quarantine due to the COVID-19 pandemic limited this access even further. This project headed by LoveYourself, a community-based organization, aims to conduct a demonstration study of HIV self-screening (HIVSS) among men having sex with men (MSM) and transgender women (TGW) in Metro Manila and to evaluate its feasibility and acceptability.
Methods: The selected participants were 18-49 years old, MSM or TGW, living or working in Metro Manila, not diagnosed HIV-positive, and not on HIV PrEP. The recruited participants were given the self-screening kit with instructional materials (both printed and a link to an online instructional video), key messaging strategies (developed by volunteers), and a 24-hour hotline that they could access for concerns. Digital assistants, Cat and Pao, were created to explain the whole process and what to do next, whether the client is non-reactive or reactive. Peer volunteers were on standby in various channels for guidance, counseling, and linkage to confirmatory testing.
Results: Because of the COVID-19 quarantine, what was initially slated to be a 12-month project only lasted for a month. There were 2,543 qualified participants, 1,690 received their kits, and 1,281 reported their results via an automated system. After validation of the results, 1,169 were non-reactive, 94 tested reactive, and 18 had an invalid result. Among the reactive participants, 56 were linked to confirmatory testing and began their HIV treatment, with 35 of them being first-time testers.
Conclusions: In total, there were 4,163 that expressed their interest to be included in the demonstration study, showing high demand for HIVSS in the country. There was also high reporting rate of the participants (1,281/1,690, 75.8%) regardless of their HIV status. The study also showed a high reactivity rate demonstrating that this can be another way to reach the rest of the target population for testing. Providing different avenues for the clients to report the results in the most discreet way possible is essential. This service is strongly recommended for future use and scaling.

PED669

Effectiveness of home based care model in the treatment, care and support for persons living with HIV in Turkana Central Sub County, Turkana County

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Background: Turkana County with a population of 1,045,579, is estimated to have 22,136 people living with HIV, among them children are estimated to be 2, 536 (KAIS Estimates, 2018). The County has a prevalence rate of 3.6 % among the adults. The Global Fund HIV program funding through Kenya Red Cross Society is among the partnerships that has been in the fore front in the bridging the gap for the achievement of sustained impact in the fight against HIV & AIDS. The grant is implemented by World Vision Kenya in collaboration with Ministry of Health, Turkana County.
Description: Retaining PLHIV on Highly Active Antiretroviral Therapy (HAART) is key to achieving viral suppression. For this to be achieved, the program employed a Home-Based Care (HBC) model where at most 20 PLHIVs were linked to one Community Health Volunteer (CHV) for follow up at the household level monthly and provided; health education, psychosocial support, nutritional and adherence counselling. The Program currently supports ninety-six (96) CHVs, who have followed up 1,669 clients. Data drawn from the DHIS was used to conduct a comparative analysis on performance of facilities supported by the program against randomly selected health facilities that are not supported by the HBC program.
Lessons learned: The findings show that retention rates for facilities supported by the program was 59.4 %, as opposed to 51.8% for facilities not supported by the program. Further, at a p-value of 0.036, showed significant statistical impact of the program on the retention rates. The monthly follow-ups by cHVs at the household level is an approachwhcich has high impact and can be sustained with minimal investment.
Conclusions/Next steps: The findings affirm that indeed the Home-Based Care model is effective in improving treatment, care and support outcomes for PLHIV. As a sustainability measure, the program intends to transition the CHVs and SGL to the county government in order to sustain the gains. This model could be up-scaled to other facilities across the county for PLHIV to receive viral suppression.

PED670

A novel participatory learning collaborative approach to expand STI services for Nigerian youth

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Background: The uptake of sexually transmitted infections (STIs) is sub-optimal among young people in Nigeria. This study examined the impact of participatory learning collaboratives that combined open contests and apprenticeship training on the design, refinement, and pilot implementation of STI services targeting young people aged 14-24 in Nigeria.

Description: Between 2018 and 2020, we organized four participatory learning collaboratives to increase the uptake of STI services in Nigeria – an open call, a designathon, apprenticeship training bootcamp and pilot feasibility trial. The open call solicited creative ideas to promote youth-friendly services, then had experts evaluate them. The designathon brought together diverse youth teams to further revise their ideas from the open call and incorporate feedback from mentors. Teams determined to be exceptional from the designathon were invited to a four-week capacity building innovation bootcamp. Selected teams from the bootcamp were then supported to pilot-test their youth-friendly STI services in their community over a 6-month period. Participation was measured using the 12-item Tiffany-Eckenrode program participation scale.

Lessons learned: A total of 2,962 Nigerian youth participated in the four learning collaboratives (2,403 for the open calls, 127 for the designathon, 45 for the bootcamp and 387 for the pilot trial).

We observed substantial youth participation (mean score: 37.2/48.0; SD=7.3). The youth noted that these participatory activities provided agency for them to be involved in more than a consultative or advisory capacity, including in the design of the intervention as youth researchers.

The iterative nature of the learning collaboratives built trust and helped to reinforce relationships between youth, government leaders, and public health officials. This bottom-up approach helped to tailor services to be more youth-friendly in the local context.

Conclusions/Next steps: Convening a participatory learning collaborative is a promising approach for developing and implementing novel youth-led STI services in low resource settings. This approach could be used to enhance active youth participation and leadership in the design and implementation of youth-friendly health services.

PED671

Reducing vulnerability to TB co-infection and morbidity of opportunistic infections from biomass fuel-household air pollution amongst positive women & children in rural households in Kisumu county

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Background: The level of exposure to Bio-Mass Fuel (BMF) pollutants in rural poor households is 100 times greater than the UN recommended maximums. A normal child is 2 to 3xmore likely to contract ALRI while women are 4x more likely to suffer from COPD since most women spend a lot of time indoors with children by their side.

However, HIV+ Women and children are 5 - 10times more exposed to health effects of BMF-Household Air Pollution (BMF-HAP). The health effects of BMF-HAP may arise after just a single exposure and/or long or repeated exposure.

The short-term effects are treatable; however, the long term effects can be severely debilitating and/or fatal. BMF-HAP pollutants are involved in altering macro-phage function thus increasing vulnerability to active Pulmonary TB.

Description: We conducted a study over a period of 60months to investigate the general health effects of BMF-HAP in poor rural households of PLWHA in Kisumu County when switching from the traditional BMF sources to simple low cost modern alternative energy Solutions. Special consideration was given to women, infants and Children under 10years in each of the households. Analysis was done on all diseases but special emphasis was given to TB, ALRI, COPD and eye infections.

Lessons learned: Over 65% children and 66% women reduced incidences of respiratory Tract infections within 21days. There was a 60% deceleration in the development of ALRI among children and 80% decelerated development of COPD among women within 6months. Over 95% experienced over 90% reduction in the short-term effects of BMF-HAP. There was 30% reduction in Pulmonary TB infection.

Conclusions/Next steps: Using BMF is a common human daily activity that increases the vulnerability to TB and other diseases. A combination of HIV infection and exposure to BMF-HAP is a double tragedy to women & children. BMF-HAP is responsible for the deaths of over 1.1 million women and children. Reducing BMF-HAP is a new frontier and a viable HCBCS strategy that focuses on a Community/Human Behaviour Change in the fight against HIV/AIDS & TB. It improves indoor air quality and lower the health risks and eventually improve health outcomes in the HIV treatment.

PED672

HIV and COVID-19 during a national lockdown: results of a phone-based survey of participants in the Rakai Community Cohort study - Uganda

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Background: The COVID-19 pandemic and associated response have disrupted critical, routine health service delivery, including HIV treatment. In Uganda, major COVID-19-related restrictions, enforced from April 1st – Sept 20th, 2020, included limiting travel by public or private transport to essential services only. As a result, ART services in this setting were delivered through outreach mechanism.
This study sought to use a safe data collection tool, phone-based surveys, to:
i. assess the impact of COVID-19 restrictions on access to HIV services, and;
ii. assess the prevalence of COVID-19-like symptoms among participants by HIV status to inform HIV care and treatment needs during the COVID-19 pandemic.
Methods: Between May 21 - July 31, 2020 participants aged 18-49 years with phone contacts drawn from the longitudinal Rakai Community Cohort Study (RCCS) were contacted for participation in the structured phone-based survey. Participant sampling included 50% of previously identified HIV-positive participants from the prior RCCS survey (2018-2019) matched 1:1 to HIV-negative controls by age, sex, and geographic community.
To avoid impersonation, participants were screened using questions obtained from previous RCCS participation, enrolling with verbal informed consent.
Results: Out of 6,162 eligible participants, 4,611 (75%) consented and participated. The 4,610 with complete questionnaire data were included in this analysis. Of the 47% (n=2,181) known HIV+ participants, 92% (n=2,018) reported being on long-term medication with only n=31 (1.5%) reporting trouble taking medicine in the past seven days. Commonly reported reasons for difficulties were transport interruption (58%, n=18) and not being able to access drugs because of recent migration (23%, n=7)). At least one symptom possibly consistent with COVID-19 was reported by 11% of all participants, with 6.5% reporting ≥2 symptoms and 4.3% reporting ≥3 symptoms. There was no difference in symptom prevalence by HIV status (Table 1). Due to COVID-19 restrictions, ~27% reported food insecurity and ~80% reported financial insecurity.
Conclusions: With an HIV care outreach program, ART access disruption was rare. As of mid-2020, COVID-19 symptom prevalence was in this cohort and did not differ by HIV status. COVID-19-related food and income insecurity, however, were high, posing potential future risks that warrant further investigation.

Community mobilization and demand creation

PED673

Participatory PMTCT: community engagement for co-created PMTCT programming in 2 districts of Zimbabwe

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Background: Zimbabwe has a mother-to-child transmission (MTCT) rate of 7.8%. Community engagement in intervention design is recommended to improve acceptability, feasibility and effectiveness of PMTCT programs.
Our aim was to conduct participatory action research (PAR) workshops to identify contextual risk factors and co-create a MTCT risk screening tool and maternal motivation package.
Description: From August-September 2020 we conducted 12 PAR workshops at 8 health facilities in Bulilima and Makoni Districts, Zimbabwe. PAR workshops engaged key stakeholder groups of ≤15 participants: male partners, village health workers, health care workers, pregnant and lactating women and adolescent girls and young women (AGYW).
A semi-structured facilitation guide explored the knowledge, perceptions and practices that increase MTCT risk in project communities and identification of subpopulations at increased risk.
Participatory activities including brain storming, listing and sorting, use of visual aids and storytelling were used to facilitate participant engagement. PAR activities were documented through written, oral and visual methods and qualitative data analyzed thematically, including within and between group comparisons.
Lessons learned: A total of 174 stakeholders participated in 12 PAR workshops. PAR workshops revealed key themes on community MTCT risk across ecological domains for consideration in tool design and program strategy.

Figure. Key Themes for Community MTCT Risk Drivers

Participants emphasized the importance of holistic strategies that include facility- and community-based engagement to reach the most vulnerable and marginalized. Community stakeholders expressed their desire for adaptable PMTCT programming tailored to the needs of multiple target groups within the same community (men, AGYW, religious groups) and community engagement at all project stages, not just inception and evaluation.

Conclusions/Next steps: PAR workshops meaningfully engaged community stakeholders in the co-design of a parental motivation package and job aid for community- and facility-based MTCT risk identification and action. Future research is required to measure the impact of participatory co-design on PMTCT program outcomes.

PED674

Get out of our community: the impact of COVID-19 vaccine fears on routine community-based HIV testing services

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Background: The Centre for HIV-AIDS Prevention Studies (CHAPS) implements community-based HTS across multiple settings in South Africa. Having provided CHTS in communities in the North West Province for over 3 years, these communities are familiar with CHAPS and routine HTS and linkage to ART. With the pending introduction of the COVID-19 vaccine in SA, communities, especially in rural settings, have become more vocal in their mistrust of the vaccine. The fear and mistrust of healthcare services has impacted on routine care and HIV screening services.

Description: The CHAPS HTS teams who have been active in the North West Province for several years were repeatedly forced to leave community settings amidst fears of inconspicuously vaccinating clients presenting for HTS. For the period between December 2020 and February 2021, HTS teams were threatened with violence and actively chased out of routine HTS settings by fearful community members and leaders. HTS teams conduct on average 3500 tests on unique individuals per month, with a mean positivity rate of 6%. However, the service interruptions caused by the consistent community conflict due to COVID-19 vaccine fears, has resulted in less than 1200 HTS tests and a positivity rate of less than 2%. CHAPS introduced a community-led campaign through traditional leaders to address the community and dispel fears related to HTS vs vaccination.

Lessons learned: Through dialogues and using trusted avenues such as churches and traditional chiefs, communities were encouraged to discuss their fears that we addressed openly. Use of social and mainstream media are ineffective platforms to engage with local communities who are mistrusting of any mass media campaign.

Community engagement through active platforms endorsed by traditional leadership in rural settings are pivotal in enabling communities to participate fully in public health campaigns.

Conclusions/Next steps: COVID-19 vaccine fears prevents effective community-based HIV prevention and treatment programs from achieving objectives, eroding gains achieved through decades of trust established with communities. New public health crises should build on existing best practices to keep communities informed and engaged in their own healthcare. Communication and credibility is essential to maintain community participation in HIV services, amidst fears of the evolving COVID-19 pandemic.

Couples- or family-centred approaches

PED675

The impact of a couple-based intervention on one-year viral suppression among HIV-infected pregnant women in Malawi: a randomized controlled trial

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Background: Couple-based approaches may improve HIV treatment outcomes for HIV-infected pregnant women, but this hypothesis requires testing in a clinical trial with long-term outcomes.

Methods: A randomized controlled trial was conducted among 500 HIV-infected pregnant women (indexes) attending antenatal care at Bwaila District Hospital in Lilongwe, Malawi from 2017-2019. Indexes were randomized 1:1 to either the standard of care (SOC) or a couple-based behavioral intervention (BI) and followed for one year.

The BI offered:

1. provider-assisted partner notification;
2. enhanced couple counseling and testing at baseline and six months; and;
3. an option for male partner ART pick-up.

Risk differences (RD) and 95% confidence intervals (CIs) comparing the BI and SOC arms for index viral suppression (<1000 copies/ml) one year after enrollment were calculated using intention-to-treat and complete case analysis. Post-hoc analyses explored modification by marital/cohabitation status and recent history of physical intimate partner violence (IPV).

Results: Nearly all indexes were married or cohabitating (93.3%) and reported no recent physical IPV (91.8%). Eighty-one percent completed their final study visit and 90.6% provided a one-year viral load measure. Trends towards greater viral suppression in the BI arm were observed in intention-to-treat (RD: 6.8, CI: -1.7, 15.3, p=0.1) and complete case analyses (RD 6.6, CI: -0.8, 14.0, p=0.08) (Table 1).

	Standard of care (n/N, %)	Intervention (n/N) %	Risk Difference	(95% Confidence Interval)	p-value
Intention to treat	(145/250) 58.0%	(162/250) 64.8%	6.8%	(-1.7%, 15.3%)	0.1
Complete case	(145/178) 81.5%	(162/184) 88.0%	6.6%	(-0.8%, 14.0%)	0.08
Relationship type					
Married/ cohabitating	(127/159) 79.9%	(155/174) 89.1%	8.1%	(0.2%, 16.0%)	0.05
Not married/ cohabitating	(18/19) 94.7%	(9/10) 90.0%	-4.7%	(-25.9%, 16.4%)	0.7
Recent physical violence					
No	(131/161) 81.4%	(154/173) 89.0%	7.7%	(<0.1%, 15.4%)	0.05
Yes	(14/17) 82.3%	(8/11) 72.7%	-9.6%	(-41.6%, 22.3%)	0.6

Table 1.

A positive intervention effect was observed among indexes who were married/cohabiting (RD: 8.1%, CI: 0.2, 16.0, p=0.05), but not among those who were not (RD: -4.7%, CI: -25.9, 16.4, p=0.7) and among indexes without recent IPV (RD: 7.7%, CI: 0.0, 15.4), but not among those with recent IPV (RD: -9.6%, CI: -41.6, 22.3).

Conclusions: High viral suppression was observed among women in the BI arm, with significant intervention effects in substantial population segments. Couple-based approaches can enhance viral suppression among married/cohabiting pregnant women and those without recent IPV.

PED676

Correlates of couples HIV testing and counseling and reported interpersonal barriers to uptake among adolescents and young adults: results from two population-based surveys conducted in Malawi and Zambia

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Background: Most HIV seroconversions in sub-Saharan Africa occur among adolescents and young adults (AYA, aged 15-24) in heterosexual serodiscordant primary partnerships. Thus, couples HIV testing and counseling (CHTC) is a promising modality to reduce transmission. However, CHTC uptake remains low as partnerships involving AYA tend to be novel and emerging during these formative developmental stages, making CHTC especially challenging. We evaluated correlates of CHTC uptake and age- and gender-specific interpersonal barriers to CHTC.

Methods: We conducted a pooled analysis using data from Malawi's (2015-2016) and Zambia's (2016) Population-based HIV Impact Assessments, two nationally-representative household surveys. To identify correlates of CHTC with a primary partner, we used multivariable logistic regression. To characterize barriers to CHTC uptake, we used chi-squared tests to determine gender- and age-related differences.

Results: Among 7227 AYA, 37% (2678/7227) engaged in CHTC; of which, most were female (55%), aged 20-24 (63%), and Malawian (54%). CHTC correlates (Figure 1) included female gender (Ref: male; aOR:1.96 [1.65-2.33]), 20-24 years (Ref. 15-19; aaOR:1.39 [1.16-1.67]), Zambian (Ref: Malawian; aOR:2.33 [1.95-2.78]), ever-married/cohabited status (Ref: never; aOR:3.13 [2.51-3.91]), urban setting (Ref: rural; aOR:0.72 [0.56-0.89]), having a partner living with HIV (Ref: HIV-negative; aOR: 0.59 [0.37-0.93]), and not knowing partner's HIV status (Ref: HIV- negative; aOR:0.01 [0.01-0.02]). Reasons for non-engagement varied by gender and age (p<0.001). Males and individuals aged 15-19 were more likely to report an unofficial partnership with their primary partner or never discussing CHTC, while females and individuals aged 20-24 years were more likely to report partner refusal.

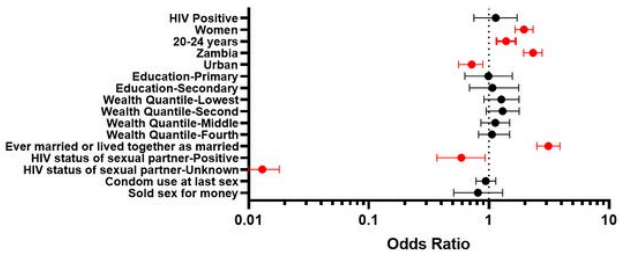

Figure 1. Forest plot of odds ratios assessing correlates of couples HIV testing and counseling among adolescent and young adults.
*p-value <0.05 highlighted red

Conclusions: In 2016, CHTC uptake was relatively common among Zambian and Malawian AYA, contradicting reports of low utilization. To build on the positive foundation and amplify CHTC uptake, efforts to develop effective, acceptable interventions targeting men, adolescents, and interpersonal barriers, such as status disclosure and communication, are needed.

PED677

Making the case for joint decision-making: the influence of partner preferences on future dual prevention product use

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Background: Research on novel HIV prevention methods in sub-Saharan Africa has often focused on women due to their increased risk of HIV. However, relationship considerations, such as lack of male partner support, may be important barriers to women's product uptake and adherence.

Methods: The MTN-045/CUPID study assessed preferences for future dual-purpose HIV and pregnancy prevention (DPP) products among 400 heterosexual couples in Uganda and Zimbabwe, to inform the product development process. A purposive sub-sample of couples (female partners aged 18-40 and HIV-negative) completed in-depth interviews (IDIs). Couples represented a range of relationship durations and communication patterns (evaluated by trained observers). IDIs explored relationship dynamics, preferences for DPP products, and partner influences on preferences. Key themes were documented in debriefing reports and analyzed using the Framework Method, stratified by individual (a comparison of separate male and female partner reports) or joint interview mode and communication patterns.

Results: Among 39 couples, 20 male and female partners were interviewed individually and 19 jointly, with 13 classified as male-dominated, 12 female-dominated, and 14 equal communicators. The average relationship length was five years. Regardless of observed communication pattern, the majority of couples described a process of joint decision-making with greater emphasis on women's attribute preferences. 'Male-dominated' couples interviewed individually frequently expressed contradictions in how decisions were made and whose influence dominated. A desire to have positive communication, as well as greater satisfaction in their ultimate choice of products and attribute characteristics, was cited by most female-dominated and equal contribution couples interviewed jointly, as rationales for shared decision-making. Women held more sway when product characteristics would impact their body (e.g., side effects), while men's preferences held more importance when attributes (such as impact on menses) may also affect the couples' sexual experience.

Conclusions: The inclusion of couples in DPP preference studies is novel and offers an opportunity to understand how relationship dynamics impact prevention choices and decision-making. Most men supported their female partner's decisions regardless of the couple's communica-

tion style. Therefore, engaging men in DPP decision-making offers an opportunity to create a dynamic whereby men can support women's product preferences without dominating their decisions.

PED678

"If there is joy...I think it can work well" – Investigating relationship factors impacting HIV self-testing acceptability among pregnant women and male partners in Uganda

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Background: Secondary distribution of HIV self-test (HIVST) kits from pregnant women to their male partners may promote HIV couples testing and disclosure, and is being scaled up in sub-Saharan Africa. Understanding couple-level barriers and facilitators influencing HIVST uptake is critical to identifying strategies for strengthening clinical guidelines for HIVST distribution.

Methods: We conducted gender-stratified focus group discussions (N=14) and in-depth interviews (N=10) with pregnant women, and male partners of pregnant women, in Uganda from April 2019 to February 2020 (N=122 participants).

We purposely sampled men and pregnant women living with HIV to assess how perspectives differed from those without HIV. Interview topics included acceptability and barriers for HIV testing and HIVST, and perspectives on disclosure and gender roles impacting HIVST use. Transcripts were transcribed and translated from Luganda to English and analyzed thematically by two coders using NVIVO. We adapted the Interdependence Model of Communal Coping and Health Behavior Change to explore factors impacting HIVST acceptability.

Results: Participants felt that relationships characterized as having facilitating predisposing factors, such as trust and open communication, would have a higher likelihood of women delivering HIVST kits to their partners and subsequently exhibiting communal coping behaviors such as couples self-testing and disclosure.

Conversely, participants mentioned that relationships with breaches of trust, infidelity, or intimate partner violence were more likely to experience negative consequences of disclosure, such as violence and/or relationship dissolution, and would be hesitant to distribute/use HIVST. Pregnancy was described as a critical motivator for self-testing, while gender dynamics served as a barrier to HIVST acceptability, with for example some women mentioning concerns about asking their partners to use HIVST. Generally, participants felt HIV-negative women were more likely to give HIVST to their partners, while HIV-positive women would have concerns, particularly in navigating discordant relationships and disclosure without a counselor.

Conclusions: While HIVST generally had high acceptability, a subset of participants, particularly those with negative predisposing factors, may benefit from targeted counseling and disclosure support before and after HIVST distribution to increase uptake.

Results may help support policy guidelines regarding HIV self-testing of pregnant women and their partners, and recommendations for counseling support.

Prevention of vertical transmission

PED679

Lessons learned from a breastfeeding HIV-exposed uninfected infant cohort: getting to under 1% vertical transmission

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Background: South Africa implemented option B+ for the prevention of mother to child transmission (MTCT) in 2015. We report here on the MTCT of HIV in a cohort of breastfeeding infants born to women enrolled in a PMTCT program.

Description: Between 2013 and 2018, we enrolled 1219 infants born to HIV positive women into a non-inferiority trial assessing the current co-trimoxazole prophylaxis guidelines for HIV exposed uninfected infants. Breastfeeding mothers and infants were enrolled and followed up at one of two clinics in eThekwini, KwaZulu-Natal, until 12 months of age. Peer counsellors provided breastfeeding and adherence counseling at clinic visits.

During the study period, 8 infants seroconverted (<1% transmission); these were likely 4 birth transmissions and 4 breastfeeding transmissions. Median birthweight was 3.24 kg (IQR: 2.70 – 3.78), which was similar to the main cohort [median 3.11 kg IQR: 2.87-3.42)]. There were three male infants vs 5 female infants who seroconverted, while 5 were vaginal births vs 3 caesarian births. Two of the breastfeeding transmissions were foreign national mothers who went to their home countries for several months before returning, which could indicate poor adherence or access to antiretrovirals while outside of South Africa.

Lessons learned: Peer counseling likely contributed to the low MTCT rate observed in this cohort. Mothers viral load (VL) monitoring is critical in the last trimester and at birth to prevent birth transmission and to ascertain whether the mother has responded adequately to her prophylaxis regimen. Mothers with a higher VL at birth could be provided with additional ARV prophylaxis for the infant, which can be extended until the VL is undetectable.

Additionally, breastfeeding mothers need to have regular VL testing. This will help determine which mothers are either not responding to their ARV regimen or not completely adherent to their regimen, facilitating the necessary steps to protect the infant from HIV transmission.

Conclusions/Next steps: Peer counselling support is critical during this vulnerable time for pregnant and breastfeeding mothers. Point-of-care VL testing in the last trimester, at birth and regularly while breastfeeding would facilitate real-time counselling and adjustment of mother and infants' prophylaxis regimen.

PED680

The effect of a mentor mothers program on maternal and infant PMTCT outcomes in Zambézia province, Mozambique

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Background: Mentor Mothers (MM) provide peer support to pregnant and lactating women with HIV (PLW) navigating the cascade of prevention of mother-to-child transmission (PMTCT) services. MM were implemented in Zambézia province, Mozambique starting in August 2017. The objectives of this evaluation were to determine whether MM had an effect on retention in PMTCT services, viral suppression, and/or vertical transmission.

Methods: A retrospective interrupted time series analysis was done using routinely collected aggregate data from 85 health facilities in nine districts of Zambézia. Data were captured from August 2016 through April 2019. All PLW who enrolled in PMTCT services and initiated antiretroviral therapy (ART) and their HIV-exposed infants (HEI) were included. Outcomes included the proportion per month per district of: PLW retained in care 12 months after ART initiation; PLW with viral suppression (HIV RNA <1000 copies/ml); and positive HIV DNA PCR tests among HEI (vertical transmission) tested for HIV by 9 months of age. Temporal trends in outcomes were adjusted by districts and the effect of MM on outcomes were assessed using logistic regression.

Results: Median district-level 12-month retention rates among PLW ranged from 35-61% in the year before MM implementation and 56-72% in the year during MM implementation. The odds of 12-month retention increased 1.5% per month in the pre-MM period, compared to an increase of 7.6% per month with-MM (p<0.001). Median viral suppression rates among PLW were 49-85% pre-MM and 59-80% with-MM. The odds of being virally suppressed decreased by 0.9% per month in pre-MM period, compared to an increase of 3.9% per month with-MM (p<0.001). Median vertical transmission rates were 0-14% pre-MM and 4-10% with-MM. The odds of vertical transmission decreased 8.9% per month in the pre-MM period, compared to a decrease of 0.4% per month with-MM (p<0.001).

Conclusions: Implementation of a MM program was associated with improved retention in PMTCT services and higher viral suppression rates among PLW. While there was ongoing but diminishing improvement in vertical transmission rates following MM implementation, this could be explained by having reached a plateau or increased uptake of HIV testing among high-risk HEI who were previously not getting tested.

PED681

Early detection during pregnancy, saving lives: active case follow up leading to prevention of vertical transmission Ahana project in 14 states of India

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Background: Govt. of India is aiming for EMTCT by 2020. While there have been progress, but HIV testing among pregnant women stood at 36% in the key 14 states with estimated 16 million annual pregnancies. Ahana project funded by The Global fund is complementing National PMTCT programme by upscaling community level HIV testing of pregnant women, facilitating early linkages to treatment, providing care and support to HIV positive pregnant women and HIV exposed children through a first 1000 day ECCD approach.

Methods: A longitudinal study carried out in a cohort of 6,500 HIV positive pregnant women in the 14 intervention states of India. Findings were triangulated with the national pregnant women database HMIS and HIV Strategic Information Management System to understand the cascade integration and effectiveness of intervention. The data was analysed using Microsoft excel and SPSS.

Results: With service expanded till the peripheral level and with introduction of community based screening the HIV testing access increased manifold. More than 40 thousand peripheral health workers were trained to carry out finger prick test at the village level under the project. This resulted in increase in HIV testing among pregnant women from 36% in 2015-16 to 54.7% during 2017-18 and to 77% during period of April-September, 19 with a 225% increase in the HIV testing service access. The increase in HIV testing resulted in identification of more than 2 thousand additional HIV positive pregnant women every year and bringing them into PMTCT programme successfully. 2,315 HIV exposed babies delivered by HIV positive mothers were followed up through 18 months and provided with treatment, care and support and was linked to 18 months confirmatory testing. HIV transmission could be prevented successfully among 2,207 babies out of the 2,282 received confirmatory testing.

Conclusions: Early detection, linkage to treatment and continuous follow-up with care and support services remained as the key to successfully preventing the transmission from mother to child. Home based care and support delivered through a convergent model service delivery including immunization, nutrition and other primary health care services could successfully prevent the vertical transmission among 2,207 HIV exposed babies.

Financial incentives, micro-finance, and other economic approaches

PED682

Evaluation of a social risk screening tool to predict retention in HIV services among adults on antiretroviral therapy receiving financial incentives for clinic attendance in Tanzania

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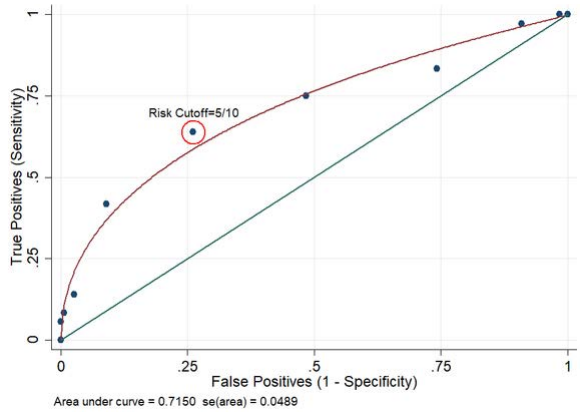
Background: Financial incentives have demonstrated success at promoting retention in HIV services, however modest incentives alone may not always sufficiently overcome barriers. To inform future targeting of additional support to those most vulnerable, we developed and evaluated a screening tool to predict risk of loss to follow-up (LTFU) among individuals starting antiretroviral therapy (ART) given financial incentives.

Methods: We analyzed data from a 2018-2019 randomized controlled trial at 4 clinics in Shinyanga region, Tanzania. Intervention participants included 346 adult (≥18 years) ART initiates (≤30 days) allocated a monthly financial incentive conditional on clinic attendance [10000 or 22500 TZS (≈US $4.50 or $10.00)] for ≤6 months; 36 (10.4%) were LTFU (≥28 days) at 6 months [vs. usual care: 30/184 (16.3%), chi-square p=0.05]. This analysis identified the best set of baseline survey predictors of 6-month LTFU among intervention participants using cross-validated LASSO regression, developed a screening tool from these predictors, and evaluated its classification performance with a ROC curve.

Results: Model-selected ordinal predictors of 6-month LTFU included self-rated health, mental health, education, and employment; summing response levels of these indicators created a risk score (0-10) for each individual (Table). A 'high-risk' cutoff at 5/10 (Figure) optimized the tradeoff of true positives (63.9%) versus false positives (26.1%) and yielded a subgroup size feasible to target for more intensive support (30%).

Model-Selected Predictors of LTFU	Retained in Care (n=310), mean (SD)	Lost to Follow-Up (n=36), mean (SD)	T-test p-value
Self-rated health *(0:"excellent" to 4:"poor")*	1.6 (1.0)	2.2 (1.2)	0.001
Feeling no interest in things *(0:"not at all" to 3:"extremely")*	0.27 (0.58)	0.64 (0.87)	0.001
Educational attainment *(0:>primary, 1:primary, 2:<primary)*	1.2 (0.70)	1.4 (0.65)	0.050
Worked in the past week *(0:yes, 1:no)*	0.39 (0.49)	0.61 (0.49)	0.012
Sum: LTFU Risk Score ***(0:lowest to 10:highest)***	3.5 (1.5)	4.9 (2.0)	<0.001

Table.



Figure

Conclusions: A simple 4-item screener administered to individuals receiving HIV treatment can identify future LTFU risk using limited resources. Building on the effectiveness of financial incentives, social risk screening and predictive analytics could enable timely and efficient allocation of complimentary 'cash plus' strategies to prevent LTFU, such as combining incentives with social support.

PED683

Agricultural livelihood interventions on male gender role conflict and women's relationship power in western Kenya: results from the Shamba Maisha trial

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Background: Gender power imbalances and inequitable gender norms are associated with suboptimal HIV and reproductive health outcomes among women and poor mental health among both men and women. Because food insecurity and poverty exacerbate gender power imbalances, we evaluated the impact of an agricultural livelihood intervention on gender role conflict and sexual relationship power among people living with HIV (PLHIV) in western Kenya.

Methods: Study participants were enrolled in *Shamba Maisha*, an agricultural cluster randomized controlled trial conducted across sixteen health facilities (NCT02815579) in 2016-2020. Intervention participants received a water pump, seeds, and agricultural and financial training; control participants received standard care. Participants were assessed at in-person and home visits semiannually over two years. We assessed the gender role conflict score (GRCS) among men, a validated scale that measures men's internal tension toward traditional gender roles (range 22-88, higher=less gender role conflict), and the validated sexual relationship power score (SRPS) among women, which combines subscales of relationship control and decision-making dominance to measure their power in sexual relationships and everyday decision-making (range 1-4, higher=female holds more power). We compared changes between endline and baseline by arm by employing longitudinal multilevel difference-in-difference linear regression models accounting for clustering of facilities using the intention-to-treat cohort.

Results: We enrolled 720 participants (366 intervention, 354 control); two-year retention was 94%. Median age was 40 (interquartile range 34-47). Approximately 55% of participants were female. Among men, average baseline GRCS scores were 52.4 vs. 53.0 in the intervention and control arms, respectively. At 24-months the average endline scores were 57.8 vs. 54.5, leading to a 4.3 points greater increase in GRCS in the intervention than the control arm (p<0.001). Among women, average baseline SRPS was 2.2 for both arms. The intervention resulted in 0.25 points greater increase in the SRPS in the intervention compared to the control arm (p<0.001).

Conclusions: Among PLHIV, the *Shamba Maisha* livelihood intervention resulted in less gender role conflict in men and greater sexual relationship power for women. Agricultural livelihood interventions may be a powerful tool to improve gender power imbalances and should be considered in programs among PLHIV and other populations.

PED684

The effectiveness of a cash transfer conditional on attendance of a combination HIV intervention in young women in a community setting

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Background: Conditional cash transfers (CCT) are promising interventions to minimize risky sexual behaviors in adolescent girls and young women (AGYW) in Africa. Effective programmes that conclusively reduce HIV and pregnancy incidence and improve access to care remain elusive prompting recommendations to augment CT's with behavior change and service improvement interventions.

Methods: Women of Worth (WoW), a multi-phase, quasi-experimental study, assessed the impact of a CT of ZAR300 ($22) conditional on attendance of a sexual reproductive health (SRH) BI ("cash + care" C+C) in Cape Town, South Africa from May 2017 to December 2019. 5000 young women aged 19-24y were randomized 1:1 to "C+C" or BI without CT ("care"). BI entailed twelve empowerment workshops with referral to adolescent and youth friendly services (AYFS). Phase 1a entailed monthly BI attendance and phase1b weekly attendance. HIV and pregnancy prevalence and SRH/HIV vulnerability indicators were assessed via a self-administered questionnaire at baseline, after session 11, and 6 - 30 months post intervention. Logistic regression for multiple mixed effects was used for analysis.

Results: Of 5116 records, 904 (17,7%; 452 participants per arm) were enrolled in phase 1a and 4212 (82,3%; 2039 Care participants: 2173 C+C participants) were enrolled in phase 1b. Retention (attendance of 11 or more sessions) was higher in phase 1b (1977, 91%) versus phase 1a (200, 44%) in the "C+C" arm and <10% in the non-incentivized "care" arm. Post intervention follow-up in 180 participants for median 13,8 months (IQR 11,5;16,8). No impact on HIV & pregnancy prevalence was observed. "C+C" participants were less likely to report transactional sex (OR 0.79; 95%CI 0.64; 0.98; p =0.029) vs "care" participants. Exposure to BI, regardless of CT exposure, increased the likelihood of HIV testing (OR 1.56; 1.24; 1.95, p<0.001), contraception use (OR 1.58; 1.25;1.99 p<0.001), and STI treatment (OR; 1.27;1.03; 1.58, p=0.024). Similarly, a 3 fold increase in the likelihood of employment (OR 3.01; 2.01;4.52, p<0.001) was observed.

Conclusions: CT's augmented with a combination HIV/SRH intervention may ensure persistent participation in empowerment programs for young women in low income settings which may in turn impact economic, structural and other determinants of HIV vulnerability.

Interventions to reduce stigma and discrimination

PED685

HIV and intersectional stigma reduction strategies in NYC: a mixed methods study

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Background: Stigma remains a pervasive barrier to optimal health and psychosocial outcomes for people with HIV (PWH) in New York City (NYC); however, little is known about what HIV-focused clinical and community-based organizations do to address stigma among PWH in NYC at the structural, interpersonal, and individual levels. As part of a federal Ending the HIV Epidemic initiative implementation science planning process, we mapped multi-level HIV-related stigma-reduction activities implemented by such organizations, assessed their evidence base, and characterized barriers and facilitators to stigma reduction at HIV-related organizations in NYC.

Methods: From March to August 2020, we interviewed and surveyed a convenience sample of staff at 27 organizations providing HIV prevention and/or care services in NYC, including 51 staff members at these organizations. We conducted a descriptive analysis of survey findings and integrated these with a rapid qualitative analysis of structured interview notes as part of a mixed-methods design.

Results: HIV-focused organizations in NYC utilized various common practices to reduce stigma, although a number of practices were not sustained over time. Strategies that were viewed as the greatest facilitators of stigma reduction included integration of HIV care with other health services, hiring staff who reflect the communities served, and conducting staff trainings related to reducing stigma. Multiple intersecting stigmas relevant to the HIV epidemic were addressed through the integration of HIV care with mental health and substance use services. Few practices were formally evaluated to assess strategies' impact on stigma. Barriers to implementing stigma-reduction activities were multi-level, with organizational structure and capacity, including high client volumes, frequent staff turnover and burnout, and bureaucratic processes cited as the most challenging.

Conclusions: We mapped common, multi-level stigma reduction practices to determine "best practices" to address HIV-related stigma in service settings in NYC. Care integration, staff diversity, and frequent training were strongly supported. However, important gaps were found, including a lack of evaluation and practices designed to measure and address intersectional stigma within HIV prevention and clinical settings. Effectiveness-implementation hybrid research designs may improve the uptake, scaling, and evaluation of effective stigma-reduction approaches.

PED686

The need to destigmatise antiretroviral treatment to improve uptake and retention in care of young people living with HIV in rural Malawi

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Background: Although advances in biomedical prevention and treatment have brought the prospect of ending AIDS within reach, HIV-related stigma remains a significant barrier to the global HIV response. There is consensus that reducing HIV-related stigma is critical to achieving an end to AIDS. However, most of our knowledge about drivers of HIV-related stigma stems from a time when HIV was an acute and untreatable illness.

We explored how HIV-related stigma and its drivers shaped antiretroviral treatment (ART) service uptake and adherence by young people living with HIV (YPLHIV). The study aimed to inform interventions addressing stigma in the current context in which HIV has transitioned into a chronic condition.

Methods: Focus groups involving 25 YPLHIV (13 females and 12 males) and individual semi-structured interviews involving 28 YPLHIV (16 females and 12 males) were conducted between August and December 2018. Study participants were between 15 and 24 years and from a rural district in Malawi's southern province. A realist-informed analysis was undertaken to theorise how stigma drivers shape access to health services by YPLHIV.

Results: Two theories were developed:

1) If YPLHIV experience stigma and discrimination; they are continually devalued and have their existence discredited by those around them, then YPLHIV are likely to have low self-esteem and poor future orientation, leading to inconsistencies in their management of HIV.

2) If a sickly appearance drives HIV-related stigma, then YPLHIV who are on treatment will be motivated to appear healthy to avoid stigma, leading them to adhere to antiretroviral treatment.

Alternatively, if antiretroviral drugs are both the marker of HIV and driver of stigma and the predominant discourse around ART among peers is negative, then HIV-negative young people will fear getting tested for HIV and YPLHIV on treatment will fear being seen near ART collection points or taking medication, leading to late diagnosis, absenteeism from clinical appointments and poor adherence, undermining service uptake and retention in care.

Conclusions: HIV-related stigma has evolved alongside the transition of HIV from an acute to a chronic illness. Apart from interventions addressing stigma driven by misconceptions regarding HIV, there is a need for interventions addressing misconceptions regarding antiretroviral drugs.

PED687

Reproductive coercion and HIV stigma experiences among women living with HIV in Metro Vancouver, Canada

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Background: Reproductive coercion is the interference of the autonomous decision-making process for an individual's own reproductive health. Women living with HIV (WLWH) often experience high levels of reproductive and HIV stigma within the healthcare system.

Our study examined reproductive coercion and the association with HIV stigma experiences among cisgender (cis) and transgender (trans) WLWH in Metro Vancouver, Canada.

Methods: Data were drawn from a longitudinal community-based open cohort, the Sexual Health and HIV/AIDS: Women's Longitudinal Needs Assessment (SHAWNA) of cis and trans WLWH aged 14 and older (2014-present). The relationship between 'Ever experiencing reproductive coercion' (defined as experiencing any of being:

i) coerced into using birth control;

ii) advised to have an abortion; or

iii) advised not to become pregnant by a health professional) and HIV stigma experienced in the last six months (three outcomes including anticipated; perceived; and internalized HIV stigma) were analyzed using bivariate and multivariable logistic regression models with generalized estimating equations for repeated measures over time. Adjusted odds ratios (AOR) and 95% confidence intervals[95%CIs] are reported.

Results: Our study included 256 participants with 940 observations over three years of follow-up (Mar/16-Feb/19). Of the sample, 56.3% were Indigenous, 9.0% were otherwise racialized persons and 34.8% were White; 35.9% identified as sexual minority WLWH (i.e., gay, lesbian, bisexual, two spirit, asexual, queer, or other) and 9.0% identified as gender minority WLWH (i.e., transgender, Two-Spirit, transsexual, genderqueer, other).

From baseline and over the study period, 34.8% had ever experienced reproductive coercion (16.4% coerced birth control; 14.8% advised to have an abortion; 19.9% advised not become pregnant). In multivariable analysis after adjusting for key confounders, ever experiencing reproductive coercion was associated with: anticipated HIV stigma (AOR:1.64,95%CI:1.01-2.65), perceived HIV stigma (AOR:1.83,95%CI:1.24-2.71) and internalized HIV stigma (AOR:1.61,95%CI:1.05-2.47).

Conclusions: Many WLWH in our study have been denied their right to autonomous reproductive choices and our study suggests that these experiences may heighten how WLWH internalize, anticipate and perceive HIV stigma, key barriers to other types of health services access, including HIV treatment and care. Safe, supportive reproductive health services that emphasize patient-centred, trauma-informed principles should be available to all cis and trans WLWH.

PED688

Changes in HIV-related stigma among school teachers receiving multi-media training in Western Kenya

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Background: For adolescents living with HIV (ALWH), school may be the most important but understudied social sphere related to HIV stigma. Teachers are role models in the classroom and community, and their knowledge, attitudes and beliefs (K/A/B) towards people living with HIV (PLWH) may have critical psychosocial and treatment ramifications for youth. Altering teachers' K/A/B about HIV could reduce the stigmatizing content within their classrooms, improving the environment for all youth.

Methods: We implemented a school-level, cluster-randomized trial to assess the impact of one-day multi-media training on the K/A/B of primary and secondary school teachers in Western Kenya. Trainings included lectures, educational films and animations, teacher roleplay, and Q&A sessions facilitated by an ALWH peer educator. HIV-related K/A/B were assessed using the Genberg HIV/AIDS Stigma Assessment, a validated tool in this setting. Only teachers in the intervention group underwent training. All participants completed baseline and 6-month follow-up assessments.

Results: Among 312 randomized participants at ten primary and ten secondary schools (56.09% female, mean age 36.41 years, 64.10% secondary school, mean 10.78 years teaching experience), 311 completed the trial. At baseline, participants scored high on sub-scale 1 (shame/blame/social isolation, mean 4.76/5) and sub-scale 3 (equity, mean 4.66/5) indicating positive regard for PLWH, but scored poorly on sub-scale 2 (discrimination, mean 2.84/5). At 6-months, the intervention and control groups did not significantly differ in overall score (mean 4.17 vs. 4.16; adjusted difference, 0.02 [95% CI, -0.05-0.08]) or sub-scale score. In exploratory analyses of secondary school teachers only, the intervention and control groups did significantly differ in overall score (mean 4.14 vs. 4.10; adjusted difference, 0.05 [95% CI, 0.00-0.11]) and sub-scale 2 score (mean 2.98 vs. 2.81; adjusted difference, 0.17 [95% CI, 0.02-0.31]).

Outcome		Control Group			Treatment Group			Treatment Effect	95% Confidence Interval
		N	Mean	SD	N	Mean	SD		
All teachers	Overall Stigma Score	128	4.16	0.33	183	4.17	0.29	0.02	-0.05 to 0.08
	Subscale 1: Shame/Blame/ Social Isolation	128	4.84	0.20	183	4.81	0.19	-0.02	-0.06 to 0.02
	Subscale 2: Discrimination	128	2.97	0.82	183	3.06	0.77	0.02	-0.16 to 0.20
	Subscale 3: Equity	128	4.83	0.28	183	4.80	0.28	-0.01	-0.08 to 0.07
Secondary school teachers only	Overall Stigma Score	78	4.10	0.29	121	4.14	0.28	0.05	0.00 to 0.11
	Subscale 1:	78	4.88	0.18	121	4.90	0.17	0.03	-0.02 to 0.07
	Subscale 2:	78	2.81	0.68	121	2.98	0.70	0.17	0.02 to 0.31
	Subscale 3:	78	4.82	0.30	121	4.80	0.29	0.00	-0.10 to 0.11

Table 1. Six-month Scores, by Treatment Assignment

Conclusions: These data suggest one-day multimedia training may improve secondary school teachers' K/A/B related to HIV discrimination.

PED689

Online interventions effectively reduce HIV-related stigma among the general population

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Background: Stigma is a major barrier to healthcare access and treatment retention among people living with HIV (PLHIV). Experiencing stigma and discrimination is also associated with broader negative health and wellbeing outcomes. Despite this, evidence regarding the effectiveness of initiatives to reduce HIV-related stigma is limited.

This project assessed the effectiveness of brief, online interventions with members of the Australian general public in reducing stigmatising attitudes towards PLHIV.

Methods: This project was part of a larger study investigating interventions to reduce stigma towards people living with blood-borne viruses (HIV, hepatitis B, hepatitis C), people who inject drugs, and sex workers (n=2,010). A convenience sample of Australian adults was recruited via social media and randomly allocated to an intervention group (n=320) or control group (n=126). Participants completed four separate scales measuring various attitudes towards PLHIV. The intervention group were then presented with a short video of PLHIV describing their lived experiences before completing the four scales again.

All participants were invited to complete a follow-up survey after three months. Changes in attitudes over the three time points were assessed using a mixed effects regression model.

Results: In general, participants reported relatively positive attitudes towards PLHIV at baseline. Over time, significant improvements were evident in relation to perceived controllability of stigma (i.e. blaming PLHIV for their infection, β=-.01, p=.02) and personal distance (i.e. willingness to be in contact with PLHIV, β=-.01, p=.02). Demographic and personal variables were also identified that were associated with less stigmatising attitudes towards PLHIV (e.g. gender, sexual identity, conservatism).

Conclusions: In what we believe is world first research, brief online videos depicting PLHIV were found to be successful in reducing stigmatising attitudes towards HIV among members of the Australian public.

Online contact interventions such as these have the potential to be tailored, scaled up, and rolled out across jurisdictions at national and international levels.

PED690

Discrimination response, an alternative forum to resolve grievance

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Background: HIV-related stigma and discrimination (S&D) refers to prejudice, negative attitudes and abuse directed at PLHIV. In India discrimination towards PLHIV has widely reported in healthcare, work place, education and domestic set ups which is also confirmed in the UNAIDS study that over 50% of people report having discriminatory attitudes towards PLHIV. Government of India has taken various steps to reduce stigma including confidentiality policy, HIV legislation and sensitizations. However, S&D are still prevailing.

Description: Under care and support (CSC) programme, 310 discrimination response team (DRT) has been established across India to respond to S&D cases. Each team comprises the representatives from the gov-

ernment officer, lawyer, PLHIV and some eminent person from the society. There are several activities has been undertaken such as, rights based awareness for PLHIV, dialogue and advocacy with stakeholder, policy influencer and linkage with grievance redressal mechanism. Once the complaint has received, the DRT/CSC team will talk to complainant and accused, take support of authority and take appropriate action.

Lessons learned:

- As a outcome, a total 7022 cases report on stigma from the period of Jan-18 to Nov-19, among them 6311 (89%) cases has been resolved with the support/intervention of DRT and local community and other unresolved cases referred to grievance redressal mechanism/ legal justice system
- Majority of cases are coming from family and workplace, involvement of Government/influence people in the DRT have helped to provide speedy solution to the grievances.
- The DRT system has empowered PLHIV and become a bridge between community and justice system and helped National treatment programme to increase the retention.
- Strengthen documentation: it was observed due to lack of knowledge on justice system and education, people are not making any written complaints to appropriate forum, so CSC has taken this challenges as consideration and CSC team is facilitating the client to file complaint

Conclusions/Next steps: The DRT has played a vital role to addressed the stigma cases, Sustaining the existing the DRT modal and expand to other country/state and strengthening the linkage between existing grievance redressal mechanism. The awareness on HIV legislation will increase the knowledge on the rights.

Access to appropriate healthcare services, including for co-infections and co-morbidities

PED692

Therapeutical itineraries and coping strategies with sexually transmitted infections among transgender women in Brazil: a qualitative study

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Background: Transgender women (TGW) face a disproportionately burden of HIV and other sexually transmitted infections (STI) in Brazil and elsewhere. However, studies on the HIV/STI diagnostic and care trajectories among this population are still scarce. Thus, we aimed to analyze knowledge, perceptions, care practices and itineraries in health services for the diagnosis and treatment of STI among TGW.

Methods: Qualitative study with data from 30 TGW interviewed in five focus groups (FG): (i) three exploratory FG about meanings attributed to STI, levels of STI knowledge, and STI care, and (ii) two FG directed only to TGW who already had a syphilis infection. FG were separated according to TGW professional profile and activism. Six semi-structured interviews with TGW who participated of the FG were also conducted. The participants were recruited by two peer educators in Salvador/Brazil, as part of the TransOdara Study. FG and interviews were transcribed, analyzed and categorized.

Results: Some STI names were spontaneously mentioned by participants during FG. TGW's experience with the diagnosis and treatment of syphilis and gonorrhea was reported with a sense of guilty or considered normal in the daily life of a TGW.

Two sets of diagnosis and treatment paths were characterized:

i. related to the health services of the Brazilian National Health System (SUS) including primary health care services;

ii. a point of the care service in a research health clinic;

ii. private health services appointments and paid laboratory tests with subsequent treatment in the SUS health services.

Discrimination due to gender identity by health professionals during STI treatment was reported; and the lack of convenience working hours of SUS health services (e.g at night) was reported as access barriers.

Conclusions: Our findings point to the importance of the recognition of the needs of this population in the health services. Discrimination constituted an access barrier that must be addressed, integrating state policy with strategies in different areas. These strategies involve the inclusion of the discussion since graduation in health and professional qualification, improvement of reception in health services with guaranteed access and better articulation of points in the healthcare.

Llate breaker oral abstracts

OALA01LB Track A late-breaker oral abstracts

OALA01LB01

In-vivo imaging using anti-ENV probes in SIV infected monkeys: a reproducibility study

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Background: It has been reported that positron emission tomography (PET) with anti-ENV monoclonal antibodies (mAbs) can be used to non-invasively image SIV in tissues of chronically infected as well as combination antiretroviral treated (cART) and viral-load suppressed animals. Recent clinical studies have attempted to reproduce these findings in cART-treated and untreated HIV-infected patients; however, conflicting observations have been reported. We attempted to reproduce the anti-ENV imaging system in SIV-infected RMs.

Methods: Two anti-ENV probes- 7D3, and a mixture of ITS06.01 and ITS103.01 were radiolabeled for PET or single-photon-emission-computed (SPECT) imaging, and administered intravenously (Table). Binding specificity was tested in-vitro. Uninfected or SIV-infected animals were imaged up to day 5 post-radiotracer injection, followed by necropsy studies. Spleen and lymph node (LN) sections, and LN primary cells from two additional uninfected and two additional SIV-infected RMs (PVL ~10^6 copies/mL) were used for *ex-vivo* autoradiography and cell-binding assays using ^{89}Zr-Df-7D3 mAb. To test for presence of endogenous Abs in plasma that compete for the 7D3 binding site, plasma binding assay coupled with radio-HPLC were run for RMs utilized in this study and 5 additional SIVmac239-nef-stop RMs during the first year of infection.

Anti-ENV mAb	RMs infection status	Healthy\Infected RMs Body weight; Viral load; CD4+ T-cells	Radiotracer; Injected activity; mAb mass	Imaging Camera; post-radiotracer injection hours; post infection timepoint
7D3	Uninfected\SIVmac239 -nef-stop chronically infected	7.1 \ 10 kg; NA \ ~10^6 SIV-RNA copies/mL; 450 \ 2 cells/µL	^{89}Zr-Df-7D3 ~2mCi ~650 µg	PET/CT 40h ~24 months
7D3	Uninfected\SIVmac239 pre-acutely infected	8.0 \ (9.4; 8.6) kg; NA \ To be determined (TBD) (SIV-RNA copies/mL); 900 \ TBD (36%; 45% drop in lymphocyte count by day 7 of SIV-infection)	^{89}Zr-Df-7D3 ~2mCi ~1,000 µg	PET/CT 40h, 108h Day 9
ITS06.01 + ITS103.01	Uninfected\SIVmac239 -nef-stop chronically infected	6.2 \ 8.2 kg; NA \ ~10^6 SIV-RNA copies/mL; 600 \ 300 cells/µL	^{123}I-ITS ~0.75mCi ~100 µg	SPECT/CT 24h ~13 months

Table

Results: Plasma binding assay revealed that competing endogenous Abs were absent at day 7 post infection (p.i.), inhibited 7D3 binding from 0-52% (mean 25%) at day 14 p.i., and fully abrogated binding in all RMs at year 1 p.i. Consistently, competing endogenous Abs were absent in the two animals imaged during pre-acute SIV-infection but fully abrogated binding in the chronically SIV-infected animal. Autoradiography, binding assay of primary cells, and *in-vivo* imaging up to 5 days post-anti-ENV probe injection did not detect differences in probe uptake between the uninfected and the SIV-infected RMs.

Conclusions: In SIV pre-acutely or chronically infected RMs, radiolabeled anti-ENV mAb tracers did not detect ENV expression *in-vivo* or *ex-vivo*.

OALA01LB02

Dual IL-10 and PD-1 blockade in SIVmac239 infected macaques promotes sustained virologic control in absence of ART

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Background: IL-10 production and PD-1 expression are both elevated during chronic HIV/SIV infection under ART. Both are associated with virus persistence and T cell impaired effector function, which leads to virus rebound upon analytical treatment interruption (ATI).

We hypothesized that IL-10 and PD-1 blockade will act synergistically to simultaneously reduce the SIV reservoir and boost T-cell function, leading to improved control of viral rebound after ATI.

Methods: 28 rhesus macaques (RMs) were infected i.v. with SIVmac239, initiated ART (TDF/FTC/DTG) at day-42 post-infection, which was maintained for 14-months prior to therapeutic intervention. RMs received rhesus aIL-10 (#10), aIL-10/aPD-1 (#10), or vehicle (#8), with infusions every 3-weeks (Fig.1).

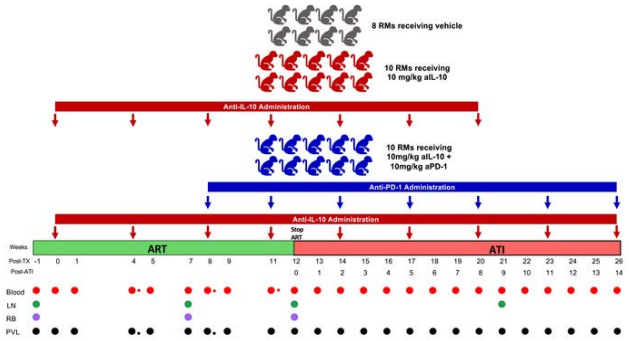

Figure 1. Study design

Animals interrupted ART 12-weeks after dose 1, and continued infusions for 14-weeks after ATI.

Results: PD-1 receptor occupancy was demonstrated in all aPD-1 treated animals in blood and tissue throughout the intervention.

Through 14-weeks of ATI, 8/10 aIL-10+aPD-1 animals demonstrated viral suppression with plasma viremia (pVL) <100 copies/mL at least once after viral rebound, compared to 1/8 control and 3/10 aIL-10 animals (Fig.2).

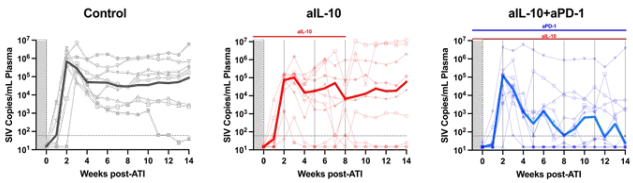

Figure 2. Viral loads after ATT (individual animals as lines+symbols, median as bold line)

Suppression was durable, with 6/10 aIL-10+aPD-1 animals exhibiting, in the first 14-weeks post-ATI, between 4-12 weeks of pVL <400 copies/mL. Notably, aIL-10+aPD-1 treatment resulted in enhanced ability to control viremia at ATI as compared to the pre-ART value, with 4-log lower viral load, as compared to 1.4-log lower in controls (p=0.007).

Conclusions: These data demonstrate that combined anti-IL-10 and anti-PD-1 blockade can facilitate sustained virologic control in the absence of ART and interventions targeting these pathways represent a promising path towards HIV cure.

OALA01LB03

Combination therapy with the broadly neutralizing antibody VRC07-523LS and the latency reversal agent Vorinostat fails to substantially reduce latent, resting CD4+ T cell infection or reduce low-level viremia

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Background: Approaches to deplete persistent HIV infection are needed. We investigated the combined impact of the latency reversing agent vorinostat (VOR) and VRC-07-523-LS, a broadly-neutralizing HIV antibody with prolonged half-life, on the HIV reservoir in HIV+ participants on stable antiretroviral therapy (ART).

Methods: Participants with HIV-1 Infection on ART with a CD4 T cell count ≥ 350 cells/mm^3 and viral suppression for ≥ 24 months received two cycles of intravenous VRC07-523LS at 40 mg/kg followed by 10 oral doses of 400 mg VOR every 72 hours. Cycles were separated by at least one month. ART was maintained throughout the study. Change in low-level HIV viremia, resting cell-associated HIV RNA (rca-RNA), Intact Proviral DNA assay (IPDA), and the frequency of resting CD4$^+$ T-cell infection (QVOA; quantitative viral outgrowth assay) was measured at baseline and after the treatment cycles.

Results: No serious treatment-related adverse events were observed among eight participants. Following cycles of VRC07-523LS and VOR, declines of IPDA or QVOA were seen, that did not reach statistical significance. Of note, we observed significant declines of rca-RNA despite exposure to VOR in three participants although non-significant depletions of IPDA and QVOA were observed. Viral isolates recovered from resting CD4 cell outgrowth assays did not acquire increased resistance to VRC-07 during the study. Low-level viremia (≤50 copies/mL) was absent or barely measurable in most participants. However, one participant maintained viremia of ca. 30 copies/ml throughout the study, despite the lack of evidence of VRC07 resistance.

Conclusions: VRC07-523LS and VOR were safe and well-tolerated. Downward trends in some parameters of HIV persistence were observed, but a definitive reduction in the HIV reservoir as measured by a 50% decrease in QVOA was not measured. The persistence of low-level viremia in one participant raises the concern that Ab-directed clearance may not be efficient enough to impact small populations of transiently productive infected cells. More efficacious antiviral immune interventions, likely paired with more effective latency reversal approaches that are now emerging, must be developed to clear persistent HIV infection.

OALB01LB Track B late-breaker oral abstracts

OALB01LB01

Early termination of randomisation into TB-PRACTECAL, a novel six months all-oral regimen Drug Resistant TB study

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Background: Almost 500,000 people develop multidrug resistant tuberculosis (MDR-TB) annually with a treatment success rate of around 60%. Treatment consists of up to 20 pills per day taken between 9 and 24 months. TB-PRACTECAL (NCT02589782) is a multi-arm multi-stage, randomised controlled, open-label phase II/III trial to evaluate the safety and efficacy of regimens containing bedaquiline, pretomanid and linezolid for the treatment of MDR-TB. On 18th March, 2021, randomisation was terminated early following recommendations from the trial's Data and Safety Monitoring Board (DSMB). We present the trial design, rationale for this decision and the planned next steps.

Description: Adults and children aged from 15 years were enrolled from Uzbekistan, Belarus and South Africa. An adaptive phase IIB/III design was chosen to accelerate the trial. Stage 1/phase IIB comprised of 3 investigational arms compared to locally approved standard of care (SoC). The best performing arm was selected for stage 2/PIII. In Stage 2, patients were randomised to either PRACTECAL-1 arm (B-Pa-Lzd-Mfx) or SoC.

The primary outcome was patients with an unfavourable outcome (treatment failure, death, treatment discontinuation, recurrence, loss to follow-up) at 72 weeks post-randomisation. Target sample size was 201 per arm.

Lessons learned: Recruitment termination decision was based on 120 patients randomised to PRACTECAL-1 arm and 120 to SoC. Around 25% of patients have HIV co-infection. Interim analysis of the primary outcome showeda difference of at least three standard deviations favouring PRACTECAL-1 compared to SoC. The difference was driven by a higher rate of treatment discontinuations in the SoC arm. There were five deaths in the SoC versus none in PRACTECAL-1. Total patients randomised at randomisation termination was 552.

Conclusions/Next steps: The results of the interim analyses convinced the DSMB that equipoise between the two arms no longer exists. Accumulated data of all 552 patients will be analysed and submitted to answer PICO questions for the World Health Organization Rifampicin resistant TB guidelines development process.

Results will be published by the end of the year. All patients will be followed up to at least 72 weeks. Given the positive findings, MSF is developing guidance and collaborations to scale up the regimen.

OALB01LB02

High rate of successful outcomes treating highly resistant TB in the ZeNix study of pretomanid, bedaquiline and alternative doses and durations of linezolid

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Background: In the Nix-TB trial, a 6-month BPaL regimen, starting with 1200 mg linezolid daily, resulted in 89% durable cure at 24 months post therapy follow-up, but a high rate of linezolid-related adverse events. The subsequent ZeNix trial enrolled patients with highly resistant TB in South Africa, Russia, Georgia and Moldova and treated them for 6 months with bedaquiline (B), pretomanid (Pa) and varying doses and durations of linezolid (L), with follow up to the primary endpoint 6 months after completion of treatment.

Methods: Patients were treated for 6 months with bedaquiline (200 mg daily for 8 weeks followed by 100 mg daily for 18 weeks), pretomanid (200 mg daily) and were equally randomized, dose-blinded, to daily linezolid starting at 1200 mg for 6 months (1200L6M), 1200 mg for 2 months (1200L2M), 600 mg for 6 months (600L6M), or 600 mg for 2 months (600L2M). Clinical, laboratory and sputum liquid culture evaluations were performed at baseline, weekly for 8 weeks and then every 2-4 weeks through the end of treatment, monthly for 3 months, and at the primary endpoint 6 months after completion of treatment.

Results: 181 participants with highly resistant TB were enrolled. A high success rate at the primary endpoint, similar to Nix-TB, was observed: 93% in 1200L6M, 89% in 1200L2M, 91% in 600L6M and 84% in 600L2M. Patients in the 1200L6M arm had higher rates of adverse events of peripheral neuropathy and myelosuppression: 38% and 29% in 1200L6M, 24% and 15% in 1200L2M, 24% and 13% in 600L6M, and 13% and 16% in 600L2M, respectively. Four patients had optic neuropathy that reversed, all in the 1200L6M arm. More patients in the 1200L6M arm required linezolid dose modification (reduction, interruption, or discontinuation): 51% in 1200L6M, 28% in 1200L2M, 13% in 600L6M, and 13% in 600L2M.

Conclusions: The ZeNix trial confirms the high relapse-free cure rate for the BPaL regimen in highly resistant TB and suggests that reduced doses and/or shorter durations of linezolid than 1200 mg for 6 months have similar efficacy and improved safety.

OALB01LB03

Single high-dose liposomal amphotericin based regimen for treatment of HIV-associated Cryptococcal Meningitis: results of the phase-3 Ambition-cm Randomised Trial

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Background: Cryptococcal meningitis (CM) is a leading cause of HIV-related mortality. Based on phase-II study data showing that a single high-dose of 10mg/kg liposomal amphotericin-B (AmBisome, Gilead Sciences Inc) was non-inferior to 14 days of standard dosing in clearing Cryptococcus from the cerebrospinal fluid we performed a phase-III randomised controlled non-inferiority trial to examine the impact of a single high-dose of AmBisome in averting all-cause mortality from CM.

Methods: HIV-positive adults with a first episode of CM in Botswana, Malawi, South Africa, Uganda and Zimbabwe were randomised to induction therapy of either (i) single, high-dose AmBisome (10mg/kg) given with 14 days of flucytosine 100mg/kg/day and fluconazole 1200mg/day (AmBisome) or (ii) 7 daily doses of amphotericin B deoxycholate (1mg/kg) plus 7 days of flucytosine 100mg/kg/day, followed by 7 days of fluconazole 1200mg/day (control). All participants received consolidation therapy of fluconazole 800mg/day for eight weeks. The primary endpoint was all-cause mortality at 10 weeks with the trial powered to show non-inferiority with a 10% margin.

Results: We randomised 844 participants from January 2018 to February 2021. 60.2% were men, with median age of 37 years, median CD4 of 27 cells/mm2, and 28.5% had abnormal mental status; 30 participants met early withdrawal exclusion criteria, leaving 814 in the intention-to-treat (ITT) population. None were lost to follow-up. In the primary ITT analysis 10-week mortality was 24.82% (101/407) in the AmBisome arm and 28.75% (117/407) in the control arm. The difference in mortality between the AmBisome arm and control arm was -3.93%, with the upper limit of the 1-sided 95%CI for the difference being 1.17%, well below the pre-specified 10% non-inferiority margin. The single high-dose AmBisome treatment was well tolerated.

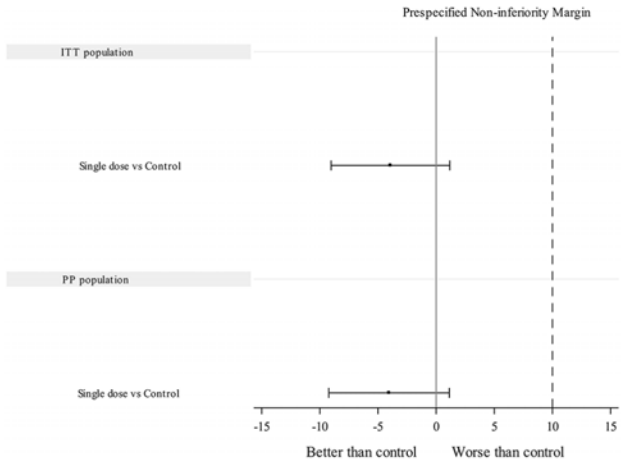

Figure. Point estimate for difference in mortality between arms with 90% confidence intervals (equivalent to one sided 95% confidence interval) and 10% NI margin shown for reference.
ITT: intention to treat. PP: per-protocol

Conclusions: Single high-dose AmBisome on a backbone of flucytosine and fluconazole was non-inferior to the current WHO recommended standard of care for HIV-associated cryptococcal meningitis.

OALC01LB Track C late-breaker oral abstracts

OALC01LB01

Adherence to the dapivirine vaginal ring and oral PrEP among adolescent girls and young women in Africa: interim results from the REACH study

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Background: Adolescent girls and young women (AGYW) account for most new HIV infections in sub-Saharan Africa. WHO has endorsed oral PrEP and dapivirine vaginal ring (ring) for women at substantial risk of HIV infection. However, adherence to both products was lower among younger women in randomized placebo-controlled trials. We assessed interim safety, adherence and acceptability of both products among AGYW between February 2019 and April 2021.

Methods: MTN-034 (REACH) enrolled 16–21-year-old HIV-uninfected, non-pregnant AGYW from South Africa, Zimbabwe, and Uganda. In the first two study phases, AGYW were randomized to either monthly dapivirine ring or daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) for six months, then switched to the second product for six months. Safety is assessed by ≥ grade 2 adverse events (AEs); adherence by residual drug levels in returned rings and plasma dried blood spots (DBS) for oral PrEP. In this analysis, dapivirine levels indicating release of ≥0.1071mg/day (0.9mg/28d) were defined as moderate and ≥0.1426mg/day (3.0mg/28d) as high adherence. DBS concentration of ≥700fmol tenofovir diphosphate/punch was defined as moderate adherence(associated with 100% efficacy among men who have sex with men) and ≥1200fmol/punch as high. Acceptability was measured by self-report.

Results: 247 AGYW were enrolled with an average age of 18. Twenty six months into the study, retention to study visits is 94.4%. Approximately 35% of participants had at least 1 sexually transmitted infection at baseline (chlamydia: 28.7% [71/247]; gonorrhea 8.5% [21/247]). Most participants had at least moderate adherence to ring (77.8% [1064/1368]) and oral PrEP (58.6% [768/1310]).

High adherence was observed in 50.2% of ring and 22.4% of oral PrEP users (687/1368 and 294/1310 of timepoints). AEs of ≥ grade 2 were experienced by 78% (187/241) of ring users and 77% (188/245) of oral PrEP users. Acceptability varied, with 88.5% (193/218) liking ring and 63.9% (140/219) liking oral PrEP. One HIV acquisition and 4 incident pregnancies were reported.

Conclusions: Adherence to oral PrEP and dapivirine ring was higher than previously observed among African AGYW, and both were well-tolerated and highly acceptable. Dapivirine ring is a viable, promising new HIV prevention method, and adherence to both products can be achieved with support strategies.

OALC01LB02

High rates of drug resistance in individuals diagnosed with HIV in tenofovir disoproxil fumarate (TDF)-based pre-exposure prophylaxis rollout programs in Kenya, Zimbabwe, Eswatini and South Africa

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Background: The ongoing rollout of oral TDF-based PrEP has the potential to reduce HIV incidence in Sub-Saharan Africa (SSA) but HIV drug resistance (HIVDR) in PrEP breakthrough infections could threaten treatment effectiveness, contribute to spread of resistance, and undermine efforts to control HIV. Accordingly, the Global Evaluation of Microbicide Sensitivity (GEMS) project was established to monitor HIVDR in PrEP rollout programs in SSA.

Methods: USAID/PEPFAR-supported GEMS implemented resistance monitoring in PrEP users diagnosed with HIV while participating in national PrEP programs in Kenya, Zimbabwe and Eswatini, or rollout projects in South Africa. Blood samples were collected from consenting participants diagnosed with HIV on PrEP. Demographics and self-reported adherence

were collected via questionnaire. Tenofovir-diphosphate (TFV-DP) levels were measured by liquid chromatography–mass spectrometry. HIVDR mutations were detected by population genotyping and analyzed using Stanford HIVdb v9.0.

Results: Of 204 reported seroconversions on PrEP, 175 (86%) participants provided a sample, including 72 (41%) from South Africa, 58 (33%) from Kenya, 28 (16%) from Zimbabwe and 17 (10%) from Eswatini. These 175 participants had a median age of 24 years (range 16-67) and 74% were female.

Key populations included HIV serodiscordant partnerships (21%), female sex workers (10%), men who have sex with men (9%), and transgender individuals (6%). 26% of infections occurred within 60 days of PrEP initiation. TFV-DP was detectable (≥31.25 fmol/punch) in 63 of 86 (73%) samples, with 49 of those 63 (78%) self-reporting good/fair adherence. 104 (59%) samples were successfully genotyped; insufficient HIV RNA (35% of all samples) was the predominant reason for no result.

At least one major HIVDR mutation was detected in 47 (45%) samples, including 3TC/FTC-associated M184IV (21%), TDF-associated K65R (3%) and K70EN (3%). Transmitted NNRTI mutations unrelated to PrEP included K101E (1%), K103NS (13%), V106IM (5%), Y181C (2%), and G190A (7%).

Conclusions: The high frequency of HIV drug resistance in HIV-infected individuals on PrEP (21% with M184IV; 3% with K65R) exceeds background levels of transmitted nucleoside/tide resistance in SSA (≤5%). Improved identification of acute infection before initiating PrEP, and HIVDR monitoring on PrEP is essential for PrEP rollout programs to preserve antiretroviral options for both treatment and prevention.

OALC01LB03

Safety and pharmacokinetics of oral islatravir once monthly for HIV pre-exposure prophylaxis (PrEP): week 24 analysis of a phase 2a trial

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Background: Islatravir (ISL) is a nucleoside reverse transcriptase translocation inhibitor in development for prevention of HIV-1. Phase 3 trials of oral ISL 60mg once monthly (QM) are enrolling. We present unblinded safety and pharmacokinetic (PK) results through Week 24 of an ongoing phase 2a trial of monthly ISL for PrEP.

Methods: This randomized, double-blind, placebo-controlled, parallel-group, multicenter trial (NCT04003103) assesses the safety, tolerability, and PK of oral ISL in adults (age 18-65 years) at low-risk for HIV-1 acquisition. Participants were randomly assigned (2:2:1) to receive 6 QM doses of ISL 60mg, ISL 120mg, or matching placebo. ISL in plasma was measured in all participants; ISL-triphosphate (ISL-TP) in peripheral blood mononuclear cells (PBMCs) was measured in a subset. Safety assessments included adverse event (AE) reporting and laboratory results monitoring. Aggregate safety results through 05-Apr-2021 are reported here; unblinded safety results for all participants through Week 24 will be available for presentation.

Results: Of 242 participants randomized (median age 31 years, 67% female, 53% white, 42% Black or African American),189 completed dosing, 15 discontinued study intervention, and 38 were ongoing as of 05-Apr-2021. AEs were reported by 60% of participants; the most common AEs were headache (9%), diarrhea (5%), and nausea (5%). AEs considered drug-related by the investigator were reported in 15% of participants; all drug-related AEs were mild or moderate (DAIDS grade 1-2).

Two participants discontinued study drug due to drug-related AEs (mild foreign body sensation in throat; moderate rash and pruritis). Two serious AEs (including one death) were reported; neither was considered drug-related. Grade 3-4 laboratory values were uncommon (Table).

ISL-TP trough concentrations after both ISL 60mg and 120mg QM dosing remained above 0.05 pmol/10^6 PBMCs, the pre-specified threshold for PrEP.

Conclusions: Oral ISL 60mg and 120mg QM were well-tolerated over 24 weeks and achieved the pre-specified PK threshold for HIV-1 prevention.

Parameter	Criteria	% of Participants
Aspartate Aminotransferase (IU/L)	Grade 3: 5.0 to <10.0 x ULN	0.4
Creatine Kinase (IU/L)	Grade 3: 10.0 to <20.0 x ULN	0.8
	Grade 4: ≥20.0 x ULN	0.4
Creatinine Clearance, estimated (mL/min)	Grade 3: <60 to 30, or 30% to <50% decrease from baseline	4.1
	Grade 4: <30, or ≥50% decrease from baseline	0.4
Lipase (IU/L)	Grade 3: 3.0 to <5.0 x ULN	1.7
	Grade 4: ≥5.0 x ULN	0.4
Neutrophils (10^9/L)	Grade 3: 0.400 to 0.599	0.4
	Grade 4: <0.400	0.4

ULN = Upper limit of normal
For graded criteria, participants are counted once per test in the highest grade reported. Criteria based on Division of AIDS 2017 Table for Grading the Severity of Adult and Pediatric Adverse Events.

Table. Grade 3 or 4 laboratory values

OALD01LB Track D late-breaker oral abstracts

OALD01LB01

Factors associated with 12-month retention after referral to a differentiated service delivery for HIV treatment model in Zambia

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Background: Many countries across sub-Saharan Africa are rapidly scaling up differentiated service delivery (DSD) for HIV treatment models to support person-centered care. We assessed the associations between patient and facility characteristics and 12-month retention after referral to DSD across DSD models in Zambia.

Methods: A retrospective record review using electronic medical records was done including adults (≥15 years) who started DSD between October 2019 and March 2020. Retention was defined as in ART care on 31 December 2020. We categorized DSD models into six groups: multi-month dispensing (MMD), fast-track, group models, alternative pick-up points, home delivery, and extended facility hours. Relative risk of loss to follow-up (LTFU) was estimated by DSD model adjusted for age, gender, location (urban/rural), and care level stratified by antiretroviral therapy (ART) dispensing interval. Using linear regression, a facility-level analysis assessed the association between mean percentage of patients LTFU per facility with location, care level, number of DSD models and percentage of patients receiving 4-6MMD.

Results: Of 90,829 patients referred to DSD models, the majority (78.3%, n=71,101) received 4-6 MMD. Among those receiving 4-6 MMD, those in fast-track and group models had lower adjusted risk of LTFU after 12 months compared to those receiving only MMD (adjusted risk ratio (aRR) 0.63, 95% confidence interval (CI) 0.59-0.67; aRR 0.72, 95%CI 0.62-0.84, respectively) (Figure 1). Among those receiving 3MMD, there was no difference in LTFU by DSD model. At the facility level, the adjusted risk of LTFU increased with having multiple DSD models available at the facility compared to having just one DSD model (increased LTFU of +2%, 95% CI: 0%-5%).

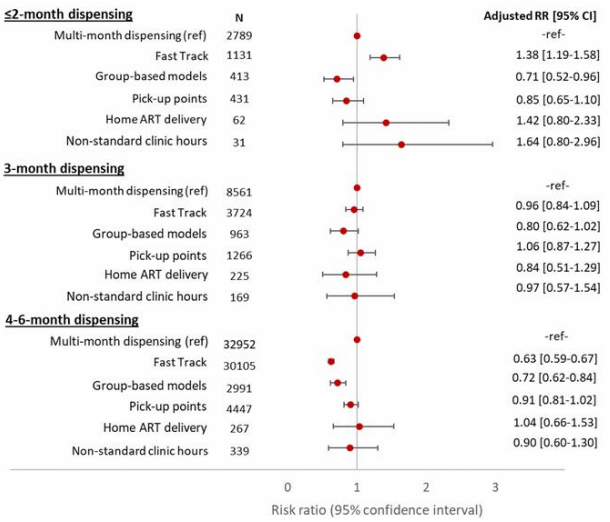

Figure 1. Adjusted risk ratio of loss to follow-up by ART dispensing interval and DSD model (reference group: multi-month dispensing)

Conclusions: Twelve-month retention varied by DSD model, MMD duration, and facility-level characteristics in Zambia. Efforts are needed to support long-term retention in DSD models and understand the interaction between specific models, health facility and patient level characteristics.

OALD01LB02

Community-led quality improvement of HIV services using community scorecards in Vietnam

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Background: Meaningful community engagement decreases stigma and discrimination (S&D) and improves the quality of HIV services. Community scorecards (CSC) were introduced in two Vietnamese high-burden provinces to reduce S&D, facilitate community engagement, and improve services.

Description: The CSC is a two-way, participatory, community-led quality improvement tool adapted for the Vietnamese context. Community representatives led CSC indicator development with inputs from health staff (HS). Communities and HS both rated 15 quantitative indicators (score, 1 [poorest quality] to 10 [best quality]) covering prevention, counseling and testing, care and treatment, facilities, policy and procedures, and overall satisfaction. Discussions also provided qualitative data for all indicators. Each CSC scoring meeting included 15-20 representatives from HS and the community. Quarterly CSC implementation began in January 2020 at seven sites; three successive rounds have been completed by April 2021 with advocacy action plans.

Lessons learned: CSC substantially improved services, as exemplified by two sites (Figure 1). After CSC, clients reported increased access to free prevention commodities (e.g., condoms, needles) and informational materials. Facilities also designated individual counseling rooms to meet clients' request for increased privacy. Finally, CSC promoted friendlier services. Facilities improved client spaces and comfort (e.g., restroom, waiting space furniture) and introduced new procedures to reduce waiting time and S&D. No incidents of S&D were reported after round 2.
Quantitative scores sometimes did not accurately reflect service quality. For example, at times clients gave high scores, HS gave themselves low scores, but qualitative discussions indicated intermediate quality. Clients and HS reported that CSC provided a platform to review service quality, understand service gaps, and build trusting relationships.

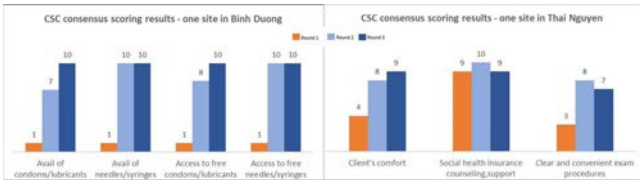

Figure 1. Three rounds of community scorecard (CSC) consensus scoring results at two sites in Vietnam (January 2020 - April 2021). Results from seven of the total 15 indicators are demonstrated. Each indicator is scored from 1 (poorest quality) to 10 (best quality), with consensus from both health staff and community representatives/service users during the interface meeting.

Conclusions/Next steps: CSC in Vietnam successfully facilitated meaningful partnerships between the HIV-affected community and HS and led to improvements. Both groups shared decision-making responsibility. Future efforts will include expansion of CSC to more sites across Vietnam and linking CSC findings with community-led monitoring initiatives.

OALD01LB03

RAPID-VL intervention improves viral load ordering, results turnaround time and viral suppression: a cluster randomized trial in HIV clinics in Uganda

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Background: HIV viral load (VL) monitoring is crucial for long-term antiretroviral therapy (ART) success. However, challenges in Africa include suboptimal VL ordering by clinicians, delayed VL turnaround time, and suboptimal VL counseling/interpretation.

Methods: A cluster-randomized controlled "pre-post" trial was conducted in 20 PEPFAR-supported HIV clinics (10 intervention/10 control) in southwestern Uganda. We enrolled four high-risk patient groups (pregnant/breastfeeding women, children/adolescents (2-17years), viremic patients, patients overdue for VL), and non-high-risk adults. Retrospective clinic data (2017-2018 "pre-intervention") on N=1200 participants (60/clinic; 20 clinics) was obtained, and N=1200 new participants enrolled prospectively (2018-2020 "post-intervention"; N=2400 total).

The RAPID-VL intervention included: (1)-a VL-ordering flowsheet with quarterly performance feedback, (2)-rapid near-point-of-care VL testing (Cepheid GeneXpert) with same/next-day telephone delivery of VL results to patients, and (3)-clinician training on VL results counseling. Control clinics used standard-of-care VL ordering/testing/counseling per Uganda's national program.

Primary outcomes were (1)-VL turnaround time (result delivery to patients) and (2)-% of visits with guideline-concordant VL ordering. Secondary outcome was VL suppression one-year post-intervention. Intervention effect was analyzed by cluster-adjusted difference-in-difference estimation.

Results: Of 2400 participants, 66.4% were female, mean age 37 (range 18-88), and median ART duration 2.8 years. Pediatric participants were 50.9% female, mean age 9 (range 2-17), and median ART duration 3 years. Pre-intervention VL turnaround time was not significantly different between intervention and control clinics (mean 73.4 days;p=0.20 cluster-adjusted).

Post-intervention, turnaround time was significantly reduced in intervention vs. control clinics (median=1 vs. 56 days). Intervention-associated change in mean turnaround time, adjusting for temporal trends and clinic-level clustering, was -67.3 days (p<0.0001). Significant reductions were seen within every patient subgroup. Pre-intervention, VL ordering was not significantly different in intervention vs. control clinics (70.5% vs. 72.2%;p=0.081). Post-intervention, the intervention-associated improvement in VL ordering was +10.4% (p=0.01). One-year viral suppression post-intervention in measured participants was 83.1% in intervention clinics and 76.0% in control clinics (+7.1%, p=0.0091).

Conclusions: In this large cluster RCT in Uganda, a multi-component intervention with boosted clinician training and rapid near-point-of-care VL testing: (1)-significantly reduced VL turnaround time, (2)-significantly improved guideline-concordant VL ordering, and (3)-significantly improved 1-year viral suppression. The RAPID-VL intervention may strengthen VL operations within national ART programs.

OALX01LB IAS 2021 Co-Chairs' Choice

OALX01LB01

Comparative functional analysis of HIV-1 accessory proteins Nef and Vpu in African LTNPs and chronic progressors

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Background: HIV-1 Nef and Vpu enhance viral pathogenicity through partially overlapping immune evasion functions, but few studies have assessed both proteins together in HIV-infected individuals exhibiting slower disease progression. Here, we analyzed and compared the functions of Nef and Vpu sequences isolated from 38 HIV-1 infected long term non-progressors (LTNPs) from Rwanda with those of 24 Vpu and 92 Nef sequences isolated previously from chronically infected individuals (CI).

Methods: HIV RNA was extracted from plasma and nested RT-PCR was used to amplify Nef and Vpu coding regions. Amplicons were cloned into an expression vector, which features dual promotors driving Nef/Vpu and GFP expression. Nef and Vpu clones were transfected by electroporation into an immortalized CD4+ T-cell line (CEM).

The ability of each Nef clone to down-regulate CD4/HLA and each Vpu clone to down-regulate CD4/Tetherin was quantified by flow cytometry and the resulting data normalized to that of negative (empty vector) and positive (Nef SF2 and Vpu NL4.3) controls.

Results: Normalized Vpu-mediated downregulation activity among LTNPs (median [IQR]) was 0.97 [0.78-1.11] for CD4 and 0.93 [0.79-0.99] for Tetherin, while Nef-mediated downregulation activity was 0.98 [0.90-1.0] for CD4 and 0.71 [0.47-0.74] for HLA. Vpu-mediated CD4 downregulation activity and Nef-mediated HLA downregulation functions were significantly lower in LTNPs compared to CI (p=0.003 and p<0.0001, respectively).

Conclusions: Our results show variable Nef and Vpu activity in LTNPs versus CI, suggesting a modest functional impairment in LTNPs that may contribute to a delayed clinical disease.

OALX01LB02

Efficacy and safety of long-acting subcutaneous lenacapavir in phase 2/3 in heavily treatment-experienced people with HIV: week 26 results (Capella study)

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Background: Lenacapavir (LEN), a long-acting first-in-class HIV capsid inhibitor with full activity against multidrug-resistant mutants, is in clinical development. The ongoing Phase 2/3 Capella study in heavily treatment-experienced (HTE) people with HIV (PWH) failing their current regimen with multidrug-resistance achieved the primary endpoint demonstrating short term potent antiviral activity of LEN vs placebo during the 14-day functional monotherapy period.

Methods: In the randomized cohort, participants were randomized (2:1) to add oral LEN or placebo to their failing regimen (600 mg on Day 1[D] and 2 and 300 mg on D8). At D15, those on oral LEN received subcutaneous (SC) LEN 927 mg (Q6M); those on placebo started the oral lead-in, followed by SC Q6M. All randomized participants initiated an investigator-selected, optimized background regimen (OBR) at D15. In the non-randomized cohort, participants started OBR concurrent with LEN (oral lead-in à SC).

We report the secondary endpoint of Week 26 (W26) efficacy in the randomized cohort, and additional available efficacy and safety from both cohorts.

Results: 72 participants enrolled: 36 in each cohort. Overall, 25% were female; 38% Black. Median age was 52 years; median CD4 count was 150 cells/μL; mean HIV-1 RNA (VL) was 4.17 $\log_{10}$ c/mL. Resistance to ≥ 2 ARVs in each class was 99%(NRTIs), 97% (NNRTIs), 81% (PIs) and 69% (INSTIs). At W26 in the randomized cohort, 81% (29/36) had VL<50 c/mL via FDA-Snapshot algorithm. In participants with data through W26 from both cohorts, 79% (33/42) had VL<50 c/mL via missing=failure. Median CD4 count increased by 82 cells/μL.

Four randomized participants had emergent LEN resistance; 3 suppressed afterwards, one with OBR change and two without. Resistance analysis in non-randomized participants is ongoing. There were no study drug-related serious adverse events (AEs) or AEs leading to discontinuations. LEN-related ISRs occurred in 56% (40/72) and were mostly mild or moderate (38/40). Most common ISRs (>20%) were swelling (26%) and erythema (24%); both resolved within days.

Conclusions: Subcutaneous LEN in combination with OBR led to sustained virologic suppression in 81% of HTE PWH at W26. LEN was safe and well tolerated. These results support the ongoing evaluation of LEN for treatment and prevention of HIV-1 infection.

OALX01LB03

Initial results of recent HIV infection surveillance in Cambodia, 2020

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Background: Recent HIV infection surveillance can help to identify populations and geographies with active transmission. We compared risk factors among recent and long-term infections from the initial ten months of recent HIV infection surveillance in Cambodia to help target prevention interventions and rapid treatment initiation among newly diagnosed individuals of recent HIV infection.

Methods: We used demographic and risk data collected in the National HIV Voluntary Counselling and Testing (VCT) data from March through December 2020. Clients aged ≥15 years and newly diagnosed as HIV-positive were offered recency testing at 66 facilities in all 25 provinces of Cambodia. Blood specimens from consenting individuals were tested by the Asante HIV-1 Rapid Test for Recent Infection (RTRI). We compared the distribution of clients with RTRI-recent and long-term infection by select characteristics using chi-square tests in STATA16.

Results: Of 2,464 newly diagnosed HIV-positive VCT clients, 2,080 (84%) consented to RTRI testing, and 161 (8%) were classified as RTRI-recent infections. The percentage of clients with recent infection did not vary by sex (men, 76%; women, 24%; p=0.629).

Overall, there were statistically significant differences in some age groups, population groups, and provinces. Recent infections were significantly more frequent among clients aged 20-34 years (p<0.001), entertainment workers (p=0.001), and men who have sex with men (MSM) (p<0.001) compared to those with long-term infections. Similarly, recent infections were more frequent identified in Siem Reap (p=0.010) and Phnom Penh (p=0.038) provinces (Table 1).

Demographic Characteristics	Percentage of RTRI-Long-term infection (n=1919)	Percentage of RTRI-recent infection (n=161)	P-value
<20 years	6% (109)	6% (9)	0.962
20-34 years	60% (1145)	76% (123)	<0.001
>=35 years	35% (664)	18% (29)	<0.001
Male	75% (1433)	76% (123)	0.629
Female	25% (486)	24% (38)	
Siem Reap province	12% (234)	19% (31)	0.010
Phnom Penh province	42% (815)	51% (82)	0.037
Other provinces	26% (496)	12% (20)	<0.001
Risk group characteristics			
Entertainment worker	3% (54)	7% (12)	0.001
Men who have Sex with Men	41% (793)	58% (94)	<0.001
General population	50% (967)	32% (51)	<0.001

Table 1. Comparison of RTRI-long term and RTRI-recent by demographic and risk group characteristics

Conclusions: Initial recent HIV surveillance data suggest that recent transmission in Cambodia may be driven by several age, population, and geographic groups different from those with long-term infections. Continued surveillance may facilitate improved targeting of HIV prevention and treatment interventions.

OALX01LB04

Impact of COVID-19 on HIV treatment interruption in seven PEPFAR countries, April–June 2020

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Background: Modeling estimates indicated that the COVID-19 pandemic would impact access to treatment for people living with HIV due to national lockdowns, restricted mobility, and overwhelmed healthcare infrastructures.

We evaluated seven U.S. President's Emergency Plan for AIDS Relief (PEPFAR)-supported countries to determine if the COVID-19 pandemic caused interruption in HIV services.

Methods: We reviewed quarterly program data from Centers for Disease Control and Prevention HIV treatment sites among seven PEPFAR-supported countries with mature treatment programs (>80% treatment coverage). Interruption in treatment (IIT) in the months with the most restrictive mitigation measures or lockdown (April–June 2020 [P2]) were compared with the 3-month periods before (January–March 2020 [P1]) and after (July–September 2020 [P3]). Narrative data were reviewed for context.

Results: During December 2019, 1,838,396 individuals were receiving antiretroviral therapy (ART) in the seven PEPFAR-supported countries assessed. Overall, in the quarter before the lockdowns (P1 vs. P2), 23% more patients experienced IIT; in the quarter after the lockdowns (P3 vs. P2), 10% fewer patients experienced IIT (Table 1).

Country	Patients Experiencing an Interruption in Treatment (IIT)			*positive value indicates P1 had a greater IIT than P2	*negative value indicates P2 had a greater IIT than P3
	January-March 2020 (P1)	April-June 2020 (P2-lockdown)	July-September 2020 (P3)	% change between P1 and P2: (P1 - P2)/P2×100	% change between P3 and P2: (P3 - P2)/P2×100
Total	51,966	42,133	37,780	23	-10
Botswana	221	1,891	1,113	-88	-41
eSwatini	298	181	186	65	3
Namibia	2,276	1,974	2,047	15	4
Rwanda	548	534	525	3	-2
Uganda	16,115	23,046	15,069	-30	-35
Zambia	25,968	9,060	14,806	187	63
Zimbabwe	6,540	5,447	4,034	20	-26

Table 1. Interruptions in treatment during the COVID-19 pandemic

Although results varied by country, the number of patients experiencing IIT after the lockdown was either less than that during the lockdown or remained lower than before the lockdown, with the exception of Botswana. Common themes from narratives showed that programs used alternate facility refills, multi-month dispensation, community-based ART refills, and social distancing and mitigation measures in clinics to adapt to the COVID-19 pandemic.

Conclusions: During the initial COVID-19 lockdowns, treatment interruptions did not increase across PEPFAR-supported countries with high ART coverage. These findings suggest the rapid adoption of innovative strategies including policies around multi-month dispensing and community ART access sustained HIV treatment during the initial months of the COVID-19 pandemic. However, further research is warranted to understand the variation in IIT among these countries.

LATE BREAKER E-POSTERS

Track A late-breaker posters

PEALB01

HIV-1 segmentation-based transcript models define 5′ Untranslated Region (UTR) and Open Reading Frame (ORF) Classes, elucidate total viral protein-coding capacity, and are summarized by a new HIV-1 mRNA naming convention

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Background: Biologically relevant open reading frames (ORFs) were hidden across many reported HIV-1 isoforms. We developed the locus segmentation method leveraging long-read RNA-seq to define HIV-1 mRNAs and prioritize the study of biologically relevant isoforms.

Methods: We compared long-read data from 15 HIV-1 virion preparations and NL4-3 and 89.6 HIV-infected CD4+ lymphocytes. Reads were aligned to references using Minimap2 –splice, and then assembled using StringTie. Transcripts satisfying 0.0001 (0.1%) minimum isoform fraction were retained. Data from relevant runs were merged and curated by comparing to aligned reads in the Integrative Genomics Viewer and SnapGene.

Results: Our models prioritized differentially expressed regions of HIV-1 (a model genomic locus) which we call segments. We found 11 segments. Although eight non-constitutive segments could form 256 isoforms, we only detected 40. These HIV-1 transcript models were first classified based on presence of conserved UTR segments. This ontology enabled a precise transcript naming scheme which unambiguously captures ORFs available for translation.

Our models predict 14 new viral proteins (GENER1A, *GENER1B, GENER2, GENER3, *GENER4, *GENER5, *GENER6/8, *GENER7, *GENER9, GENER10, GENER11, GENER12, GENER13, GENER14; *polyproteins), including 5 unexplored integrase isoforms. Most ORFs >75 amino acids. These more than double the total number of HIV-1 proteins previously reported.

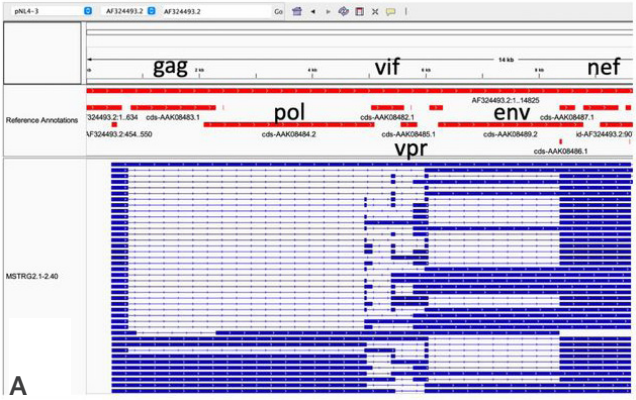
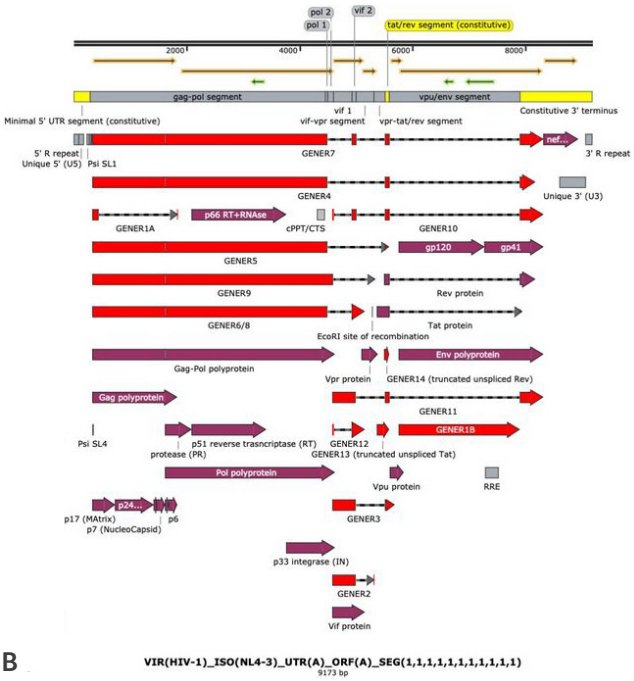


Figure. HIV-transcript models (A) enable HIV-1 mRNA segmentation which define 14 new putative HIV-1 proteins (B). A. Transcript models made from Ngyuyen et al. 2020 (Ocwieja et al. 2012 and virion not shown) in blue as .gtf anchored to NL4-3 in IGV. Non-specific artifacts removed.



B. Unspliced HIV-1 NL4-3 (MSTRG.2.4). Open reading frames (ORFs) in orange (+) or green (-). Constitutively expressed segments (yellow) define complete HIV-1 transcripts. Classic HIV proteins (maroon). New ORFs are (+) and red. Antisense protein not shown because of lack of evidence in virion (our work) and NL4-3- infected CD4+ T cell lysate datasets (others'). 89.6 and virion not shown but conserved many of the above. Locus segmentation nomenclature defines transcripts unambiguously as string with virus name (VIR), strain/isolate name (ISO), UTR Class (UTR), ORF Class (ORF), and segmental binary string (SEG; where 1 = expressed, and 0 = not expressed

We used our transcript models to measure HIV-1 gene expression in the NL4-3 dataset, and recapitulated others' findings in a simplified and reproducible pipeline.

Conclusions: Locus segmentation improves HIV-1 bioinformatics by clarifying intron/exon ambiguity and enabling others to prioritize differentially expressed HIV-1 segments. We propose new UTR and ORF classifications to unambiguously define most common HIV-1 mRNAs for the first time.

Our method is tractable for transcript modeling and transcript profiling (measuring mRNA expression) with newer long-read datasets, and is reverse-compatible with existing short-read RNA-seq. For the first time, we reveal HIV-1's protein-coding potential and can begin determining putative protein expression and function.

PEALB02

HIV-1 productive infection is dependent on the NLRP3 inflammasome in monocytes, macrophages, and CD4 T cells

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Background: HIV-1 infection drives inflammatory comorbidities uncontrolled by modern drug regimens. The mechanisms underscoring this chronic inflammation remain undefined. The NLRP3 inflammasome is a mediator of inflammatory signaling activated by HIV-1 cellular entry. It is a cytosolic multi-protein complex that contains the adaptor protein ASC. Dual inhibitors of HIV-1 infection and HIV-induced inflammatory

cascades have been characterized, and the relationship between HIV-1 and NLRP3 is of growing interest. Here, we investigate the role of NLRP3 inflammasome constituents in mediating HIV-1 productive infection.

Methods: THP-1 ASC and NLRP3 knockout lines were infected with the mCherry reporter virus HIV-1 $NLCI_{NL4-3}$. Cell infection and viability were measured 5 days post-infection by flow cytometry. This experiment was repeated in PMA-differentiated THP-1 macrophages. MT-4 cells and THP-1 monocytes were treated with serial dilutions of NLRP3 inhibitors NBC6 and NBC19, tubulin inhibitor colchicine, and purinergic receptor antagonist NF449. Cells were infected with HIV-1 $NLCI_{NL4-3}$. Infection and viability were measured by flow cytometry at 2 and 4 days post-infection, respectively.

Results: Deletion of ASC or NLRP3 resulted in significantly reduced HIV-1 $NLCI_{NL4-3}$ infection in THP-1 monocytes and macrophages. Viability was unchanged between control and test cell lines. HIV-1 infection was abrogated by treatment with NLRP3 inhibitors NBC6 and NBC19 in MT-4 T cells and THP-1 monocytes in a dose-dependent manner.

Conclusions: We demonstrate a novel requirement for NLRP3 inflammasome function in HIV-1 infection through monocyte and macrophage knockout models and pharmacologic inhibition in monocytes and T cells. These results suggest that NLRP3 inflammasome constituents may serve as mediators of HIV-1 productive infection. The NLRP3 inflammasome may be an attractive therapeutic target for dually antagonizing HIV-1 infection and inflammation. Further characterization of HIV-1 and NLRP3 inflammasome interactions is needed to elucidate mechanisms of HIV-induced chronic inflammation and advance HIV therapeutics.

PEALB03

Regulatory T cells (Tregs) dynamics and epigenetic regulation following antiretroviral therapy initiation during the acute HIV infection

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Background: HIV infection promotes the expansion of regulatory T-cells (Tregs), contributing to immune dysfunction, mucosal fibrosis, and disease progression. Early antiretroviral treatment (ART) upon HIV exposure improves CD4 count and decreases immune activation and reservoir size. However, Tregs dynamics following early ART initiation remain understudied.

Methods: Peripheral blood mononuclear cells (PBMCs) were collected from 123 individuals, including untreated HIV-infected in acute and chronic phases, ART-treated in early infection (median of ART initiation: 0.46 years post-infection), elite controllers (EC), immunological controllers (IC), and HIV-uninfected controls. Tregs were characterized by multiparameter flow cytometry. The methylation status of six regulatory regions of the *foxp3* gene was assessed using MiSeq sequencing technology.

Results: Total Treg frequency increased over time during HIV infection, which was normalized in early ART recipients. Tregs in untreated individuals expressed higher levels of activation and immunosuppressive markers (CTLA4, CD39, and LAP(TGF-β1)), which remained unchanged following early ART. Expression of gut migration markers (CCR6, CCR9, Integrin-β7) by Tregs was elevated during HIV infection and suppressed after treatment. Notably, gut-homing Tregs expressing LAP(TGF-β1) and CD39 remained higher despite early treatment. Additionally, the increase in LAP(TGF-β1)$^+$ Tregs and extrathymic Helios$^-$FoxP3$^+$ Tregs overtime during HIV infection were consistent with higher demethylation of conserved non-coding sequence (CNS)-1 in the *foxp3* gene. Remarkably, LAP(TGF-β1)-expressing Tregs in EC and IC were significantly higher than uninfected subjects, while the markers of Treg activation, migration, and function remained similar in these individuals.

Conclusions: Early ART initiation was unable to control the levels of immunosuppressive Treg subsets and their gut migration potential, which could ultimately contribute to gut tissue fibrosis and disease progression.

PEALB04

Expression of the CD127 receptor in T lymphocytes from naive HIV-1 patients

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Background: HIV-1 infection is characterized by a gradual lymphopenia and an increase in the levels of circulating interleukin-7 (IL-7) as the disease progresses to HIV/AIDS. The IL-7 receptor is constituted by two subunits IL-7Rα (CD127) and IL-7Rγ (CD132). CD127 is crucial for the survival, differentiation, function of T cells and mediates the signal of homeostatic proliferation.

The objective of the work was to quantify the population and the expression of the CD127 molecule in CD4$^+$Tand CD8$^+$T lymphocytes in HIV-1$^+$ naive patients.

Methods: The design of the work was observational, descriptive, prospective and analytical. We studied 49 HIV-1$^+$ naive individuals (39 men and 10 women) older than 18 years, treated at the Rawson Hospital, Córdoba, Argentina and as a control group 17 healthy individuals (9 men and 8 women). The following studies were performed: blood count, CD4$^+$T and CD8$^+$T count and viral load. The expression of the CD127 molecule in CD4$^+$T and CD8$^+$T was carried out by flow cytometry. The results were expressed as X ± SD in percentage value. Statistical analysis was performed with the InfoStat 2010 program.

Results: It was observed in the HIV-1$^+$ individuals, that the percentage of CD4$^+$T and CD8$^+$T expressing CD127 was significantly diminished with respect to the controls (CD4$^+$T: 45.75 ± 12.50% and 53, 3 ± 9.70% respectively, p =0.033 and D8$^+$T: 19.40 ± 16.60% and 40.90 ± 26.00% respectively, p=0.016). The expression of CD127 measured by the mean fluorescence intensity (MFI) in both T populations was found to be significantly decreased with respect to the controls (p <0.05). When the patients were grouped in the different clinical stages, it was observed in both populations of T lymphocytes that the percentage of CD127 cells and the MFI for CD127 decreased significantly in the HIV-1/AIDS stage with respect to the different groups and control (p <0.05).

Conclusions: The decrease of CD4$^+$TCD127$^+$ and CD8$^+$TCD127$^+$ populations and of IMF of CD127 in these cells in naive HIV$^+$ patients could limit the effect of IL-7 on T cell survival and homeostatic proliferation as a consequence of HIV-1 infection.

PEALB05

Transcriptome network analysis reveals the role of Tripterygium *wilfordii* hook F on interferon signaling pathway and immune activation in HIV immunological non-responders

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Background: The chronic immune activation persists in HIV patients, despite viral suppression under ART. The residual systemic inflammation is contributed to the destruction and dysfunction of CD4+ T cells, inspiring the need to develop anti-inflammatory therapeutic interventions in addition to ART. Our previous study demonstrated that the application of traditional Chinese medicine, Tripterygium *wilfordii* Hook F (TwHF), able to improve CD4 and reduce T cell activation. However, the mechanisms remain to be elucidated.

Methods: We enrolled 8 immunological non-responders (INRs) patients (ART > 4 years and CD4 < 350/μl) and 8 matched immunological responders (IR). 4 INR patients started to treat with TwHF (10mg TID) for 48 weeks. We performed RNA extraction, cDNA library preparation, and whole transcriptome sequencing on PBMCs in Illumina Hiseq 2500 platform. Differentially expressed genes (DEG) were analyzed by DESeq2. The canonical pathway analysis on DEG is performed with Ingenuity Pathway Analysis (IPA) and the reactome pathway analysis on whole sequencing data is performed with Gene Set Enrichment Analysis (GSEA).

We screened TwHF compound and related targets via TCM databases, and used SwissTargetPrediction and TargetNet to obtain possible targets. The interaction network of TwHF-related targets and experimental DEG was generated by STRING and analyzed in Cytoscape.

Results: The INR patients were characterized with lower CD4+ T cell counts (INR 252 [211-290]: IR 900 [829-1116]/μl), while after TwHF treatment, they experienced an average of 124/μl improvement. We found 316 DEG (146 upregulated and 160 downregulated) in INR patients, these DEG mostly enriched in the interferon (IFN) signaling pathway (-logP=7.48, Zscore=2.83). GSEA analysis also enriched the IFN-α response (ES=0.62) and the IFN-γ response (ES=0.59) pathway. The application of TwHF inhibited the IFN-signaling pathway (IPA Zscore=-2.12 in M3, -3.16 in M6). We collected 213 TwHF compounds and 592 targets for network analysis. Furthermore, triptolide, celastrol, and kaempferol were identified as major ingredients, and IFNG, STAT1, and NFKB were identified as the core targets involved in the mechanism of TwHF on INR immune activation.

Conclusions: Our findings show that the activated IFN-signaling pathway is involved in the immunopathology mechanism of INR, and TwHF able to reduce systemic inflammation through multi-components, multi-targets, and multi-pathways.

PEALB06

Mitochondrial disorders in activated memory CD4+ T cells derived from HIV-infected immunological non-responders

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Background: Immunological non-responders (INRs) are HIV-infected HAART-treated subjects that poorly restore CD4+ T-cell counts despite suppressed viral replication. In INRs, CD4+ memory T-cells cycle but don't divide, which is linked to chronic lymphopenia formation and adverse clinical outcome. As mitochondria impacts cell proliferation, we evaluated mitochondrial parameters in resting and stimulated CD4+ memory T-cells of INRs *in vitro*.

Methods: Blood mononuclear leucocytes derived from INRs (CD4+ T-cells <350/ul), immunological responders (IR; CD4+ T-cells >500/ul) and healthy controls (HC) were analyzed by flow cytometry (BD Fortessa). Activated/cycling CD4+ memory T-cells ($CD4^+T_M$; $CD4^+CD45RA^-$) were identified as being positive for CD71. MitoTracker Green and MitoTracker Orange (Invitrogen) were used to assess mitochondrial mass and charge, respectively. Oxygen consumption rate (OCR) was measured in isolated $CD4^+T_M$ using the Seahorse XFe96 Analyzer in order to determine mitochondrial respiration at basal state, after 40 minutes exposure to phytohemagglutinin (PHA; 15 ug/ml), and subsequent Rotenone/Antimycin A (0,5 uM) injection.

Results: Mitochondrial masses were similar in $CD4^+T_M$ of HIV-infected and healthy subjects (p>0.05). However, mitochondrial charge in $CD71^+CD4^+T_M$ of INRs when compared to IRs was decreased (p<0.05) indicating lower oxidative phosphorylation activity. In line with that, $CD4^+T_M$ derived from INRs compared with those derived from IRs (p=0.010) and HCs (p=0.0007) exhibited lower OCR. Subsequent stimulation of $CD4^+T_M$ with PHA increased OCR in all groups. Nevertheless, as opposed to activated cells of HCs, stimulated $CD4^+T_M$ of HIV-infected subjects showed lower OCR (INR – p<0.0001; IR – p=0.028). Moreover in INRs, OCR in activated $CD4^+T_M$ was even lower than that in IRs (p=0.027).

Conclusions: Our novel findings demonstrate that in immunological non-responders, CD4+ memory T-cells exhibit reduced mitochondrial respiration. This malfunction was shown in both resting and activated lymphocytes, and it can't be explained by mitochondrial mass deficiency. CD4+ memory T-cells are known to be the main source for immune reconstruction in HIV-infected patients receiving HAART. Thus, mitochondrial disorders found in these cells might be linked to poor immune restoration.

PEALB07

RNAi screening of the RabGTPase family of proteins reveals a critical role of Rab35 during HIV-1 replication

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Background: During infection, HIV-1 hijacks several intracellular trafficking pathways to promote its replication and evade immune defense. The Rab GTPase family of proteins are key regulators of these pathways and some of its members have been previously shown to control HIV-1 replication, including our report describing the role of Rab27a in viral assembly. Nonetheless, the full picture of the role of Rab proteins in HIV-1 infection remains unclear. Here, we aimed to identify Rabs involved in HIV replication by performing an unbiassed RNAi screen in CD4+T lymphocytes.

Methods: Five different lentivirally-encoded shRNAs targeting each member of the Rab GTPase family (64 proteins) were independently transduced into Jurkat cells - a CD4+ T cell model-, generating a library of 320 cell lines. Subsequently, cells were infected in triplicates with a low MOI of the wild-type HIV-1 strain NL4-3 to allow multiple rounds of replication. As a screen readout, we quantified the release of the viral antigen p24 into the cell culture supernatants at day 5 post-infection. Additionally, Scramble and Rab27a shRNAs were included as negative and positive controls.

Results: As anticipated, several Rabs were identified as required for HIV-1 replication. Rab35, a protein involved in cytokinesis, actin remodelling and immune signalling, strongly inhibited viral replication with three independent shRNAs. Importantly, this phenotype could be reversed by overexpression of an shRNA-resistant form of Rab35. We observed that Rab35-silenced cells exhibited increased susceptibility to HIV-induced apoptosis, even though in uninfected cells the viability was similar to controls. In primary CD4+ T cells, silencing of Rab35 led to higher levels of the activation marker CD25 and increased secretion of IFN-γ and IL-2 after TCR stimulation. Interestingly, no differences in TCR endocytosis or the TCR signalling pathway were seen.

Conclusions: Altogether, we postulate that following HIV-1 infection, Rab35-silenced cells become over-activated, resulting in heightened susceptibility to apoptosis. As a consequence of the increased apoptosis, the number of virus-producing cells is reduced, thus impairing viral propagation.

PEALB08

Naive infection predicts HIV reservoir size and diversity in individuals with a spectrum of immunological control

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Background: Naive cells have been considered inconsequential to HIV persistence. In this study, we compared the contribution of naive and memory cells to the reservoir in individuals with a spectrum of reservoir sizes and variable immunological control.

Methods: We used proviral sequencing at limiting dilution to study the reservoir of 5 elite controllers (ECs) off ART and 5 chronic progressors (CPs) on antiretroviral therapy (ART). We obtained ~6000 sequences after sorting of naive and memory subsets.

Results: The levels of naive infection were barely detectable in ECs despite extensive sampling (~8 million naive cells assayed per individual) and ~300-fold lower compared to CPs (1.9 vs. 655 copies/million cells, p=.02). Moreover, the ratio of infected naive to memory cells was significantly lower in ECs compared to CPs ($p<10^{-6}$). Naive cells were a major contributor to the intact reservoir of CPs, whose reservoirs were generally very diverse. In contrast, the reservoirs of ECs were dominated by proviral clones (74 vs. 15%).
Critically, the fraction of proviral clones increased with cell differentiation from naive to effector memory cells, with naive infection predicting reservoir diversity. Longitudinal sequencing suggested that the reservoir of ECs was much less dynamic compared to CPs.

Conclusions: Naive infection predicts reservoir size and diversity. As cellular subsets mature, diversity diminishes. Taken together, our data suggests that direct infection of naive T cells surely occurs *in vivo*. Moreover, it suggests that naive T cells play an important role in reservoir replenishment.

PEALB09

Differential expression of HIV envelope epitopes on the surface of HIV-infected macrophages and CD4+ T cells

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Background: HIV-infected macrophages persist in the tissues of people living with HIV on antiretroviral therapy and contribute to viral rebound upon therapy disruption. Antibody-dependent cellular cytotoxicity (ADCC) against HIV-infected cells represents a promising approach to eliminate HIV and relies on HIV envelope (Env) epitopes being exposed on the target cell to allow opsonisation by antibodies. However, little is known regarding Env epitopes expressed on HIV-infected macrophages to predict which antibodies will be useful for such strategies.

Methods: Monocyte-derived macrophages (MDM) and activated peripheral blood mononuclear cells from HIV-seronegative blood donors were infected *in vitro* with the R5-tropic HIV_{BaL} strain. Flow cytometry and fluorescence microscopy were used to assess productive infection (presence of intracellular HIV p24) and surface expression of Env on MDM and CD4+ T cells quantified using a panel of antibodies against discrete Env epitopes. The expression of HLA-A/B/C on HIV-infected MDM was also assessed by flow cytometry.

Results: We identified differences in the Env epitope profiles expressed on the surface of HIV-infected MDM and T cells. Infected MDM were more effectively recognised by the anti-Env antibody NIH45-46 (median=40.4% of HIV p24+ cells) compared to infected CD4+ T cells (13.6%; p=0.002), which were more susceptible to opsonisation by 17b and 447.52D antibodies (88.6% and 45.6% respectively) compared to MDM (30% and 6.7%, p=0.002 and 0.004 respectively). Certain effective neutralising antibodies (10E8, PGT145) did not opsonise either cell type efficiently, suggesting the presentation of Env on the surface of infected cells differs to that on virions. Whilst some HIV-infected MDM which expressed Env also downregulated surface expression of HLA-A/B/C, a portion of HIV-infected MDM exhibited neither surface expression of Env or HLA downregulation, suggesting they may evade recognition by immune effector cells.

Conclusions: HIV-infected macrophages may present Env on their cell surface in a different conformation to T cells, which affects the recognition of these cells by anti-Env antibodies. These findings have impli-

cations for antibody-mediated approaches for HIV elimination such as ADCC that targets HIV-infected cells and highlight the need for cell type-specific approaches to HIV elimination strategies.

PEALB10

HIV-1 Tat stimulates hepatitis B surface antigen expression in hepatocytes co-infected with HIV and hepatitis B virus

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Background: HIV infection significantly alters the natural history of chronic hepatitis B (HBV). Compared to HBV mono-infection, HIV-HBV co-infected individuals experience accelerated progression of liver disease and increased liver-related mortality. Despite HBV-active antiretroviral therapy (ART), liver-related mortality and morbidity remain increased in co-infected individuals. We hypothesized that direct interactions between HIV and HBV in hepatocytes, in the presence and absence of HBV-active ART, drives adverse liver outcomes.
Methods: Hepatocyte cell lines with (HepG2) or without (AD38) HBV expression were infected with pseudotyped VSV.G-HIV-NL4.3-EGFP virus. HepG2-NTCP cells were infected with HBV and subsequently with HIV. EGFP expression was quantified by flow cytometry; integrated HIV DNA by qPCR; intracellular hepatitis B surface antigen (HBsAg) by western blot; HBV RNA by northern blot and qPCR. Viral and cellular gene expression levels were analysed by single-nuclei RNA-sequencing. HIV proteins were expressed by DNA plasmid transfection. Cells expressing each HIV protein were then enriched by flow sorting.
Results: VSV.G-HIV-NL4.3-EGFP infection resulted in 60-70% of cells expressing EGFP consistent with high levels of infection, which was inhibited with either reverse transcriptase or integrase inhibitors. HIV infection of AD38 or HepG2-NTCP resulted in a significant increase in intracellular HBsAg and a 2-fold up-regulation of HBs RNA level. Single nuclei RNA-sequencing confirmed a significant increase in HBV viral gene expression in HepG2-NTCP with HIV and HBV co-infection, compared to cells only infected with HIV and HBV. Surprisingly, the cellular transcriptome was largely unchanged in co-infected cells. Over-expression of HIV Tat but not Gag, Nef, Rev, Vpr or Vpu led to a 2-fold increase in HBs mRNA level.
Conclusions: HIV infection of HBV positive hepatocyte cell lines led to significant increases in HBs RNA and intracellular HBsAg. Given that HIV Tat alone up-regulated HBs RNA and single cell analyses showed no change in cellular gene expression in co-infected hepatocytes, we propose that the changes in HBsAg are a result of HIV Tat that directly stimulates HBs transcription. These changes may contribute to accelerated liver disease in individuals with HIV-HBV co-infection, even on effective ART and with low frequency of HIV infection of hepatocytes in vivo.

Track B late-breaker posters

PEBLB11

Incidence trends of five common sexually transmitted infections excluding HIV from 1990 to 2019 at the global, regional, and national levels: results from the Global Burden of Disease Study 2019

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Background: Sexually transmitted infections (STIs) are common worldwide and pose a serious risk to individuals. We conducted this study to assess the annual incidence of five common STIs, including syphilis, chlamydia, gonorrhoea, trichomoniasis and genital herpes, at the global, regional, and national levels.
Methods: We obtained detailed data on STIs excluding HIV from 1990 to 2019 from the Global Burden of Disease (GBD) 2019 database. Estimated annual percentage change (EAPC) was calculated to quantify trends in age-standardized incidence rates (ASR) of STIs, stratified by gender, sociodemographic index (SDI) region, and pathogenic microorganism.
Results: Globally, incident cases of five common STIs increased by 58·15% from 486·77 million in 1990 to 769·85 million in 2019, but annual change in ASR was only −0·04% (95% confidence interval [CI], −0·09 to 0·01) per year. EAPC was 0·16 (0·06 to 0·26) for syphilis, 0·09 (0·05 to 0·13) for genital herpes, 0·06 (0·03 to 0·09) for trichomoniasis, −0·21 (−0·36 to −0·06) for chlamydia, and −0·14 (−0·19 to −0·08) for gonorrhoea. EAPC was higher for syphilis and gonorrhoea among men than women. High SDI regions reported the largest increases in ASR.
Conclusions: The burden of disease from STIs remains large and is increasing in high SDI countries. Globally, over the past 20 years the ASR has remained stable for trichomoniasis and genital herpes, decreased for chlamydia and gonorrhoea, and increased for syphilis. Current prevention strategies should be maintained in lower SDI regions and strengthened in high SDI regions to mitigate the observed increase in STIs.

PEBLB12

24 week randomised study of switch to DTG/RPV in subjects with HIV RNA <50c/ml and archived K103N

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Background: The 2-drug regimen of DTG/RPV has been studied in switch for subjects with no prior history of treatment failure or resistance. Viruses with the NNRTI resistance mutation K103N retain in vitro susceptibility to RPV. We investigated the potential to maintain viral suppression with DTG/RPV in subjects with documented K103N currently suppressed on other regimens.

Methods: This is an interim analysis of an on-going open-label, multicentre, randomised 2:1 trial of switch to DTG/RPV vs continue current suppressive regimen (CSR) in HIV-1 infected, treatment experienced subjects with a documented, prior K103N mutation in RT. All PI and NRTI mutations were permitted. Mutations known to reduce susceptibility to RPV, a history of INSTI failure or contraindications to DTG or RPV were exclusions.

Results: Week 24 results were available for 123 randomised subjects (DTG/RPV 83, CSR 40). Subjects were well matched for baseline characteristics with a median age of 52yr, 80% male, 70% white and CD4 621c/uL. Baseline regimens included NRTIs 80%, PI/b 63%, INSTI 47%. The proportion of patients with treatment success (HIV-RNA<50 copies/mL) by ITT FDA Snapshot at week 24 was was DTG/RPV 95.2% vs CSR 87.5% (+7.7%, 95% CI -3.5 - +18.9). One virological failure (2x>50c/ml) occurred in the CSR arm, no genotype is available. Other discontinuations were administrative. Adverse events (AEs) occurred in 66.3% vs 52.5% (p=0.063), and were mostly grade 1. The most common drug related AEs were psychiatric or CNS n=9 (11%) vs 1 (2.5%), and gastrointestinal n=8 (10%) vs 0 for DTG/RPV and CSR, respectively and consistent with established safety profiles. One grade 3 AE occurred on DTG/RPV and no subjects discontinued due to AEs. Changes in laboratory parameters were mostly non-significant. Triglycerides but not other lipids improved significantly with switch to DTG/RPV vs CSR (p=0.019). Weight change was +1kg vs 0 (p=0.11), respectively.

Conclusions: In subjects with archived K103N currently suppressed on standard regimens, switch to the 2-drug DTG/RPV regimen maintains virological suppression, is well tolerated with no unexpected AEs and improves in some lipid parameters.

PEBLB13

Lower HIV reservoir size in individuals who maintain higher CD4+ T cells counts prior to antiretroviral therapy initiation: the Strategic Timing of Antiretroviral Treatment (START) HIV reservoir study

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Background: HIV cure strategies may be enhanced by identifying factors that determine the frequency of latently infected CD4+ T cells on antiretroviral therapy (ART). We investigated the role of the CD4+ T cell count in people initiating ART with > 500 CD4 cells/mm^3 for HIV persistence on ART.

Methods: In this study nested within START, we enrolled people with HIV (PWH) who were randomised to commence immediate ART at enrolment with CD4+ T cell counts of either 500-599, 600-799 or ≥800 cells/mm^3. Samples for HIV reservoir analyses were collected after 36-44 months on ART. Total HIV DNA, cell-associated unspliced HIV-RNA (CA-US HIV RNA) and 2-long terminal repeat HIV DNA in CD4+ T cells and measured plasma HIV RNA by single-copy assay were quantified We measured T cell expression of HLA-DR, programmed death-1 (PD-1) and phosphorylated signal transducer and activator of transcription-5 (pSTAT5). Virological and immunological measures were compared across CD4+ strata and analysed for associations with clinical characteristics at ART initiation.

Results: A total of 146 study participants were enrolled, 36 in the 500-599, 60 in the 600-799 and 50 in the ≥800 CD4+ T cell strata. Of these, 59 (40%) were males, 87 (60%) were females, 124 (89%) were Black and 20 (13.7%) were Hispanic. Following 36-44 months of ART, total HIV DNA, plasma HIV RNA and HLA-DR expression was significantly lower in PWH with CD4+ T cell count ≥800 cells/mm^3 at ART initiation compared to 600-799 or 500-599 cells/mm^3. Expression of pSTAT5 did not differ across CD4+ strata but was highly correlated with lower levels of HIV DNA and CA-US HIV RNA. Virological measures were significantly lower in females compared to males.

Conclusions: We report that commencing ART with a CD4+ T cell count ≥800 cells/mm^3 compared to 600-799 or 500-599 cells/mm^3 was associated with a significantly lower level of total HIV DNA, plasma HIV RNA and T

cell activation after 36-44 months of suppressive ART. Our study revealed considerable differences between women and men in measures of HIV persistence and that pSTAT5 is associated with a reduced frequency of latently infected cells.

PEBLB14

Update on neural tube defects with antiretroviral exposure in the Tsepamo study, Botswana

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Background: Prior Tsepamo Study analyses of women receiving dolutegravir from conception demonstrated a modest decline in neural tube defect (NTD) prevalence from March 2019 (0.30%) to April 2020 (0.19%). We report updated data collected through March 2021.

Methods: The Tsepamo Study conducts birth outcomes surveillance study at government hospitals throughout Botswana, currently covering ~70% of all births. Midwives perform surface examinations of all live births and stillbirths and describe abnormalities. Research assistants photograph major abnormalities after maternal consent, which are reviewed by a birth defects expert blinded to exposures.

Prevalence of NTDs was determined by maternal HIV and antiretroviral exposure status (95% CI by Wilson method) and the primary analysis evaluated prevalence differences by exposure status (95% CI by Newcombe method).

Results: Since April 2020, 39,188 additional births were recorded, including 2,269 additional DTG conception exposures. Since August 2014, there have been a total of 191,432 deliveries; 190,982 (99.8%) had an evaluable infant surface exam, with 140 (0.07%, 95% CI 0.06%, 0.09%) NTDs identified (93 with photo, 47 by description only).

Among women on dolutegravir at conception, 9/5860 NTDs[RZ1] occurred (0.15%; 95% CI 0.08%, 0.29%): 4 myelomeningoceles, 1 anencephaly, 3 encephaloceles, and 1 iniencephaly. In comparison, NTDs occurred in 22/22,475 (0.10%; 95% CI 0.06%, 0.15%) women delivering on any non-dolutegravir antiretrovirals from conception, 8/13,217 (0.06%; 95%CI 0.03%, 0.12%) on efavirenz from conception, 3/5,535 (0.05%; 95% CI 0.2%, 0.16%) on dolutegravir started in pregnancy, and 97/144,967 (0.07%; 95% CI 0.05, 0.08%) women without HIV. NTD prevalence differed non-significantly between dolutegravir and any non-dolutegravir antiretrovirals from conception (0.06% difference; 95%CI -0.03%, 0.20%).

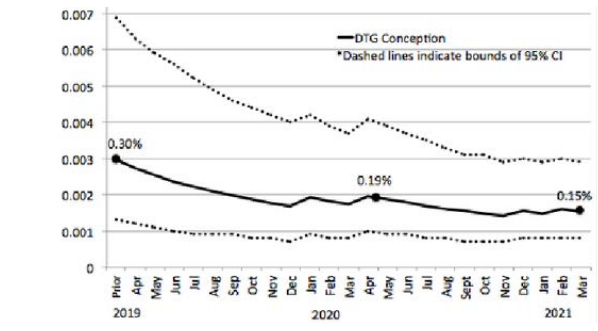

Figure A. Trend in prevalence with Dolutegravir (DTG) at conception.

Exposure group vs. comparison group	Prevalence Difference (%) (95% CI)
DTG at conception vs. Non-DTG at conception	0.06 (-0.03, 0.20)
DTG at conception vs. EFV at conception	0.09 (-0.00, 0.23)
DTG at conception vs. DTG started in pregnancy	0.10 (-0.03, 0.24)
DTG at conception vs. Non-DTG started in pregnancy	0.08 (-0.04, 0.23)
DTG at conception vs. Women without HIV	0.09 (0.01, 0.23)

Table. Current prevalence difference by exposure categories.

Conclusions: The prevalence of NTDs among infants born to women on dolutegravir at conception has declined slightly to 0.15%, a non-significant difference from those exposed to non-dolutegravir antiretrovirals at conception

PEBLB15

Pharmacokinetics and safety of dispersible and immediate release FDC abacavir/dolutegravir/lamivudine in children with HIV weighing ≥14 kg: preliminary results from IMPAACT 2019

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Background: Pediatric-friendly fixed dose combination (FDC) formulations for children with HIV are limited. IMPAACT 2019 is a Phase I/II, multi-site, open-label dose confirmation study examining the pharmacokinetics (PK), safety, and tolerability of immediate-release (IR) and a novel dispersible tablet (DT) formulation of abacavir (ABC)/dolutegravir (DTG)/lamivudine (3TC). Here we report preliminary PK and Week 4 safety results for IR and DT ABC/DTG/3TC FDC once-daily in children weighing ≥14 kg.

Methods: Children <12 years were enrolled across five weight bands (WB) in Botswana, South Africa, Thailand, and the United States. The study design is summarized in Figure 1. Data for WB3, WB4, and WB5 are presented.

Results: Demographic and PK results are summarized in Table 1. Two grade 2 events in one child in WB4 and one grade 1 event in WB5 were related to DTG. One child in WB3 experienced a grade 3 eGFR decrease and serum creatinine increase (with values in normal range) unrelated to study drug. All AEs resolved without intervention and no children discontinued study treatment due to AEs.

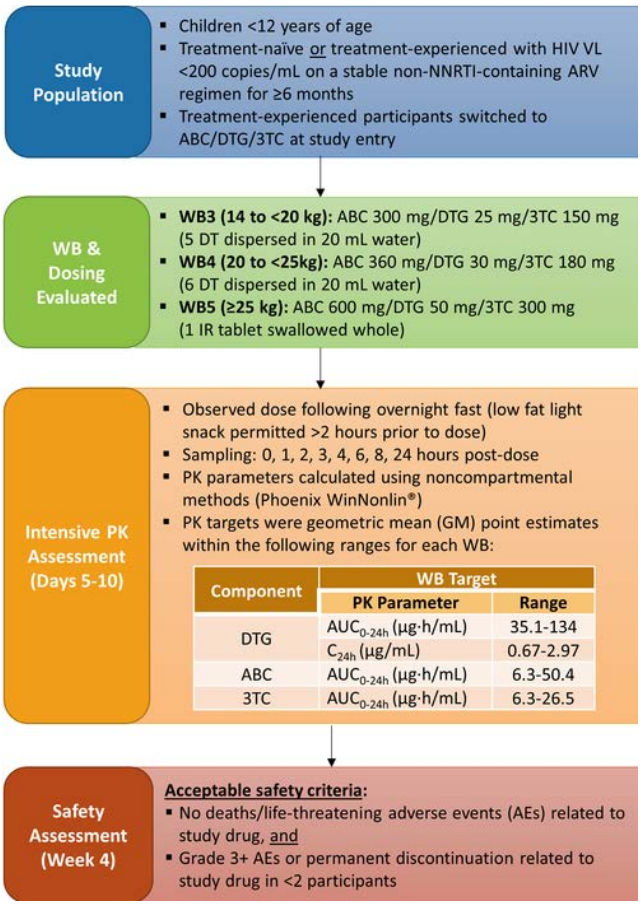

Figure 1.

Characteristic	WB 3 (n=7)	WB4 (n=7)	WB5 (n=7)
Demographics			
Sex at birth, n(%) Female Male	 4 (57%) 3 (43%)	 3 (43%) 4 (57%)	 3 (43%) 4 (57%)
Age (year), median (range)	7.4 (5.8-9.6)	8.0 (6.4-8.9)	10.3 (9.3-11.3)
Weight (kg), median (range)	18.8 (16.5-19.5)	21.6 (19.8-24.4)	28.0 (25.9-37.1)
Treatment-experienced, n(%)	7 (100%)	7 (100%)	7 (100%)
PK Results (Geometric Mean [CV%])			
DTG AUC_{0-24h} (µg·h/mL)	71.5 (23.5%)	84.5 (26.3%)	71.8 (13.9%)
DTG C_{24h} (µg/mL)	0.79 (44.2%)	1.35 (95.6%)	0.98 (27.9%)
ABC AUC_{0-24h} (µg·h/mL)	15.1 (40.3%)	17.3 (19.2%)	25.7 (14.6%)
3TC AUC_{0-24h} (µg·h/mL)	13.0 (15.6%)	14.5 (16.5%)	21.7 (26.2%)

Table 1.

Conclusions: PK targets were met for IR and DT ABC/DTG/3TC in children ≥14kg and these formulations were well-tolerated. Additional data in children <14 kg and long-term safety/tolerability data are forthcoming. These findings provide reassurance for the dosing of these FDC formulations in children ≥14 kg and are expected to support global efforts to expand the availability of pediatric-friendly DTG-containing FDCs in alignment with WHO WB dosing.

PEBLB16

Pharmacokinetics, safety and acceptability of a single dose of abacavir/lamivudine/lopinavir/ritonavir (4-in-1) fixed-dose granule formulation in neonates: PETITE study

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Background: Initiating ART in neonates is challenging due to lack of dosing information and appropriate formulations. We evaluated the pharmacokinetics (PK), safety and acceptability of a paediatric fixed-dose granule formulation containing abacavir (ABC), lamivudine (3TC) and lopinavir/ritonavir (LPV/r) (30/15/40/10 mg), referred to as the '4-in-1' in neonates and report the results following the first interim analysis.

Methods: PETITE is a Phase I/II, open-label, single arm, two-stage clinical trial conducted in South Africa. In Stage 1, term neonates exposed to HIV (birth weight of ≥2000-£4000 g) received single dose(s) of the 4-in-1 followed by intensive PK sampling. The first 8 neonates received a single dose in the 2nd week of life. After establishing no safety concerns, a second group of 8 neonates received two single doses of the 4-in-1, the first within 3-14 days of life and the second 10-14 days later. Safety visits were performed 1 week after each PK visit. An interim analysis was planned after completion of Stage 1. LPV geometric mean AUC_{0-12} was required to fall between 20-100 µg.hr/mL.

Results: Sixteen neonates with a median (range) birth weight of 3,130 (2,790 - 3,590) g were included. All 24 intensive PK sampling visits were performed between day 7 and 22 of life. ABC, 3TC and LPV mg/kg doses were 8.6 (6.6-11.4), 4.3 (3.3-5.7) and 11.5 (8.8-15.2). As expected, the geometric mean (90% CI) AUC_{0-12} of ABC and 3TC were high: 29.87 (26.3-33.93) µg.h/mL and 12.61 (10.72-14.83) µg.h/mL, respectively. LPV exposures were below the predefined target, geometric mean AUC_{0-12} was 3.49 (2.13-5.72) µg.h/mL. RTV concentrations were detectable in only 4/120 (3%) of samples. There were no adverse events related to study drug. No neonates experienced difficulty in swallowing the 4-in-1.

Conclusions: The high mg/kg ABC and 3TC doses imposed by the 4-in-1 in neonates were safe following a single dose, but LPV/r exposures were extremely low. Significant LPV/r dose increases would be required to achieve therapeutic LPV exposures, unduly increasing ABC/3TC exposures, and thereby preventing use of the 4-in-1 in neonates. Other pediatric solid formulations of LPV/r and ABC/3TC that allow different drug ratios should be studied in neonates.

PEBLB17

Virological failures and genotypic resistance in children and adolescents randomised to dolutegravir-based ART vs. standard-of-care in the ODYSSEY trial

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Background: ODYSSEY demonstrated superiority of dolutegravir (DTG) based ART versus standard-of-care (SOC) in children ≥14kg starting first- and second-line. We describe virological and drug resistance outcomes by 96 weeks.

Methods: Virological failure (VF) was defined as confirmed viral load (VL)≥400c/mL after week 36 or lack of virological response by week 24 with ART switch. Participants with VF were retrospectively tested for post-failure resistance; the corresponding baseline sample was sequenced if ≥1 major IAS mutation was identified.

	First-line ART			Second-line ART		
	DTG	SOC		DTG	SOC	
Participants with resistance post-failure ⌇						
NRTI	0/11 (0%)	18/29 (62%)	p<0.001	20/28 (71%)	28/39 (72%)	p=0.97
NNRTI	0/11 (0%)	27/29 (93%)	p<0.001	21/28 (75%)	35/39 (90%)	p=0.18
PI	0/11 (0%)	0/29 (0%)	---	2/28 (7%)	2/39 (5%)	p=1.00
INSTI*	0/10 (0%)	---	---	4/22 (18%)	---	---
Participants with emergent resistance, of those with resistance post-failure ⌇⌇						
NRTI	---	13/13 (100%)	---	0/16 (0%)	3/23 (13%)	p=0.26
NNRTI	---	18/19 (95%)	---	0/18 (0%)	3/26 (12%)	p=0.26
PI	---	---	---	1/2 (50%)	1/1 (100%)	p=1.00
INSTI*	---	---	---	4/4 (100%)	---	---

⌇Post-failure resistance up to week 96, using the latest sample with VL≥1000c/mL after failure and prior to treatment change. Major IAS drug resistance mutations defined according to 2019 update of the IAS drug resistance mutations. Percentage with resistance post-failure, of those with virological failure by week 96 and post-failure resistance test available for drug-class (integrase gene not sequenced for SOC arm).
⌇⌇Percentage with emergent resistance (at least one new IAS mutation detected post-failure compared to baseline sample), of those with resistance post-failure and baseline resistance test available for drug-class.
*4 participants with emergent INSTI resistance: 2 Q148R/K, 1 G118R, 1 G118R+R263K,

Table: Genotypic resistance in the ODYSSEY trial

Results: 311 children started first-line ART (154 DTG, 157 SOC [92% efavirenz]) and 396 started second-line (196 DTG, 200 SOC [72% lopinavir/r, 25% atazanavir/r]). On first-line, 11(7%) DTG vs. 30(19%) SOC experienced VF by 96 weeks, and on second-line, 31(16%) DTG vs. 40(20%) SOC.

First line ART: No participants on DTG had a major IAS drug resistance mutation post-failure. In SOC 18(62%) participants had at least one NRTI, 27(93%) NNRTI and none had PI mutations (Table). Of 13 with resistance post-failure and a baseline resistance test, all developed at least one new NRTI mutation and 18(95%) developed new NNRTI resistance.
Second line ART: Similar proportions in both arms had at least one major mutation post-failure (DTG 22(79%), SOC 35(90%)). In the DTG arm, 4 developed INSTI resistance (3/4 were on twice-daily zidovudine/lamivudine) and 1 had a new PI resistance mutation, not identified at baseline. In SOC, 3 participants developed new NNRTI resistance and 1 new PI resistance (Table).

Conclusions: ODYSSEY demonstrated that DTG has a high genetic resistance barrier and prevents emergent resistance to NRTIs in children. We identified no post-failure resistance to any drug class among children initiating first-line DTG, significantly less than first-line SOC. Among those on second-line DTG, there was no new NRTI resistance, however 4 children developed new INSTI resistance, highlighting the need for ongoing adherence support among children starting second-line ART.

PEBLB18

A randomised comparison of DTG-based ART vs standard of care in infants and young children living with HIV weighing 3 to 14kg: results from the ODYSSEY trial

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Background: Children living with HIV are rapidly transitioning to DTG-based ART. Children ≥20kg can use 50mg DTG adult tablets; global roll-out for those <20kg will require dispersible DTG, which will become available from generic manufacturers in low and middle-income countries later in 2021. ODYSSEY, a multi-country randomised trial, demonstrated superior treatment efficacy for dolutegravir (DTG) plus two NRTIs versus standard-of-care (SOC) in 707 children and adolescents enrolled weighing ≥14kg (median age 12 years; 96% ≥6 years) starting first- and second-line ART. We will report results for an additional 85 children weighing <14kg randomised to DTG-based ART (5mg DTG dispersible tablets dosed using WHO weightbands) versus SOC.

Methods: The primary outcome is a Kaplan-Meier estimated proportion of treatment failure defined as confirmed viral load(VL) ≥400c/mL after week 36, lack of virological response by 24 weeks followed by ART switch, death or new/recurrent WHO4/severe WHO3 event by 96 weeks.

Results: 85 children <14kg were randomised (Uganda 43, Zimbabwe 22, South Africa 20) between July 2018–August 2019; 42 to DTG and 43 to SOC. Median(range) age was 1.4 years (0.1-5.9); 23 were 3-<6kg, 40 were 6-<10kg, 22 were 10-<14kg; 34% were WHO stage 3/4; median(IQR) CD4% was 23(16-31). 72 children started first-line and 13 second-line.

First-line SOC participants started lopinavir/ritonavir (29), efavirenz (4) or nevirapine (4); second-line SOC participants started lopinavir/ritonavir (3), raltegravir (2) or nevirapine (1). NRTI-backbones in both groups were predominantly ABC/3TC for first-line and ZDV/3TC for second-line. On 28 June 2021, all children will have completed 96 weeks follow-up.

Results will include the estimated difference in risk of treatment failure by 96 weeks between treatment groups using a Bayesian approach, incorporating evidence from the main ODYSSEY trial of children ≥14kg as an informative prior, and the estimated difference in risk of treatment failure using data only from children <14kg. Cross-sectional VLs and safety outcomes will be compared between groups and treatment changes will be described.

Conclusions: ODYSSEY will provide the first randomised evidence for DTG in infants and young children <14kg; these results are keenly anticipated to support World Health Organization guidelines recommending DTG-based regimens down to 4 weeks of age and 3kg.

PEBLB19

Impact of HIV on COVID-19 outcomes among hospitalized adults in the United States

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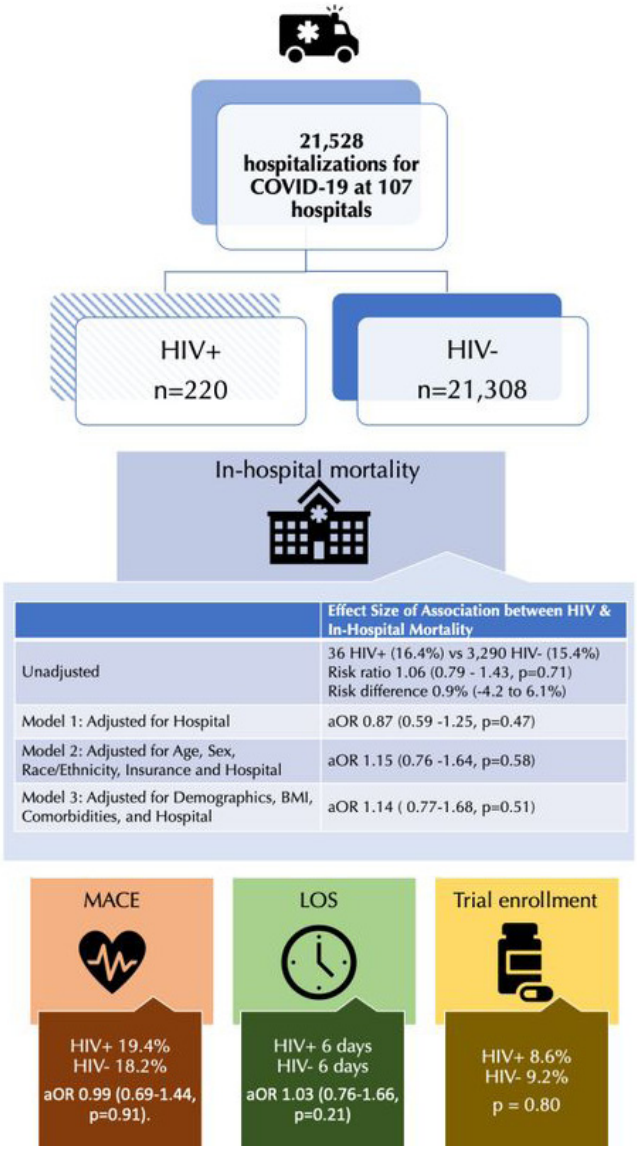
Background: Whether HIV infection is associated with differences in clinical outcomes among people hospitalized with COVID-19 is uncertain. Therefore, the objective of this study was to evaluate the impact of HIV infection on COVID-19 outcomes among hospitalized patients.

Methods: This cohort study included all adults hospitalized with COVID-19 from March-December 2020 at 107 hospitals in the US participating in the American Heart Association's COVID-19 Cardiovascular Disease Registry. The primary exposure was HIV status, and the primary outcome was in-hospital mortality. We used hierarchical mixed effects models to assess the association of HIV with in-hospital mortality accounting for patient demographics and comorbidities and clustering by hospital. Secondary outcomes included major adverse cardiac events (MACE), severity of illness, and length of stay (LOS).

Results: The registry included 21,528 hospitalization records of people with confirmed COVID-19 from 107 hospitals in 2020, including 220 people living with HIV (PLWH). PLWH were younger (56.0+/-13.0 versus 61.3+/-17.9 years old) and more likely to be male (72.3% vs 52.7%), Non-Hispanic Black (51.4% vs 25.4%), on Medicaid (44.5% vs 24.5), and active tobacco users (12.7% versus 6.5%).

Of the study population, 36 PLWH (16.4%) had in-hospital mortality compared with 3,290 (15.4%) without HIV (unadjusted Risk ratio 1.06, 95%CI 0.79-1.43; risk difference 0.9%, 95%CI -4.2 to 6.1%; p=0.71). After adjustment for age, sex, race, and insurance, HIV was not associated with in-hospital mortality (aOR 1.13, 95%CI 0.77-1.6; p 0.54) even after adding body mass index and comorbidities (aOR 1.15, 95%CI 0.78-1.70; p=0.48). HIV was not associated with MACE (aOR 0.99, 95%CI 0.69-1.44; p=0.91), severity of illness (aOR 0.96, 95%CI 0.62-1.50; p=0.86), or LOS (aOR 1.03, 95% CI 0.76-1.66, p=0.21) among adults hospitalized with COVID-19.



Conclusions: In this registry-based study of over 21,000 people hospitalized for COVID-19, HIV was not associated with adverse outcomes including in-hospital mortality, MACE, or severity of illness.

PEBLB20

Clinical characteristics and prognostic factors in people living with HIV hospitalized with COVID-19: findings from the WHO Global Clinical Platform

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Background: Published literature on clinical outcomes and prognostic factors in SARS-CoV-2 infection in people living with HIV (PLHIV) remains inconclusive. The World Health Organization has established a Global Clinical Platform aimed to assess clinical features, outcomes and risk factors among individuals hospitalized with suspected/confirmed COVID-19 around the globe.

Methods: Between January 2020-April 2021 anonymized individual-level clinical data from 268 412 hospitalized patients were reported to the WHO Platform from a mix of sentinel health facilities and national health registries worldwide. Reported standardized set of variables included demographics, clinical features, HIV status, medications, co-morbidities and outcomes. Bivariate and regression analyses were conducted to determine whether HIV status was a risk factors for severity at admission and in-hospital mortality. The models were adjusted for potential correlation for clustering at the country level.

Results: Data from 15522 PLHIV out of 168 649 hospitalized individuals were reported from 24 countries. Among PLHIV, 37.1% were male, mean age was 45.5 years, 91.8% received ART and 36.2% had severe/critical illness. Most common underlying conditions were hypertension (33.2%), diabetes (22.7%), obesity (16.9%). 23.1% of PLHIV with a known outcome died in hospital. HIV infection was associated with an increased risk of severe/critical presentation (aOR 1.13), after adjusting for age, sex, comorbidity burden, and of in-hospital mortality (aHR 1.30), after adjusting by age, gender, disease severity and comorbidities burden. Among PLHIV, being >65 years (aHR 1.82), male (aHR 1.21), having diabetes (aHR 1.50) or hypertension (aHR 1.26) increased the risk of in-hospital death.

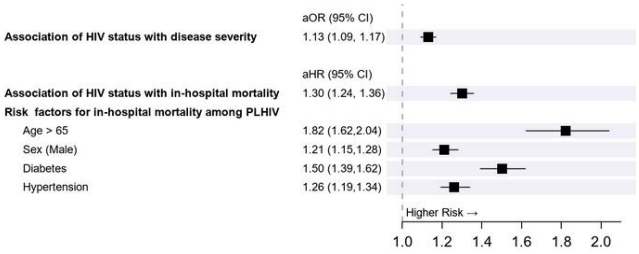

Figure.

Conclusions: Individual clinical data from 37 countries reported to the WHO Global Clinical Platform for COVID-19 indicate that HIV infection is a significant independent risk factor for both severe illness at hospital admission and in-hospital mortality. As data contribution expands, the generalizability of these findings are expected to increase and inform clinical management in this co-infected vulnerable population.

Track C late-breaker posters

PECLB21

Prevention-effective adherence trajectories among transgender women indicated for PrEP in the United States: findings from the LITE American Cohort

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Background: Sustained adherence to pre-exposure prophylaxis (PrEP) is critical for preventing HIV acquisition during periods of high-risk. We sought to describe factors associated with prevention-effective adherence trajectories in transgender women (TW) to inform interventions in this population.

Methods: Using data from The LITE American Cohort, a cohort of TW at risk for HIV, we performed group-based multi-trajectory modeling (GBMTM) to identify patterns of daily oral PrEP adherence and indication, along with correlates of each multi-group trajectory.

Results: We enrolled 728 TW into the site-based arm of The LITE Study between March 2018 and August 2020. 526 TW (72.3%) were indicated for PrEP within 18 months of enrollment based on adapted CDC guidelines. Over this period, 209 (28.7%) self-reported taking PrEP.

We identified five prevention-effective adherence trajectories using GBMTM, classified as:

1. consistently PrEP-indicated non-users (15.3%),
2. initially PrEP-indicated non-users (47.1%),
3. declining indication PrEP-discontinuers (9.5%),
4. highly adherent PrEP-users (18.5%) and,
5. PrEP-initiators (9.6%).

Declining indication PrEP-discontinuers and highly adherent PrEP-users were characterized by strong concordance between indication and adherence. Participants with an STI diagnosis over follow-up were more likely to be PrEP-indicated non-users compared to highly adherent PrEP-users (aRRR:2.54; 95%CI:1.16-5.57). TW who reported homelessness during follow-up were more likely to be declining indication PrEP-discontinuers and PrEP-initiators relative to highly adherent PrEP-users (aRRR:2.71; 95%CI:1.10-6.70 and 2.83; 95%CI:1.13-7.05, respectively).

Conclusions: Over a quarter of TW followed trajectories suggestive of prevention-effective adherence, while 15% did not initiate PrEP despite consistent indication. Elevated rates of laboratory-confirmed STI diagnosis highlight missed opportunities for PrEP engagement at STI diagnosis among this subset of TW highly likely to benefit from consistent

PrEP use. TW experiencing homelessness were more likely to initiate and discontinue PrEP relative to consistently adherent users, suggesting that structural interventions addressing housing instability may increase PrEP uptake among non-users and decrease discontinuation among current users.

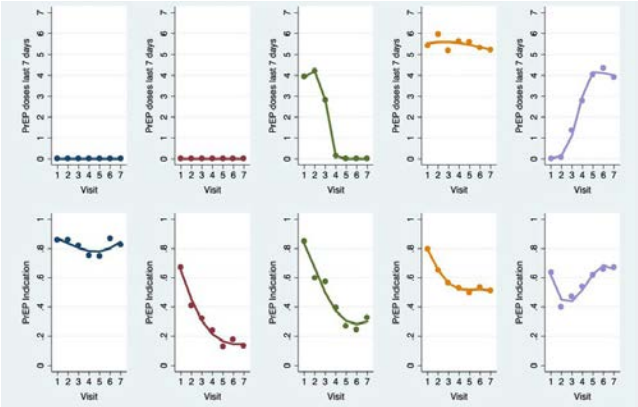

Figure. Prevention-effective adherence trajectories among transgender women in the LITE cohort.

Consistently indicated non-users (15.3%) Initially indicated non-users (47.1%)
Declining indication discontinuers (9.5%) Highly adherent users (18.5%)
New initiations (9.6%)

PECLB22

Estimating the impact of HIV on cervical cancer elimination: a comparative modelling analysis in South Africa

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Background: Sub-Saharan Africa carries the largest global burden of both cervical cancer and HIV. Women living with HIV (WLHIV) have a six-fold higher risk of cervical cancer compared to women without HIV, bringing into question the impact of HIV on recommended cervical cancer elimination strategies in high HIV prevalence settings. We conducted comparative modelling as part of WHO's Cervical Cancer Elimination Modelling Consortium to estimate the potential for eliminating cervical cancer in South Africa.

Methods: Three dynamic models, calibrated to South African data, simulated HIV and HPV transmission in age-, sex-, and risk-stratified populations, considering the underlying natural histories and interactions between the two infections. B*ase-case* interventions for HIV were: condom use, male circumcision, and antiretroviral therapy, reaching 90-90-90 targets and 70% male circumcision by 2030, and for cervical cancer: no vaccination and baseline screening. We estimated the impact of WHO-recommended cervical cancer prevention strategies introduced in 2020 on cervical cancer incidence over 100 years including 90% girls vaccinated at ages 9-14 years, 90% women screened twice, 90% treated (*WHO strategy*), with specific strategies for WLHIV: (1) multi-age-cohort vaccination up to age 24 years, and 2) three-yearly HPV screening and treatment between ages 25-50 years (*WLHIV strategy*). We present results as the median and range from the three models.

Results: All models predict that elimination of cervical cancer (age-standardised incidence rate of <4 cases/100,000 women) is possible by 2081 (range 2067-2093) with the *WHO strategy*. Although cervical cancer incidence is unlikely to reach the elimination threshold among WLHIV, a reduction to <10 cases/100,000 could be achieved by 2086 (2069-2120). The *WHO strategy* is expected to prevent 28% (17-32%) of cervical cancer cases overall, and 27% (16-30%) in WLHIV over the next 25 years compared to the *base-case*. Compared to the *WHO strategy* alone, the *WLHIV strategy* is expected to prevent an additional 24% (17-27%) of cervical cancer cases among WLHIV over the next 25 years.

Conclusions: Cervical cancer elimination in South Africa is plausible within the next century with WHO's recommended strategy. In the short term, cervical cancer cases can be substantially reduced if WLHIV receive vaccination and additional screening.

PECLB23

Effectiveness and medication adherence of daily and event-driven pre-exposure prophylaxis regimens among Chinese men who have sex with men: a real-world CROPrEP study

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Background: HIV protection data were scarce between daily and event-driven regimens of pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM). We sought to evaluate the effectiveness and adherence of PrEP in the real-world study setting.

Methods: From December 2018 to October 2020, PrEP was offered to MSM with a self-chosen regimen of daily or event-driven TDF/FTC in four Chinese cities Beijing, Shenyang, Chongqing and Shenzhen. PrEP initiators were followed up on 3-month intervals for 12 months. Medication adherence was measured by the reported proportion of covered sex acts by PrEP. MSM who were unwilling to initialed PrEP from local metropolis were provided parallel follow-up. HIV Incidence Risk Index for MSM (HIRI-MSM) was employed to evaluate the baseline HIV risk. Poisson regression was used to analyze the HIV incidence rate ratio (IRR) for assessing PrEP regimens' effectiveness.

Results: Of 1023 MSM who initiated PrEP (median age 29 years; median HIRI score 18, IQR: 12-22), 520 chose using daily dosing regimen and 503 chose using event-driven regimen. Meanwhile, 507 local MSM were PrEP non-users (median age 33 years; median HIRI score: 12, IQR: 7-18). Overall, 88% (904/1023) of PrEP users and 89%(452/507) of the non-users completed the 12-month follow-up, respectively. The proportion of covered sex acts by PrEP≥90% increased over time in event-driven PrEP users (from 57% to 78%, p<0.001 for trend), while the opposite trend was observed in the daily group (75% to 72%, p=0.025 for trend). The overall HIV incidence was 0.64 per 100 person-years(PY) among PrEP users and 0.90/100PY in

daily regimen users and 0.37/100PY in event-driven regimen users, which were both lower than that among nonusers (5.10/100PY, *P*<0.001). There is overall 87% reduction in incidence (aIRR: 0.21, 95% CI: 0.08-0.55) (daily PrEP aIRR 0.10; event-driven PrEP aIRR: 0.05) after adjusted for HIRI score and age.

Conclusions: This real-world study showed that PrEP can effectively reduce HIV risk among MSM. Compared with the traditional daily medication regimen, the event-driven regimen has increased trend of medication adherence and a better HIV protective effect.

PECLB24

Long-acting capsid inhibitor effective as PrEP against vaginal SHIV transmission in macaques

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Background: Daily oral preexposure prophylaxis (PrEP) is highly effective at reducing the risk of HIV acquisition, but its uptake, persistence, and efficacy are limited by the need for daily adherence. Long-acting PrEP could mitigate adherence challenges and improve population coverage. We recently reported the prophylactic efficacy of a long-acting capsid inhibitor GS-CA1, an analog of the investigational HIV treatment agent lenacapavir, in a rectal challenge macaque model. Here, we evaluated GS-CA1 PrEP efficacy in a macaque model of vaginal SHIV transmission.

Methods: An optimal animal model and SHIV challenge titer were chosen by comparing the rates of vaginal SHIV transmission between naïve female pigtail macaques and Indian rhesus macaques, either untreated or pre-treated with 10 mg depot medroxyprogesterone acetate (DMPA) (n=6 per group). Twenty-four naïve female rhesus macaques then received a single subcutaneous administration of vehicle (placebo), 150 mg/kg or 300 mg/kg of GS-CA1 (n=8 per group) followed by 10 weekly vaginal SHIV challenges and a 6-week follow-up. Plasma GS-CA1 exposures and viremia were measured throughout the study and used to establish PrEP efficacy.

Results: SHIV challenge with 10-100 TCID50 resulted in ≤ 1 out of 6 infections per challenge among untreated pigtail or rhesus macaques. DMPA pre-treatment increased vaginal transmission rate with 100 TCID50 titer among rhesus macaques to 50% per challenge and was selected for the efficacy evaluation. A single administration of GS-CA1 yielded exposures exceeding its protein adjusted EC95 value (30.2 nM) in the 150mg/kg and 300mg/kg groups for at least 10 and 16 weeks, respectively. All control animals became viremic by week 8 with a median time-to-viremia of 4 weeks. In contrast, only 4 animals became viremic in the 150mg/kg GS-CA1 group with a median time-to-viremia of 14 weeks, and no infections were observed in the 300mg/kg GS-CA1 group. Both GS-CA1 dose levels offered significant infection risk reduction relative to placebo (p<0.0001) based on a Cox regression analysis.

Conclusions: These preclinical data demonstrate that a long-acting GS-CA1 formulation can effectively protect against vaginal SHIV transmission in nonhuman primates and together with the rectal challenge study results support the clinical development of lenacapavir for HIV prevention in both males and females.

PECLB25

Long-acting injectable PrEP in women: laboratory analysis of HIV infections in HPTN 084

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Background: HPTN 084 was a phase 3 randomized, double-blind, double-dummy superiority trial that showed that tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) and long-acting injectable cabotegravir (CAB) were highly effective for HIV prevention in women in sub-Saharan Africa. Participants were randomized 1:1 to active CAB + TDF/FTC placebo or active TDF/FTC + CAB placebo. CAB was superior, with an 89% lower risk of HIV infection compared to TDF/FTC. We characterized the 40 observed infections in HPTN 084 (4 CAB, 36 TDF/FTC) using virology and pharmacology assays.

Methods: Participants received 5 weeks of daily oral product followed by intramuscular injections every 8 weeks (after an initial 4-week interval) and daily oral pills. The blinded trial was stopped at a planned interim Data Safety Monitoring Board review in November 2020. Further testing was conducted for all confirmed HIV infections. HIV status and the timing of infection were assessed using an antigen/antibody test, a discriminatory HIV test, a qualitative HIV RNA assay, and viral load assays. Drug resistance was assessed for samples with >500 copies/mL HIV RNA (viremic visits). Concentrations of plasma CAB, plasma tenofovir (TFV), and intraerythrocytic TFV-diphosphate (TFV-DP) were determined by liquid chromatography-tandem mass spectrometry.

Results: At the time of unblinding, the 4 infections in the CAB arm occurred in 2 women who never received injections and 2 who received injections: 1 one with episodes of delayed dosing and suboptimal drug concentrations, and one with on-time dosing. Major integrase resistance mutations were not detected. In the TDF/FTC arm, 35/36 infections occurred in women with poor or inadequate adherence (<4 pills/week based on TFV and TFV-DP concentrations) near the first HIV positive visit. One of the 36 women had the M184V mutation. Resistance to non-nucleoside reverse transcriptase inhibitors (NNRTIs) was also detected in 9/40 HIV cases overall.

Conclusions: Three of four infections in the CAB arm occurred in women who did not receive injections or received delayed injections. No major integrase resistance mutations were observed. Non-adherence to daily oral TDF/FTC likely contributed to the higher number of infections in this group. The prevalence of transmitted NNRTI drug resistance is a concern.

PECLB26

Prioritizing the evaluation of HIV prevention interventions in pregnancy: Interim results from a randomized, open-label safety trial of dapivirine vaginal ring and oral tenofovir disoproxil fumarate/emtricitabine use in late pregnancy

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Background: The monthly dapivirine vaginal ring (DVR) has been clinically shown to reduce HIV risk with no safety concerns in nonpregnant reproductive-aged cisgender women; however, data during pregnancy are lacking. Here we report interim safety data from the first cohort of pregnant participants in MTN-042/DELIVER, a phase 3b, randomized, open-label safety trial of DVR and oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC).

Methods: Eligible women aged 18 to 40 in Malawi, South Africa, Uganda and Zimbabwe were randomized 2:1 to monthly DVR or daily TDF/FTC. Participants initiated product use between 36 0/7-37 6/7 weeks' gestation and continued until delivery or 41 6/7 weeks gestation. Pregnancy outcomes and complications reported at the time of delivery were assessed and summarized using descriptive statistics and compared to local background rates obtained through a systematic chart review (MTN-042B).

	Dapivirine arm N=93		TDF/FTC N=48		Background community prevalence of complications[3]
	N	%	N	%	% (95% CI)
Pregnancy outcomes					
Stillbirth	0	(0)	1	(2)	-
Live birth	93	(100)	47	(98)	-
Full term birth	92	(99)	45	(96)	-
Preterm birth	1	(1)	2	(4)	-
Pregnancy complications[1]					
Any hypertensive disorder of pregnancy[2]	3	(3)	3	(6)	10.6% (10.0, 11.3)
Gestational hypertension	3	(3)	3	(6)	4.4% (4.0, 4.8)
Pre-eclampsia without sever features	0	(0)	0	(0)	2.2% (1.9, 2.5)
Pre-eclampsia with sever features	0	(0)	1	(2)	2.1% (1.9, 2.4)
Eclampsia	0	(0)	0	(0)	0.6% (0.5, 0.8)
Hemorrhage					
Antepartum hemorrhage	0	(0)	1	(2)	
Postpartum hemorrhage	1	(1)	1	(2)	3.2% (2.9 3.6)

[1]Other complications assessed included: chorioamnionitis, puerperal sepsis, endometritis, preterm premature rupture of membranes, and fever of unclear etiology
[2]Individuals may experience more than one form of hypertensive disorder in pregnancy, therefore the sum of the rows below may be higher than the total number of participants in this row.
[2]Data on background rates were obtained as part of a published systematic chart review: https://doi.org/10.1371/journal.pone.0248423

Table. Pregnancy outcomes and complications by study arm

Results: One-hundred and fifty participants were enrolled with 101 randomized to DVR and 49 to TDF/FTC (Malawi n=27; South Africa n=42; Uganda n=44; Zimbabwe n=37). Demographic and clinical characteristics were similar by study arm. Median age was 25 years (interquartile range [IQR] 21-28) and median gestational age at enrollment was 36.3 weeks (IQR 36, 37). To date, pregnancy outcome data were available for 141 participants (Table).
One stillbirth and one neonatal death occurred, both in the TDF/FTC arm. Pregnancy complications were rare, with hypertensive disorders being the most common complication reported (Table).
Conclusions: In this first study of a long-acting HIV prevention agent in pregnancy, adverse pregnancy outcomes and complications were uncommon when the DVR and TDF/FTC were used in late pregnancy and were generally similar to rates observed in the communities where the study is being conducted. These data support plans for subsequent investigation of safety among pregnant women using DVR earlier in pregnancy.

PECLB27

HIV-1 Env markers of prevention efficacy in HVTN 704/HPTN 085, the Antibody-Mediated Prevention (AMP) trial of broadly neutralizing antibody (bnAb) VRC01 in the Americas and Europe: genotypic sieve analysis

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Background: HVTN 704/HPTN 085 evaluated HIV prevention efficacy (PE) of VRC01, a bnAb against the CD4 binding site. PE depended on *in vitro* neutralization resistance of the acquired virus. No efficacy was observed against resistant viruses, whereas, against sensitive viruses (IC_{80}<1 µg/ml), 73.0% efficacy (95% CI, 27.6% to 89.9%) was observed. Whether PE might be influenced by Env amino acid (AA) sequence features was evaluated.

Methods: From 2016–2018, 2,699 HIV-uninfected MSM and transgender adults in the Americas and Switzerland were randomized 1:1:1 to receive q8-weekly infusions of VRC01 10mg/kg, 30mg/kg or placebo, with q4-weekly HIV testing, over 80 weeks. Viral populations (mean=184 *rev-env*-(partial) *nef* sequences/visit) from 90 infections with neutralization sensitivity data were used here. Twenty-four sequence features were pre-specified for predicted impact on VRC01 neutralization: 3 proteomic antibody resistance scores, 21 VRC01-important AA positions, and geometry features. Data were analyzed using feature-specific proportional hazards models.

Results: PE decreased with the predicted probability of IC_{80}>1 µg/ml (p=0.017), with estimated PE=80% against viruses with resistance probability 0.3, decreasing to 0% against viruses with probability 0.72 (Fig1).

Estimated PE was 75% (95% CI, 16 to 92%, p=0.015) and 5% (−51 to 41%, NS) against N144 and notN144, and −24% (95% CI, −118 to 29%, NS) and 64% (26 to 82%, p=0.004) against D230 and notD230 (Fig2), with differential PE unadjusted p-values of 0.044 and 0.008, respectively.

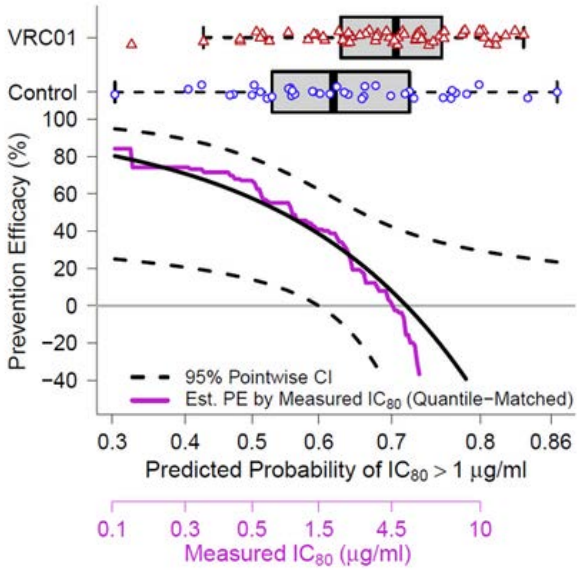

Figure 1. Estimated PE by Proteomic Antibody Resistance (PAR) score (black) correlates with estimated PE by measured IC80 (magenta).

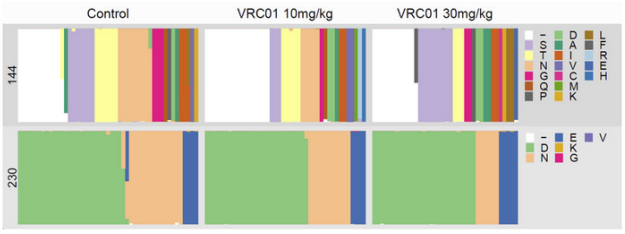

Figure 2. Distributions of AAs at HIV-1 Env positions 144 and 230. Each column along the x-axis represents an analyzed case (i.e., a primary HIV-1 endpoint with available sequence and in vitro neutralization sensitivity data). Within each column, the color(s) reflect(s) the (AA)s at position 144 or 230 in all sequences measured for a given case.

Conclusions: Viral sequence predicts IC_{80} and VRC01 PE. Assessment of viral sequences can inform identification and development of bnAbs and vaccine immunogens that may prevent HIV acquisition.

PECLB28

Integrating viral hepatitis and PrEP services through KP-led clinics in Vietnam: an opportunity to achieve dual elimination of HIV and viral hepatitis by 2030

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Background: In Vietnam, 21% of people living with hepatitis B (HBV) and 8% of people living with hepatitis C (HCV) are diagnosed, and only 5% of eligible people are treated. At the same time, the government of Vietnam (GVN) committed to enrolling 72,000 people in pre-exposure prophylaxis (PrEP) by 2025 to prevent HIV. USAID/PATH Healthy Markets partnered with GVN and key population (KP)-led clinics to pilot one-stop shop (OSS) integrative care model.

Description: Five KP-led clinics in Hanoi and Ho Chi Minh City implemented the OSS model, providing a suite of health services for KPs at high risk of HIV and viral hepatitis, including men who have sex with men (MSM), transgender people (TG), female sex workers (FSW), people who inject drugs (PWID), and sero-discordant couples (SDC). The service package includes HIV testing, PrEP, HBV/HCV testing, sexually transmitted infections, non-occupational post-exposure prophylaxis, antiretroviral therapy, mental health, and gender affirming care. Clients seeking for PrEP or non-PrEPwere offered HBV and HCV testing, and non-PrEP clients were counseled and enrolled on PrEP.

Lessons learned: From October 2020 to March 2021, 5,202 KP clients received care at OSSs. Among 1,395 PrEP users, HBV infection was higher in TG (18.4%) than MSM (3.9%) and SDC (1.6%), and HCV infection was higher in TG (18.4%) than MSM (1%) and SDC (1.6%). HBV and HCV infection were exceptionally high (20.7% and 15.8%, respectively) among non-PrEP users, including PWID (90.5% and 89.7%), SDC (45.5% and 35.7%), FSW (30% and 22.2%), TG (18.2% and 18.2%), and MSM (5.4% and 2.8). Among non-PrEP clients tested for HBV (1975) and HCV (1945) 64% and 65%, respectively transferred to PrEP uptake. Out of 109 anti-HCV positive cases, 5.5% received a confirmatory test and none initiated treatment. Out of 178 HBsAg positive cases, 24.1% received confirmatory testing, and 83.7% received PrEP or HBV treatment.

Conclusions/Next steps: OSS integrative care is an effective approach to increase uptake of PrEP and viral hepatitis services, but more work needs to be done to improve linkage to confirmatory testing and treatment for HBV and HCV. Integrating viral hepatitis and PrEP provides a tremendous opportunity to accelerate HIV and viral hepatitis elimination.

PECLB29

No impact of feminizing hormone therapy on daily oral pre-exposure prophylaxis effectiveness among Brazilian trans women vulnerable to HIV infection – the PrEParadas Study

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Background: Interactions between feminizing hormone therapy (FHT) and oral pre-exposure prophylaxis (PrEP) components (tenofovir disoproxil fumarate and emtricitabine [FTC]) could negatively affect PrEP outcomes among trans women. We aimed to evaluate the impact of FHT on PrEP pharmacokinetics (PK) in a nested study of a trans-specific PrEP demonstration conducted in Rio de Janeiro, Brazil.

Methods: According to their will to use FHT, a subgroup of *PrEParadas* (NCT03220152) participants were assigned to receive PrEP only (Group 1) or standardized FHT (estradiol valerate+spironolactone) plus PrEP (Group 2) for 12 weeks, after a washout period. The first PK evaluation (PK1) was at week 12.

Afterwards participants from both groups could start any FHT (real-life FHT); those on PrEP and real-life FHT were evaluated on a second longer-term PK evaluation (PK2) between weeks 30-48. Blood samples were collected pre-dose and 0.5, 1, 2, 4, 6, 8 and 24 hours after directly observed dosing.

We estimated PK parameters by non-compartmental analysis and evaluated correlations between covariates and tenofovir (TFV) or FTC area under the curve from zero to 24 hours (AUC_{0-24}) by Spearman rank correlation (alpha=0.05). PrEP adherence was estimated using dried-blood spots (DBS) levels.

Results: We analyzed data from 38 PK1 participants (Group 1: 14, Group 2: 24) and 17 in PK2. TFV and FTC Cmax on PK1 were significantly lower in Group 1 (254[222-290] and 1627[1434-1952] ng/mL) compared to Group 2 (318[278-396] and 1948[1662-2294] ng/mL). TFV and FTC parameters did not differ between PK1 (Group 1) and PK2 (both groups on PrEP+real-life FHT). Body mass index was significantly associated with lower TFV or FTC AUC_{0-24} (rho -0.55, p=<0.001, and rho -0.30 p=0.03, respectively). DBS levels on PK1 were compatible with 4+, 2-3, <2 FTC/TDF doses per week among 28 (73.0%), 4 (11.0%), and 6 (16.0%) participants, respectively. Almost all participants with DBS available on PK2 had levels compatible with 4+ FTC/TDF doses (14/15, 93.3%). There were no seroconversions during the study follow-up.

Conclusions: Our results provide further evidence that there is no clinically relevant impact of FHT on PrEP systemic concentrations and thereby effectiveness among trans women at high risk of HIV.

Track D late-breaker posters

PEDLB30

The importance of digital training in the dissemination of information to health professionals, through the ECHO Project, during the COVID-19 pandemic

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Background: Training and face-to-face updates have always been frequent at the IST / Aids Coordination - SP, however, due to the Covid-19 Pandemic, it was necessary for us to make adjustments so that the training could be carried out, as there was a need to meet the distancing guidelines In this way, we started virtual training and, with that, we reached unimaginable numbers of professionals' participation.

Description: The ECHO Project focuses on the discussion of complex clinical cases, but due to the Covid-19 Pandemic, it was authorized that we carry out training on STI / HIV and AIDS. It is developed through the Zoom Pro platform, the only possible platform to develop the ECHO Project. Each meeting room can accommodate up to 1500 participants.

Lessons learned: During the year 2020, 49 virtual trainings were carried out with 9415 connected points, at each point we have at least 1 participant, while in 2019 there were 8 trainings with 550 professionals participating in person. It is an excellent tool for Professional Education and Public Health Management, which allows reaching this unimaginable number of professionals. It is worth mentioning that the cost of developing the training is practically zero.

Conclusions/Next steps: With the numbers raised in the last year of face-to-face training, 2019, compared to the first year of virtual training, 2020, it is evident how important the digital acceleration that the Covid-19 Pandemic provided. As a result, training and virtual updates have become part of the work processes.

Finally, the methodology of communicating remotely, in real time, proved to be very effective, important and fundamental to become part of the definitive work process.

PEDLB31

Retention in care after early enrolment into differentiated service delivery models for antiretroviral treatment: a case for policy change

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Background: Differentiated service delivery (DSD) models intend to make HIV treatment more person-centered and support long-term retention. Most models require ≥6 or ≥12 months on ART for eligibility. However, attrition is highest among newly-initiated antiretroviral treatment (ART) patients who are usually ineligible for DSD models. We investigated attrition among patients in Zambia enrolled in DSD models, after <12 months on ART.

Methods: Data were extracted from electronic medical records of patients (age≥16 years) enrolled in six DSD models between October 2019-March 2020. We evaluated 12-month loss to follow-up (LTFU), defined at 9-15 months after DSD enrolment, comparing patients ≥12 months on ART to those enrolled after <6 and 6-12 months on ART. We adjusted for age, sex, urban/rural status, ART dispensing duration. To address potential selection bias, we conducted a sub-analysis restricted to those with known viral suppression at DSD entry.

Results: Of 90,373 patients enrolled, 3% (n=3,109) and 7% (n=6,630) were on ART <6 and 6-12 months at DSD entry, respectively. Patients on ART for <6 and 6-12 months were less likely to be LTFU compared to those on ART ≥12 months (adjusted risk ratio (aRR) 0.83, 95% confidence interval (CI) 0.72-0.95; aRR 0.84, 95%CI 0.77-0.92, respectively) for almost all models and dispensing durations. Among patients with known viral suppression (n=27,741), patients enrolled early in DSD models had equivalent or less LTFU risk compared to those enrolled after ART ≥12 months (<6 months: aRR 0.88, 95%CI 0.67-1.16; 6-12 months: aRR 0.80, 95%CI 0.68-0.92).

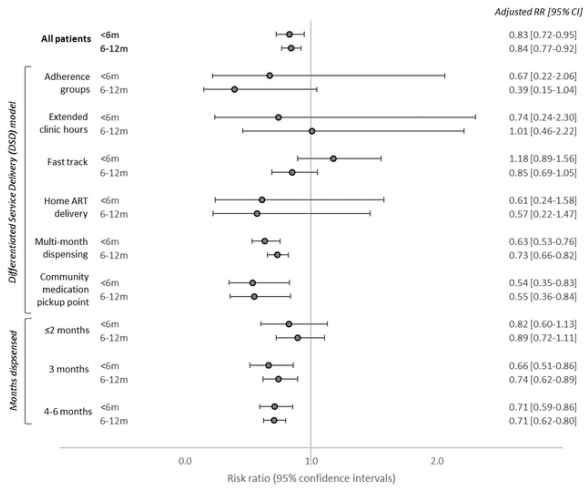

Figure 1. Risk for loss to follow-up at 12 months of DSD enrolment for patients who enrolled with <12 months' ART experience (reference: >12 months on ART at DSD enrolment)

Conclusions: Patients enrolled in DSD models in Zambia after <12 months ART were more likely to be retained in care 12 months later than patients enrolled after ≥12 months ART. In alignment with updated recommendations from the World Health Organization, criteria for determining established on treatment should be reconsidered to support earlier eligibility for DSD for HIV treatment models.

PEDLB32

Applying mathematical modeling to understand the COVID-19 related impact of VMMC service disruption on new infections in Zimbabwe

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Background: The COVID-19 pandemic has piled unprecedented pressure on health systems in Southern Africa. As a mitigating strategy, countries continue to implement measures to socially distance the population, leading to partial or full suspension of certain services. To de-escalate spread of the pandemic, Government of Zimbabwe continues to strategically prioritize health service delivery to address immediate needs. As a result, Voluntary Medical Male Circumcision (VMMC) services were disrupted in 2020 and this could be prolonged until vaccines are sufficiently scaled up. Given the efficacy of VMMC, we quantified the potential effects of VMMC service disruption on new HIV infections in Zimbabwe.

Methods: We applied the GOALS model to understand the impact of COVID-19-related disruptions on infections attributable to disruption of VMMC services and potential cost implications. GOALS is an HIV simulation model that estimates number of new HIV infections due to sexual behaviors of population groups. Parameterization of the model is based on national surveys and HIV program data, with model calibration by Avenir Health. We hypothesized three scenarios: Scenario 1: (Pre-COVID trajectory): 80% VMMC coverage by 2030; Scenario 2: (Marginal COVID-19 Impact): 60% VMMC coverage by 2030, and Scenario 3: (Severe COVID-19 Impact): 45% VMMC coverage by 2030. For the period 2030-2050 coverage was maintained across the scenarios, and the time horizon for the model was 36 years beginning in 2014 with discounting at 3%. We also assumed that the fully loaded cost of first-line ART was $165 per person per year and discounted lifetime cost of ART≈$3,710.

Results: Relative to Scenario 1, considered the baseline, the disruption of VMMC services in Scenario 2 and 3 will potentially decrease impact of VMMC program on new infections by 7K and 15K over the next 10-30 years, respectively. Thus, the disruptions could yield additional future treatment costs between $27-$55 million for Scenario 2 and 3, respectively.

Conclusions: Disruption of VMMC services is projected to contribute to 7K-15K additional new infections depending on length and severity of disruption. Unless mitigated, these disruptions could derail the goal of achieving 80% VMMC coverage, and thus it is important to enact policies to sustain VMMC service delivery.

PEDLB33

Web-based HIV self-test distribution encourages testing and linkage among young men who have sex with men and first-time testers in three provinces in Viet Nam

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Background: Approximately 15% of people living with HIV, primarily key populations, do not know their HIV status in Viet Nam. Web-based HIV self-test (HIVST) distribution was piloted to increase access to HIV testing, PrEP and ART, especially in the context of Covid-19.

Description: Web-based HIVST distribution started in Can Tho province (Nov 2020) and then Nghe An and Hanoi (mid-April 2021). Clients are encouraged to create a website account to request HIVST, together with condoms, lubricants or needles and syringes. Clients choose how test kits and other commodities, are delivered (courier/peer educator) or opt for self-pick-up. Reporting of self-test result is encouraged, but not required. Following distribution, staff or peers support clients to access

further testing, PrEP or ART. User demographic information and risk behaviors were collected at account registration and via voluntary client-satisfaction survey. Data were automatically stored and compiled in the web-system. Linkage was documented by staff and peers in the same system.

Lessons learned: As of 5th May 2021, 1269 individuals completed initial self-risk assessment via the website and 1188 opened an account and requested HIVST. Among these clients, 82.3% were male, 54.5% were ≤25-years, 67.1% were MSM, 67.6% had ≥2 sexual partners, 22.3% had an STI, 10.1% shared needles, 46.8% were first-time testers and 17.4% tested >12-months ago. 1077 received HIVST, 851 (79.0%) reported their result and 29/851 (3.4%) were reactive. 22/29 (72.4%) received confirmatory test. 21/22 were HIV-positive, and 21/21 received ART. Of the 823 reporting HIV-negative results, 124 (15.1%) enrolled in PrEP. 670/1077 (62%) of self-testers completed the satisfaction survey; of which, 81.9% were "very satisfied", 98.8% indicated the website was easy to access, 93.6% reported HIVST was easy, and 98.9% were willing to introduce to others.

Conclusions/Next steps: Web-based HIVST was well accepted to many young key populations especially MSM and first time-testers and provides an additional way to increase access to testing, prevention and treatment; especially in context of COVID-19 restrictions. The pilot will be continued in these three provinces to inform national scale-up.

PEDLB34

Using private pharmacies for decentralized distribution of antiretroviral therapy: early lessons from seven sub-Saharan African countries

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Background: Innovative approaches that increase access to antiretroviral therapy (ART) while reducing strain on the health system are needed as countries work toward HIV epidemic control. Decongesting health facilities while ensuring safe and continuous ART access has proven vital in mitigating the spread of COVID-19. The USAID- and PEPFAR-supported Meeting Targets and Maintaining Epidemic Control (EpiC) project explored the feasibility and acceptability of using private pharmacies as refill points for clients on ART.

Methods: Between June 2020 and January 2021, cross-sectional pharmacy and client surveys were conducted in seven countries (Botswana, Cameroon, Cote d'Ivoire, Democratic Republic of the Congo, Eswatini, Liberia, and Mozambique). Pharmacy surveys (self-administered online or via an interviewer) assessed physical environment, staff qualifications, willingness to dispense antiretroviral (ARV) drugs with proper documentation, and expected compensation. Client interviews (conducted online or in person) examined barriers to access ART, willingness to pay a fee, and interest in refilling at pharmacies.

Results: Of the 1,574 participating pharmacies (24–947 per country), 54%–99% expressed willingness to dispense ARVs and 80%–100% operated longer hours than public facilities, making them potentially more convenient to clients. Most pharmacies had the physical and human resource capacity to provide ARVs, including storage space and staff time required for counseling and documentation. A proportion (6%–60%) of pharmacies were willing to provide ARVs without fees. Among those that would require a fee, expected compensation ranged from USD $0.59 to $4.00 per pickup; higher in Botswana ($4.50–9.00).

A convenience sample of 1,194 ART clients participated across five countries (15–735 per country). In most countries, clients (61%–78%) expressed interest in the pharmacy model. Among those willing to pay for refills (44%–90%), USD $0.60–$1.00 was considered reasonable. Perceived benefits included convenience, friendly staff, guaranteed stock, and privacy. Client concerns included privacy, lack of full service (refilling at a pharmacy then seeking care at a public facility), and cost.

Conclusions: Private pharmacies have the capacity and are ready and willing to dispense ARVs. Many clients are interested in accessing ART at pharmacies, offering a sustainable opportunity for improving access and reducing the burden on the health system.

PEDLB35

One size does not fit all: preferences for HIV care delivery among out-of-care people living with HIV in the United States

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Background: Only half of the people living with HIV (PLWH) in the United States are retained in HIV care and 56% have achieved viral suppression, due in part to transportation barriers, stigma, mental health, substance use, and medical mistrust. Alternative community-based HIV care models have potential to address the diverse needs of patients and improve retention in care in the United States, but the success of these models is contingent on acceptance by patients and key community stakeholders.

Methods: Recognizing that the preferences of PLWH who are out-of-care (PLWH-OOC) likely differ from those retained in care, from June 2019 to May 2021, we conducted a mixed-methods study composed of surveys (n=50) with PLWH-OOC and in-depth interviews (n=41) with key clinic and community stakeholders to examine the relative preference and perceived advantages and disadvantages for 7 different community-based HIV care models. Survey data was analyzed to assess average rank preference for each care model and interview transcripts were thematically coded to examine individual and systems-level factors influencing model acceptance.

Results: Of the 50 participants surveyed, 86% were Black, 52% were sexual minorities, and 64% had annual income<$10,000. Highest preference for care delivery was via a mobile clinic (μ=2.36), followed by community-based peer navigation (μ=3.54), primary care clinics (μ=4.1), telemedicine (μ=4.46), traditional HIV subspeciality clinic (μ=4.48), homeless shelters (μ=4.9), and drug treatment centers (μ=5.44). Common factors influencing preference included convenience, accessibility, potential to preserve confidentiality, ensure quality of care, and foster rapport with their HIV care provider, access to a smart device, and stigma associated with accessing shelters and drug treatment facilities. Participants discussed the need for integration of care models and for individuals to choose different care models at different times. Providers and patients differed in preference for care model and weighting of relative advantages and disadvantages of each.

Conclusions: Findings highlight the need to integrate alternative, community-based care models into the national plan to end the HIV epidemic and allow for PLWH-OOC to choose the model most fitting for individual circumstance. Future implementation research should evaluate the relative effectiveness of the models and whether findings apply to other communities globally.

PEDLB36

Effect of COVID-19 pandemic on antiretroviral treatment use for HIV in the United States, 2020

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Background: A national emergency was declared on March 13, 2020 in the United States for the COVID-19 pandemic. The provision of HIV healthcare services might be disrupted because of limited non-emergency services available in most venues. Patients also might have delayed or avoided HIV medical care out of fear of SARS-CoV-2 exposure. Our objective was to assess the effect of the COVID-19 pandemic on antiretroviral (ARV) use in the United States.

Methods: We analyzed the IQVIA Real World Data—Longitudinal Prescriptions Database to identify ARV prescriptions for HIV treatment. We used each patient's ARV prescription date and days of medicine supply to estimate the weekly number of prevalent ARV users, and users who received a new/renewed prescription.

We developed a Bayesian structural time series model using weekly data from January 1, 2017 to March 14, 2020, adjusted for holiday effects, to predict the trajectory in ARV prescriptions during March 15–September 26, 2020. The effect of COVID-19 was inferred by the difference between the predicted and observed time series.

Results: We predicted that without the COVID-19 pandemic 625,729 prevalent ARV users would have been expected by September 26, 2020, versus 565,381 observed ARV users, which indicated a 9.6% decrease (-60,348, 95% credible interval (CI) -33,661 to -92,008). During March 15–21, we observed an immediate increase of 14.9% (7,014, 95% CI 4,613 to 9,384) of patients with new/renewed ARV prescriptions, followed by a sharp and sustained decrease during the following weeks. We predicted that during March 15–September 26, in the absence of the COVID-19 pandemic, 46,837 patients would have received a new/renewed ARV prescription each week, versus 42,914 observed patients, which indicated an 8.4% decrease (-3,923, 95% CI -10,078 to 2,364).

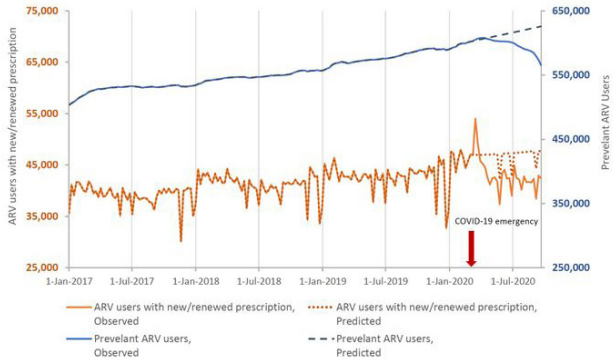

Figure. Predicted and observed trend in the weekly number of prevalent antiretroviral (ARV) users and ARV users with a new/renewed ARV prescription, IQVIA Real World Data - Longitudinal Prescriptions Database, 01/01/2017 to 09/26/2020

Conclusions: The COVID-19 pandemic and the public health response negatively affected HIV treatment services and adherence to ARV in the United States.

PEDLB37

Rapid rebound in HIV service utilization following initial interruptions to HIV prevention and treatment for key populations during COVID-19 in South Africa

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Background: COVID-19 pandemic lockdown measures interrupted the delivery of HIV prevention and treatment services globally, including in South Africa. For key populations (KP), little is known about the impact of lockdowns on HIV service utilization.

Methods: We conducted an interrupted time series analysis using weekly HIV program data collected by three USAID implementing partners between October 2019 and September 2020. Segmented linear regression models were used to assess the immediate and sustained impact of level 5 lockdown (March 26-May 1, 2020) on HIV case finding and treatment initiation for female sex workers (FSW), men who have sex with men (MSM), and transgender persons (TG).

Results: Study period reporting shows a total of 30,113 HIV tests resulting in 3,359 new HIV cases and 3,247 ART initiations, for KP. The first week of lockdown was associated with a significant reduction in HIV case finding for FSW (decrease of 33.3 cases/week (95%CI: -61.6,-5.1)) and MSM (decrease of 16.9 cases/week (95%CI: -26.5,-7.38)) compared to pre-lockdown. Thereafter, HIV case finding rebounded with higher weekly rates through 2020 for FSW (increase of 1.2 cases/week (95%CI: 0.3,2.2)), MSM (increase of 1.2 cases/week (95%CI: 0.69,1.8)), and TG (increase of 0.3 cases/week, (95%CI: 0.1,0.60)) compared to pre-lockdown trends. Similar immediate and long-term associations were observed for ART initiation.

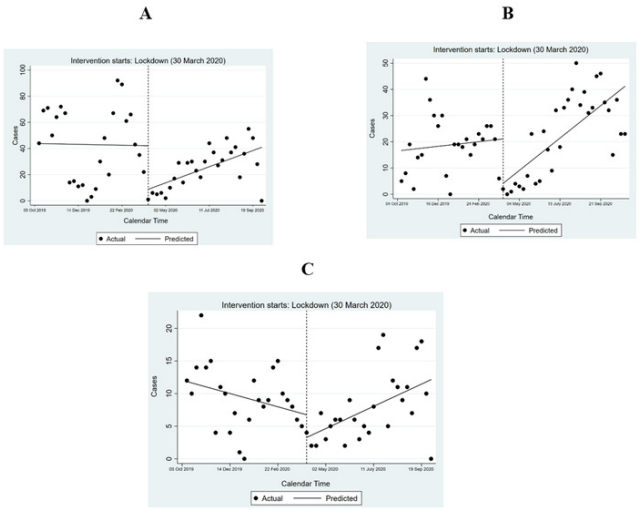

Figure 1. Trends in HIV case finding before and after lockdown among (A) FSW, (B) MSM, (C) TG in South Africa

Conclusions: The COVID-19 pandemic circumstances highlighted South African programmatic resiliency in maintaining essential HIV services for KP. While trends varied pre-lockdown, we demonstrate a rapid rebound in HIV service utilization in the weeks following initial service interruptions. These results may reflect the gradual lessening of lockdown stringency coupled with program-led service delivery innovations including increased mobile testing, ART home delivery, and amplified peer navigation.

These adaptations may have positively altered the trajectory of program performance beyond pre-pandemic levels, offering a potential roadmap to maintain continuity of services and improve the health of KP beyond COVID-19.

PEDLB38

Conclusion of the national transition to dolutegravir (DTG) formulations for adult first-line (1L) recipients of care in Malawi: early outcomes and practical lessons for low- and middle-income (LMIC) settings

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Background: Since its inception in 2001, Malawi Department of HIV & AIDS (DHA) has strived to provide optimized antiretroviral regimens for all people living with HIV (PLHIV). By 2017, over 630,000 adults were accessing the WHO-preferred 1L regimen TLE600, with an average national viral load (VL) suppression rate of 89%. Given the anticipated availability of new generic formulations, Malawi considered adopting DTG-based regimens, such as fixed-dose combination TLD given their clinical superiority over efavirenz-based regimens.

Description: DTG transition planning started in 2017. Through multi-stakeholder consensus, TLD was adopted as the preferred adult 1L regimen by end 2018. DHA recommended VL testing as best practice but not a requirement before switching to DTG, due to VL access challenges. DHA initially adopted a conservative approach for women of childbearing potential (WOCBP), given the May 2018 safety signal. A prescribing algorithm to translate TLD guidance into clinical practice was developed and at least two healthcare workers from Malawi's 750 ART facilities were trained. Pharmacovigilance tools were also developed to ensure timely and appropriate response to adverse events. The national projection was >95% of eligible patients will be transitioned to TLD by Q4 2019, staring January 2019.

Lessons learned: Early implementation monitoring conducted in 30 facilities showed low uptake among WOCBP (5%) highlighting influence of policy guidance on product adoption. When WHO updated TLD guidance in 2019, Malawi leveraged the early insights to catalyze development of a contextual, women-centered approach for TLD. Key stakeholder coordination minimized inefficiencies and facilitated uptake. Rapid guideline adaptation at onset of COVID-19 ensured sustained product access and showed the importance of swift coordination mechanisms for implementation. Routine quarterly supervision and site-level data collection systems enabled timely troubleshooting and course-correction. Analysis of programmatic TLD data between Q1 2019 and Q1 2021 shows Malawi transitioned 817,320 (~97%) patients to TLD, achieving viral suppression rates of ~98% in 1L adults. TLD uptake has been sustained at 97%.

Conclusions/Next steps: Malawi is one of the first LMICs to finish national transition to TLD. National HIV programs can learn from Malawi's implementation experience as best practice for ensuring rapid adoption to optimal products, even in light of COVID-19.

Author Index

B

C

D

E

F

G

H

I

J

K

L

M

N

O

P

Q

R

S

T

U

V

W

X

Y

Z

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