



HIVR4P 2024

abstract book

HIVR4P 2024, the 5th HIV Research for Prevention Conference

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Abstract submission

Over 1,700 abstracts were submitted to the 5th HIV Research for Prevention Conference.

The Organizing Committee (OC) is very grateful for all the abstract submissions received. While the OC found many very high-quality abstracts among the submissions, due to limitations in the conference programme, more abstracts were rejected than accepted – with an overall acceptance rate of 42% (which includes the late breaker abstracts).

All abstracts went through a blind peer-review process completed by over 110 abstract reviewers. These reviewers are international experts in the field of HIV, including members of the OC and track committees.

Each abstract was reviewed by three to four reviewers. The abstracts were reviewed for the quality and original-

ity 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 were an author or co-author, had a financial or personal conflict of interest, or did 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 highest) to five (the lowest score). Any abstracts that received less than two reviews or where there was a scoring discrepancy between reviewers were additionally reviewed by the track committees.

Statistics for abstracts

1,548 Regular abstracts submitted

774 Regular abstracts accepted

125 Oral abstracts

276 Poster exhibition abstracts

373 E-poster abstracts

192 Late-breaking abstracts submitted

46 Late-breaking abstracts accepted

21 Late-breaking oral abstracts

25 Late-breaking poster abstracts

1,740 Total abstracts submitted

820 Total abstracts accepted



HIVR4P 2024 International Abstract Review Committee

HIVR4P 2024 received more than 1,700 abstract submissions, which went through a blind, peer-reviewed process carried out by an international panel of reviewers who play a critical role in designing a strong scientific programme.

More than 110 specialists from around the world volunteered their time and expertise to serve as peer reviewers, helping to ensure that the abstracts presented were selected on the basis of rigorous review and were of the highest scientific quality.

We extend our special thanks to the large pool of abstract reviewers for the time they dedicated to the success of the conference.

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The progress that is achieved at HIVR4P 2024, the 5th HIV Research for Prevention Conference, would never reach its peak if it weren't for the resources and time given by our supporters. We thank these organizations and their employees for joining us in our efforts and showing their dedication.

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Oral abstract sessions

The big picture: Global trends in HIV prevention

OA0102

Infrequent new HIV acquisition among returning pre-exposure prophylaxis clients in PEPFAR, 2021-2023

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Background: The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) has provided pre-exposure prophylaxis (PrEP) since 2017 and, from October 2021 to September 2023, PEPFAR supported 3,380,468 new initiations. To assess whether large-scale PrEP implementation retains its HIV prevention benefits, we conducted a review of HIV infections among PrEP users in PEPFAR.

Methods: We analyzed cross-sectional, country-level HIV test result data among PEPFAR-supported PrEP clients who returned for visits after initiation. Quarterly data were abstracted from the PEPFAR Monitoring, Evaluation, and Reporting (MER) database for 24 countries and three geographic regions from October 2021 - September 2023. The PrEP_CT indicator is defined as number of clients returning to the PrEP service site at least once during the quarter, including either continuous PrEP users or re-initiating clients. PrEP_CT captures HIV testing data including Positive, Negative, and Other results.

PrEP_CT does not differentiate between daily and event-driven oral PrEP and does not allow for aggregation across reporting periods since one individual could be represented in sequential quarters. We calculated the proportion of those testing Positive among those with a Positive or Negative test result.

Results: Over the two-year review period, there were 4,415 Positive tests among the 3,089,834 Positive or Negative HIV tests, for positivity of 0.14% to 0.20% by quarter. At individual country level, quarterly positivity was mostly under 1%, ranging from 0% to 0.70% with only two instances of a country reporting $\geq 1\%$ positivity (1.60% and 1.91%), each in only one quarter. "Other" results were recorded for 19% of all returning PrEP visits overall, ranging across countries from zero to over 80% per quarter.

Conclusions: New HIV diagnoses among previously HIV negative PrEP clients (prerequisite for initiation on PrEP) were infrequent across PEPFAR PrEP programming, suggesting that most returning clients use PrEP effectively. The findings, together with UNAIDS epidemiological data, indicate that scaling up PrEP is a highly effective prevention option critical to the UNAIDS goal to end HIV as a public health threat by 2030. Tracking longitudinal client-level data and investigating "Other" results would be beneficial to better understand the dynamics of seroconversion and the contribution of PrEP to achieving epidemic control.



Oral abstracts



Poster exhibition



E-posters



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Oral abstracts



Poster exhibition



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Late-breaker abstracts



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OA0103

Advancing global HIV prevention: trends in CDC-supported pre-exposure prophylaxis (PrEP) initiation in 37 countries, 2017 – 2023

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Background: Oral pre-exposure prophylaxis (PrEP) reduces sexual HIV transmission risk by 99% when used correctly. Since 2016, the U. S. Centers for Disease Control and Prevention (CDC), with support from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), joined country governments in implementing PrEP, targeting popula-

tions at highest risk for HIV including adolescent girls and young women (AGYW) aged 15-24 years, and key populations (KPs: men who have sex with men [MSM], transgender people, female sex workers [FSW], people who inject drugs, and people in closed settings).

Methods: To contribute to a more thorough understanding of CDC's support towards PrEP scale-up, PEPFAR Monitoring, Evaluation and Reporting (MER) data were analyzed from 2017 – 2023 to describe annual and cumulative PrEP initiations by region and achievement of PrEP targets. Initiations were disaggregated by sex, age, and KP. **Results:** From 2017-2023, CDC supported 2,274,396 PrEP initiations in 37 countries (Table), with the majority (96.0%) in Sub-Saharan Africa. Annual PrEP initiations steadily increased from 8,800 to 856,238 in 2023, with 37.6% of all initiations occurring in 2023. Targets increased annually, with the highest target in 2023 exceeded by 130.7%. Overall, most PrEP users were 15-24 years old (52.4%) and female (64.0%).

Over one-third of initiations was among KPs (35.4%), which varied by region: 63.4% of KP initiations was among FSW in Sub-Saharan Africa, in the other regions, MSM predominated (69.2% European Region; 77.2% Region of the Americas; 93.0% South East Asia).

	Fiscal year*	PrEP initiations No. (%)	Achievement of annual PEPFAR target, %
Global	2017	8,800 (0.4)	77.4
	2018	37,378 (1.6)	121.9
	2019	72,606 (3.2)	100.4
	2020	144,341 (6.3)	79.9
	2021	449,479 (19.8)	93.1
	2022	705,554 (31.0)	141.2
	2023	856,238 (37.6)	130.7
	Total	2,274,396	117.7

Table. Annual CDC-supported PrEP initiations among newly initiated users by region, 2017 - 2023.

*October 1 - September 30.

Conclusions: From 2017-2023, CDC-supported over 2.2 million PrEP initiation, with the greatest uptake among AGYW in Sub-Saharan Africa. The largest uptake among KPs was FSWs in Sub-Saharan Africa and MSM in South East Asia, European Region and Region of the Americas. Robust PrEP programming and uptake among those at highest risk remains critical to achieving the UNAIDS 2025 goal for 10 million PrEP users.

OA0104

Identifying global typologies of HIV PrEP implementation: an analysis of global data using PrEP-to-need ratios and PrEP distribution volumes

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Background: To reach 10 million people in high incidence groups with PrEP by 2025, it is vital to assess the global need for and capacity to distribute PrEP using programmatic data.

The PrEP-to-need ratio (PNR) is the number of annual PrEP initiations relative to HIV incidence, and together with cumulative distribution volumes it can support identifying implementation gaps.

Methods: This retrospective analysis of global data explores PrEP implementation in countries with available data using two metrics (PNRs and volume of PrEP distributed) to identify six typologies of national implementation. PNRs were calculated as the ratio of 2023 PrEP initiations collected from AVAC's Global PrEP Tracker to estimated 2022 UNAIDS HIV incidence per 1,000 people, using World Bank's country population estimates.

Volumes distributed were proxied by the number of cumulative PrEP initiations to 2023 (Global PrEP Tracker). Both metrics were summarized using medians and interquartile ranges (IQR).

PNRs were used to determine countries leading (>5.00), growing (1.00-4.99), or emerging (<1.00) in meeting PrEP need. Volumes were categorized using 100,000 initiations as cut-off for programme size. Countries were assigned to one of six typologies based on these metrics.

Results: Eighty-four countries had available data for both metrics. The median PNR was 0.81 (IQR: 0.12-3.45). 52% (n=44), 31% (n=26), and 17% (n=14) of countries were classified as emerging, growing, or leading in meeting PrEP need, respectively. The median volume of cumulative PrEP distribution was 2,918 (IQR: 464-20,734). 88% (n=74) countries had distribution volumes <100,000 whereas 12% (n=10) had distribution volumes >100,000.

Most countries (52%, n=44) had low met need for PrEP and <100,000 PrEP distribution, and four countries (5%) were leading on met need with >100,000 distribution volumes (Table 1).

Conclusions: Most PrEP programmes globally are not sufficiently scaled-up, with countries in Eastern and Southern Africa leading on large-scale implementation. Focused efforts in Latin America and the Caribbean, Southeast Asia, and Eastern Europe and Central Asia are needed to achieve global goals. Typifying implementation scenarios may facilitate knowledge sharing, global programming, and advocacy.

Metric	Distribution volumes	
	>100,000	<100,000
PrEP-to-need ratio >5 ("Leading")	Kenya, Lesotho, Zambia, Zimbabwe	Belgium, Eswatini, France, Guatemala, Iceland, Liberia, Luxembourg, Malta, New Zealand, Portugal
PrEP-to-need ratio <5 and >1 ("Growing")	Brazil, Malawi, Mozambique, South Africa, Tanzania, Uganda	Barbados, Botswana, Burundi, Cambodia, Cote d'Ivoire, Croatia, Czechia, DR Congo, El Salvador, Ethiopia, Haiti, Honduras, Italy, Namibia, Nepal, Rwanda, Senegal, Sierra Leone, Thailand, Vietnam
PrEP-to-need ratio <1 ("Emerging")	NA	Argentina, Armenia, Azerbaijan, Bahamas, Belarus, Belize, Benin, Burkina Faso, Cameroon, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Eritrea, Gambia, Georgia, Ghana, Grenada, Guyana, India, Indonesia, Iran, Jamaica, Kyrgyzstan, Lao PDR, Lithuania, Madagascar, Malaysia, Mali, Mexico, Moldova, Mongolia, Morocco, Myanmar, North Macedonia, Panama, Papua New Guinea, Peru, Philippines, South Sudan, Tajikistan, Togo

Table 1.

OA0105

Evaluating overlap between condomless sex and prevention-effective oral pre-exposure prophylaxis (PrEP) use throughout pregnancy and postpartum in Cape Town, South Africa

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Background: Understanding the patterns of sexual behaviour and effective oral PrEP use is crucial for improving effective PrEP use in pregnant and postpartum women.

Methods: We offered oral PrEP with HIV risk counselling to 1195 HIV-negative pregnant women aged >15 years between Aug'19-Oct'21. We collected data on sexual behaviour and PrEP use during quarterly study visits.

We used logistic regression to evaluate the relationship between condomless sex and PrEP use (prevention-effective use) adjusted for *a priori* confounders: age, education, gestational age in pregnancy and postpartum time. We calculated HIV incidence using number of new HIV diagnoses and cumulative person-years for each risk category through 12m postpartum.

Results: Among 1195 participants (median age 26y; IQR:23-31, median gestational age 21w;IQR: 15-31), 72% (n=864) participants reported recent condomless sex in the past 3-months, with 84% (n=731) initiating PrEP. In the third-trimester of pregnancy, fewer participants reported recent condomless sex (25%); those reporting condomless sex were 83% less likely to use PrEP compared to those reporting consistent condom use (aOR=0.17; 95% CI=0.12-0.24). Overall 69% (n=784) reported condomless sex in their first postpartum visit, of whom 89% (n=699) reported no PrEP use in the last month.



Oral abstracts



Poster exhibition



E-posters



Late-breaker abstracts



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Oral abstracts



Poster exhibition



E-posters



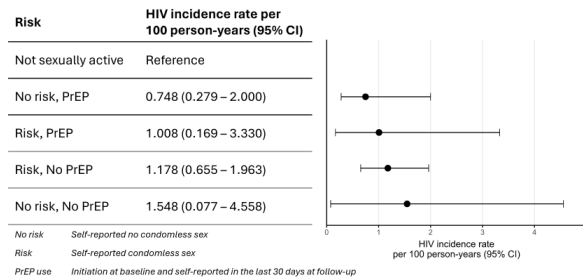
Late-breaker abstracts



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During early postpartum (9-22 weeks), participants reporting condomless sex were 91% less likely to use PrEP ($\alpha\text{OR}=0.09$; $95\% \text{CI}=0.05-0.16$). Participants reporting condomless sex and PrEP use decreased to 5% ($n=54/1109$) through 12-months postpartum.

Overall, 16 incident HIV infections were reported among 1195 participants, the overall HIV incident rate was 0.96 per 100 person-years ($95\% \text{CI}=0.49-1.42$), highest among those reporting condomless sex and no PrEP use (1.18 ; $95\% \text{CI}=0.66-1.96$).



Conclusions: There was an alignment in condomless sex and effective PrEP use in pregnancy; however, this alignment declines from birth through the postpartum period (through 12-months), when HIV incidence was elevated. There is a critical need for targeted strategies to improve effective PrEP use in postpartum.

OA106

The choice of indicators influences who is identified as priority populations for HIV epidemic response: a combined analysis of 15 mathematical models from 10 African countries

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Background: Improving the HIV response necessitates better understanding of the contribution of different groups to new infections (stemming from prevention and treatment gaps), whose levels vary widely across studies,

settings, and indicators used. We assessed to which extent the choice of indicators affects the estimated contribution of different groups to all new infections.

Methods: We compared estimates from 15 African models of the fractions of new infections: Ind1) acquired by a specific group in 2020, Ind2) attributable to direct transmissions from a group in 2020, and Ind3) which could be averted over 2020-2029 if transmission from a group was removed completely (tPAF). We focused on the following key populations (KPs): female sex workers (FSWs), their clients (CFSWs), and men who have sex with men (MSM).

Results: Ind2 attributed higher proportion of all new infections than Ind1 to KPs but lower to most non-KP, especially in Western Africa (Fig. A), meaning that most non-KP acquired more infections than they transmitted. Ind3 consistently attributed higher proportion of all new infections than Ind2 to all groups, up to 2-fold among FSWs, meaning that improving treatment as prevention services for FSW have substantial long-term effects on all new infections (Fig. B). Among the 10 models providing estimates for non-KP by age, eight identified non-KP women aged 25+ years as acquiring the largest proportion of new HIV infections (Ind1), but only one model estimated that this group transmitted the most infections (Ind2). Conversely, one model identified non-KP men 25+ years old as acquiring the most infections (Ind1), while six identified them as transmitting the most infections (Ind2).

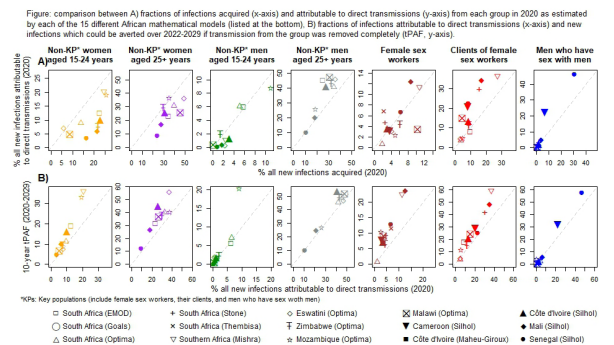


Figure.

Conclusions: Estimated contributions of groups to all new HIV infections substantially varied across indicators, especially for FSWs and their clients. Future studies should report indicators accounting for long-term effects on transmission chains alongside the fractions of infections acquired by the group.

Novel antiretrovirals and formulations for prevention

OA0202

Safety and tolerability of oral islatravir (ISL) once-monthly (QM) as pre-exposure prophylaxis (PrEP) in cisgender women at elevated risk for acquiring HIV-1

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Background: Once-monthly oral PrEP options are needed to address challenges with adherence to daily regimens and the complexity of injectable PrEP options and its barriers to scale-up, and to meet research-identified ideal product profiles. ISL is a nucleoside reverse transcriptase translocation inhibitor (NRTTI) with nanomolar potency against wild-type HIV and NRTI-resistant variants (eg, M184I/V).

Here we present safety findings from a phase 3 study of oral ISL 60mg QM compared to daily oral tenofovir-based PrEP in cisgender women at elevated risk for acquiring HIV-1 (NCT04644029).

Methods: Participants were randomized (1:1) to receive double-blind ISL QM or emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) once daily. Due to dose/exposure-related decreases in total lymphocyte and CD4 counts observed across the ISL program, enrollment and blinded intervention were stopped after ~1 year. All participants were offered open-label FTC/TDF for HIV PrEP with continued safety monitoring.

Results: Of 1145 participants screened, 730 were randomized and 727 were treated (362 with ISL; 365 with FTC/TDF) and included in the analysis. Most participants were black or African American (92.4%); median age was 25 (range 18-46) years. 94.6% of participants (343 and 345, respectively) entered the open-label phase. No participant acquired HIV-1 during the blinded phase. Adverse events (AEs) were experienced by 54.7% of participants in the ISL group and 69.9% of those in the FTC/TDF group, with <2% rated as severe (DAIDS Grade 3 or 4).

The most common AEs were headache (11.6%) in the ISL group and bacterial vaginosis (15.3%), headache (14.5%), and nausea (11.2%) in the FTC/TDF group. Infection AEs

(MeDRA terms) were reported in 22.4% of ISL participants and 40.5% of FTC/TDF participants. At Month 3, the mean percent change from baseline in total lymphocyte count was -20.8% (95%CI: -24.0,-17.6; n=159) in the ISL group and -8.9% (-11.6,-6.2; n=280) in the FTC/TDF group, with a trend of recovery observed at open-label Month 12 (-6.3% [-8.7,-3.9; n=322] and -5.3% [-8.0,-2.7; n=295], respectively).

Conclusions: In cisgender women at elevated risk of acquiring HIV-1, decreases in total lymphocyte counts observed with ISL 60mg QM were not associated with increased infection AEs and were followed by a trend of recovery after drug discontinuation.

OA0203

Safety and tolerability of oral islatravir (ISL) once-monthly (QM) as pre-exposure prophylaxis (PrEP) in cisgender men and transgender women at elevated risk for acquiring HIV-1

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Background: Challenges to daily oral adherence, operational complexity and insurance barriers to scale-up of injectable PrEP options, as well as ideal product profiles described by at-risk populations, support the development of once-monthly oral PrEP options. ISL is a nucleoside reverse transcriptase translocation inhibitor (NRTTI) with nanomolar potency against wild-type HIV and NRTI-resistant variants (eg, M184I/V).

We report the safety findings from a phase 3 study of oral ISL 60mg QM compared to daily oral tenofovir-based PrEP in cisgender men and transgender women at elevated risk for acquiring HIV-1 (NCT04652700).

Methods: Participants were randomized (2:1) to receive double-blind ISL QM or active control (emtricitabine [FTC] with tenofovir disoproxil [TDF] or tenofovir alafenamide [TAF]) once daily. Due to dose/exposure-related decreases in total lymphocyte and CD4 counts observed across the ISL program, enrollment and blinded intervention were stopped after ~1 year; all participants were offered open-label FTC/TDF or FTC/TAF for HIV PrEP with continued safety monitoring.

Results: Of 695 participants screened, 494 were randomized, treated (328 ISL, 166 control) and included in the analysis (4.5% were transgender, 41.7% white, 25.1% black/African American, 20.4% Asian); median age 27 (range 18-76) years. 93.1% of participants (306 and 154, respectively) entered the open-label phase. No participant acquired



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HIV-1 during the blinded phase. Adverse events (AEs) were reported by 64.3% of the ISL group and 77.1% of the control group and were mild or moderate in most cases (>96%). Infection AEs (MeDRA terms) were reported in 37.2% of ISL participants and 50.0% of control participants; COVID-19 was the most common AE (11.0% and 13.3%, respectively). Mean percent change from baseline in total lymphocyte count was -7.4% (95%CI: -10.6,-4.1; n=200) in the ISL group and -2.7% (-6.9,1.4; n=133) in the control group at double-blind Month 3, -17.4% (-23.4,-11.4; n=53) vs 0.4% (-6.1,6.9; n=50) at double-blind Month 9, and -0.9% (-3.9,2.1; n=263) vs -0.4% (-5.2,4.5; n=124) at open-label Month 10.

Conclusions: In cisgender men and transgender women at elevated risk of acquiring HIV-1, decreases in total lymphocyte counts observed with ISL 60mg QM were not associated with increased infection AEs and were followed by a trend of recovery after drug discontinuation.

OA0204

Acceptability of an on-demand, single-dose tenofovir rectal douche for HIV Pre-Exposure Prophylaxis in young men (ATN 163)

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Background: A behaviorally-congruent, on-demand rectal tenofovir (TFV) douche as pre-exposure prophylaxis (PrEP) to prevent HIV acquisition via receptive anal intercourse (RAI) would fill a critical gap in PrEP product availability. As part of ATN 163, we examined young men who have sex with men's experiences after participating in a Phase I trial, examining the safety, pharmacokinetics and pharmacodynamics, and acceptability of a single-dose PrEP douche candidate.

Methods: We enrolled 8 men (62.5% White and 37.5% Black; median age: 21 years; range: 18-24) at a single site between January and August 2022. One 125 mL douche containing 660 mg TFV was rectally administered. Participants completed a product experience survey and in-depth interview following dosing. We triangulated quantitative and qualitative assessments of the acceptability of rectal douche.

Results: Participants rated high overall acceptability on a scale of 1-10, with a mean of 9 (SD = 1.35), with all stating they would recommend use to others. Six (75%) of participants reported ever douching prior to enrolling in the trial. Participants familiar with traditional douching practices appreciated the behavioral congruence of a PrEP douche by aligning HIV prevention with their sexual preparation routines. When asked to select a future HIV protection as a receptive partner, the majority

of participants (n=6; 80%) stated that they would prefer the TFV douche over daily oral PrEP, with the remaining two participants (20%) valuing both the douche and daily oral PrEP equally. Participants offered recommendations regarding its design and sustainability, especially among those engaging in receptive anal intercourse, noting it would have consumer appeal among young men if it had comparable effectiveness to oral PrEP.

Conclusions: The high acceptability and behavioral congruence of a TFV douche shows promise as an on-demand PrEP product to prevent HIV among young men. Given its potential as an on-demand PrEP modality, future clinical development is warranted.

OA0205

Is the U=U status maintained after switching to a dual regimen? The answer from the Icona cohort Study

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Background: Observational studies found no linked HIV transmissions in sero-discordant couples when the partner's viral load (VL) was <200 copies/ml (U=U-status). Data on the risk of losing the U=U status after switching to a dual-regimen (2DR) when VL was ≤200 copies/mL are lacking.

Methods: We included PWH in the ICONA cohort who had reached a U=U status as of January 2014 while on triple therapy and were subsequently switched to dolutegravir (DTG)+lamivudine (3TC), DTG+rilpivirine (RPV) or darunavir/boosted (DRV/b)+3TC therapy. The number of person-months of follow-up (PMFU) spent with a U=U status

has been calculated. The main outcome was the proportion of PWH who spent >10% of their PMFU with a VL>200 cp/mL. A logistic regression model was used to evaluate the association between the use of DTG+3TC vs. other recommended 2DR as well as other key exposures and risk of losing the U=U status, after adjusting for confounding.

Results: Overall, 3,205 PWH were included. Of these, 2,509(78.3%) were switched to DTG+3TC, 696(21.7%) to other dual. 569(17.8%) were females. Overall, only 70(2.2%) participants spent >10% of their PMFU with a VL>200 copies/ml, and this proportion remained stable over time($p=0.984$).

The overall median time with VL>200 copies/ml was 4.3 (IQR: 1.7-10.5) PMFU in subjects treated with DTG+3TC and 5.4 (IQR: 2.9-10.9) in subjects treated with other 2DR($p=0.17$) and there was evidence for a difference in the proportion of PWH with>10% of time off U=U status 1.9%vs3.2%, $p=0.046$). DTG+3TC therapy showed a lower risk of losing the U=U-status in the unadjusted analysis but not after controlling for confounding factors(aOR : 0.84; 95%CI: 0.46-1.54; $p=0.57$) (Figure 1A).

Figure 1B shows that female sex at birth, being born outside Italy, and history of failure were confirmed risk factors for losing the U=U status in this setting.

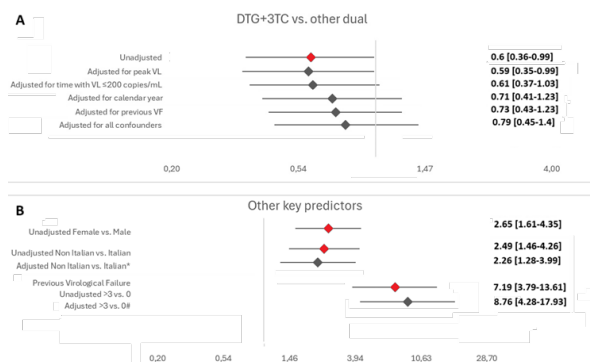


Figure 2. Forrest Plots of univariate and multivariate logistic regression estimates of factors associated with the risk of losing the U-status; **A:** univariate and multivariate to estimate the association of dual therapy eventually adjusted for calendar year, peak viral load (VL) before virological suppression, previous virological failures (VF), and time for time with VL>200 copies/mL; **B:** univariate and multivariate to estimate the association of female sex, non-Italian nationality, and previous virological failures. *Adjusted for: age, sex, mode of transmission, education level, and occupation; † adjusted for age, mode of transmission, AIDS diagnosis, and viral load before ART initiation. OR: odds ratio; CI: confidence interval; VF: Virological failure.

Conclusions: Our findings confirm a low risk of losing U=U after switching to 2DR, regardless of the type of therapy used.

OA0206

Development of a long-acting biodegradable hydrogel injectable system for single or multi-purpose prevention of HIV and/or pregnancy

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Background: There is a scarcity of long-acting (LA) injectable drug delivery systems capable of providing HIV prevention alone or as multipurpose-prevention technology (MPT) for simultaneous protection against HIV and unplanned pregnancies. Cabotegravir (CAB) nanosuspension (200mg/mL) is currently the only approved formulation for LA HIV prevention, but requires a 3mL intramuscular injection every 2 months.

Herein, we report on a LA subcutaneous injectable hydrogel depot platform that is biodegradable, provides lower injection volume and higher drug loading capacity, and may co-deliver two drugs with discretely controlled release profiles. Preclinical development of hydrogel injectable formulations containing CAB or dolutegravir (DTG) alone and combined with levonorgestrel (LNG) are reported.

Methods: Silica-based hydrogel formulations were optimized using micronized drugs to maximize drug loading and control burst release for enhanced duration. LNG was co-formulated after encapsulation in silica (Si) microparticles to create a two-compartment hydrogel matrix design for independently controlled release. Optimization efforts also included improvements on formulation injectability, homogeneity, and stability. Lead formulations were administered (0.1mL) to rats to assess pharmacokinetics, drug-drug interactions (DDIs), and injection site reactions for up to 3 months.

Results: Lead formulations containing 515 or 616mg/mL of micronized CAB, and 359mg/ml of micronized DTG and 67mg/ml LNG were selected for 3-month rat testing after meeting *in vitro* physicochemical targets including injectability through 21G needle. Both CAB formulations showed high and sustained plasma concentrations (>10,000ng/mL), while the CAB-616 formulation had a slightly lower C_{max} and more drug remaining in retrieved depots. DTG and LNG plasma levels did not show DDIs and were above 1,000ng/mL and 0.1ng/mL, respectively. There were no observed safety signals in any formulations.

Conclusions: We have developed a silica-based hydrogel injectable platform loaded with high concentrations of CAB or DTG/LNG, supporting subcutaneous administration and drug release for at least 3 months for protection against HIV and/or unplanned pregnancy. Additional studies are underway in non-human primates to better assess protective target drug concentrations and injection



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tion intervals. With the successful advancement of LA CAB injectable for HIV prevention, development of a more clinically and regulatory congruent MPT combining CAB and LNG in this hydrogel platform is ongoing.

OA0207

Global racial, ethnic, and gender diversity among participants enrolled in the PURPOSE-2 trial of lenacapavir for pre-exposure prophylaxis (PrEP)

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Background: Despite World Health Organization recommendations to make pre-exposure prophylaxis (PrEP) available to all people with increased likelihood of HIV-1 acquisition, disparities in new HIV-1 infections and PrEP use persist globally. People of color and gender-diverse people (transgender women, transgender men, and gender non-binary individuals) experience disproportionate HIV-1 incidence and have been historically underrepresented in PrEP clinical trials. These disparities are magnified in low- and middle-income countries and the Global South.

Methods: The PURPOSE-2 trial (NCT04925752) is evaluating the comparative efficacy and safety of long-acting (twice yearly) subcutaneous injectable lenacapavir for HIV-1 PrEP among cisgender men, transgender women, transgender men, and gender non-binary individuals who have condomless receptive anal sex with partners assigned male at birth. Trial sites in locations with relatively high prevalence of HIV-1 were selected. Consultative engagement with stakeholders and community advocates at these sites was initiated during the planning stages and continued throughout study enrollment to intentionally recruit a globally, racially, ethnically, and gender diverse participant population.

Results: A total of 3272 participants were randomized from seven countries across the United States, Latin America, South Africa, and Asia (Figure).

Mean age of participants was 30 (range, 17-74) years, and 22.2% were gender diverse (including 14.7% transgender women, 1.3% transgender men, and 6.2% gender non-binary individuals). The majority of participants were non-White (67.6%), including 35.7% Black or of Black ancestry and 12.6% Asian; 62.7% were of Hispanic/Latinx ethnicity.

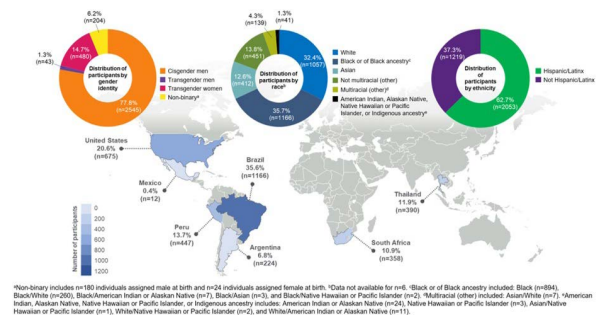


Figure 1. Distribution of participants in the PURPOSE-2 Trial by county, gender, race and ethnicity.

Conclusions: Purposeful recruitment led to a global PrEP trial with a significant majority of racially, ethnically, and gender diverse participants from settings including low- and middle-income countries and communities highly vulnerable to HIV-1.

Inclusion of these diverse participant populations will be important for understanding the efficacy of lenacapavir for PrEP in communities disproportionately affected by HIV-1 and who could benefit from PrEP.

Adaptive immune responses in vaccines

OA0302

HIV therapeutic vaccine induces CD8⁺ T cell responses targeting highly networked epitopes in a subset of participants

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Background: Functional cytotoxic CD8⁺ T-lymphocytes (CTL) targeting epitopes derived from structurally constrained regions of the viral proteome (i.e. highly networked) are associated with HIV-1 control. These epitopes are comprised of amino acid residues involved in important noncovalent interactions within the protein and therefore have reduced mutational tolerance due to putative impact on viral fitness. We previously showed that CTL responses targeting highly networked epitopes can distinguish individuals who naturally control HIV, even in the absence of protective HLA alleles. However, the extent to which a T cell-based therapeutic vaccine can elicit functional responses towards highly networked epitopes is unknown. Here, we examine the magnitude and proliferative capacity of highly networked CTL responses in individuals enrolled in an HIV DNA therapeutic vaccine trial (PENNVAX).

Methods: Forty-eight participants enrolled in the PENNVAX therapeutic vaccine trial were randomized 1:1:1 to receive DNA vaccination with multiclade Gag/Pol+IL-12, Gag/Pol/Env+IL-12, or placebo. Vaccine or placebo was administered by intramuscular electroporation at weeks 0, 4, 8, and 12. T-cell responses were evaluated at baseline and two weeks after the last dose (14 weeks). *Ex vivo* T-cell reactivity was measured by IFN- γ ELISpot and proliferative capacity through a six-day CFSE-based assay with overlapping Gag, Pol, and Env peptide pools (clade B) and individual optimal clade B epitopes (202 epitopes) matched to each participant's HLA haplotype.

Results: DNA vaccination using consensus HIV immunogens induced higher T cell reactivity and proliferation, with 45% and 36% of participants showing a two-fold increase in Gag- and Pol-specific responses, respectively (in Gag/Pol arm). However, these responses were mostly boosted responses from pre-existing T cells to known immunodominant epitopes. Interestingly, CD8⁺ T cell responses to 27 highly networked epitopes were identified in 23% of participants (n=8/37), although with only 11% of participants (n=4/37) having generated a new response. Interestingly, these *de novo* responses were observed in participants without protective HLA alleles.

Conclusions: DNA vaccination using full protein immunogens induced new responses towards highly networked epitopes, although in a low frequency of participants (~11%). These data warrant further investigation to understand the potential of these responses and immune-focusing vaccines to effectively control viral rebound after treatment interruption.

OA0303

Structural characterization of the affinity maturations of an intermediate VRC01-class bnAb elicited by immunizations in VRC01 precursor transgenic mice

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Background: Recent advances in structural biology and immunogen design have led to the identification of conserved epitopes on HIV-1 Envs that could serve as vaccine targets. However, the elicitation of VRC01-class bNAbs to overcome the steric hindrance imposed by N276 glycan in diverse Env trimers remains challenging, despite the progresses in germline-targeting immunogen designs and the development of sequential immunization strategies.

Methods: We used Cryo-electron microscopy (CryoEM) to investigate the interaction between an immunization-elicited intermediate VRC01-class bnAb, capable of neutralizing HIV-1 virus bearing N276 glycan and the cognate Env trimer.

Results: From transgenic mice expressing VRC01-germline heavy/light chain (HC/LC), which were immunized with Env-CD4i fusion protein presented on nanoparticles and a modified Env trimer, 45_01dG5 bearing N276 glycan, we have cloned a panel of VRC01 lineage mAbs to characterize the affinity maturation driven by the immunization. We observed clustered VRC01-class somatic hypermutations (SHM) in the HC/LC variable regions of these mAbs. Selected mAbs could neutralize a small panel of viruses with Envs bearing N276 glycan, one of the critical roadblocks impeding VRC01-class mAb affinity maturation. To examine the structural basis of how the affinity maturations confer Env trimer recognition, we obtained high-resolution CryoEM reconstructions of representative antibody



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(bc24) in complex with 45_01dG5 Env trimers with N276 glycan (bc24-dG5_276gl+). Around 68% of the interaction surface between bc24 and dG5_276gl+ trimer involves bc24 CDRH2, where multiple SHM mutations have been accumulated. The SHM in the LC is critical to accommodate N276 glycan: 3 out of 4 mutated residues in the bc24 CDRL1 interact with the 234/276 glycan complex. Comparison of dG5_276gl+ trimers with and without bc24 reveals significant N276 glycan movement upon bc24 binding to avoid clashes with bc24 LC: with 79° of angle rotation, and 14 Å of beta-D-mannopyranose moiety shift.

Conclusions: Our sequential immunization strategy facilitates the elicitation of antibodies, such as bc24, which lack deletion in the CDRL1 observed in the bnAb VRC01. This subclass of antibodies is able to accommodate the N276 glycan by reorienting it, a critical step for achieving neutralization breadth.

OA0304

Identification of non-neutralizing antibodies that compete with CD4 binding site-neutralizing antibodies in HIV infection

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Background: Non-neutralizing antibodies (non-NAbs) are elicited earlier than neutralizing antibodies (NAbs) and predominate in the humoral immune response to human immunodeficiency virus (HIV) during infection. However, their role in the pathogenesis of HIV infection remains poorly understood. Since the number of antibodies that can simultaneously bind to the Envelope glycoprotein (Env) is limited due to steric hindrance, non-NAbs might impede the access of NAbs to Env, reducing their anti-viral efficacy, and delaying their *de novo* generation by competitive mechanisms. Since this information is crucial to improve NAbs-based immunotherapies and refining HIV immunogens, we aimed here to define whether neutralization-interfering antibodies (NiAbs) are generated during natural HIV acquisition. Particularly, we focused on CD4 binding site (CD4bs) antibodies as they are frequently elicited during HIV infection.

Methods: Plasma samples from 19 people living with HIV (PLWH) with viral load higher than 50 copies/mL and low neutralizing activity against the HIV BaL isolate (reciprocal IC₅₀<500) were screened for the presence of CD4bs b12-blocking antibodies by ELISA, flow cytometry, and

neutralization assays. Eight HIV-1-uninfected individuals were included as controls. Env-specific antibodies were generated by RT-PCR from memory B cells isolated by FACS or single cell microcultures.

Results: IgGs from PLWH blocked b12 binding to Env, which correlated with the levels of Env-binding antibodies. Eight clonally unrelated Env-specific monoclonal antibodies were generated from a selected individual. These antibodies showed limited (n=3/8) or non-neutralizing activity (n=5/8) and targeted g120 (n=5/8), or gp41 (n=3/8). All of them bound to purified recombinant Env trimers by ELISA or the native Env expressed on the surface of chronically infected MOLT cells. Three anti-gp120 competed with CD4bs NAbs for Env-binding. Interestingly, two antibodies, one targeting gp41 and the other recognizing gp120, also reduced the neutralizing activity of the CD4bs NAbs b12 and VRC01.

Conclusions: Non-NAbs targeting different epitopes within Env reduced the binding and neutralizing activity of CD4bs antibodies (b12 and VRC01). The generation of NiAbs may represent a poorly described HIV immune escape mechanism that can hamper the development and function of NAbs. The identification of Env regions inducing NiAbs might be crucial for the design of successful HIV immunogens.

OA0305

Early neutrophil recruitment after heterologous late boost with and without new adjuvant in RV546 potentially contributes to vaccine-specific antibody responses

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Background: Neutrophils contribute to vaccine adjuvant effects by creating an inflammatory environment through cytokine and DNA release and may impact vaccine-induced antibody responses through B cell activation, but are often overlooked due to loss during processing. Here we assess fresh neutrophil responses upon heterologous booster vaccination with and without the Army Liposomal Formulation with QS21 (ALFQ) adjuvant.

Methods: RV546 enrolled participants receiving RV144 ALVAC-HIV/AIDSVAx B/E prime/boost vaccine regimen followed by late boosts (RV306) who then received an addi-

tional heterologous boost 6-8 years later with gp120-CD4 IHV01 and gp120 A244 with or without ALFQ adjuvant. Neutrophil activation and function (neutrophil extracellular nets-NETs) was assessed using flowcytometry at baseline, day(d) 1, 7, 14, and 168 post-vaccination. Binding antibodies (BAb) were measured by Luminex at d14. Interim blinded data include placebo recipients.

Results: The frequency of CD66b⁺CD16⁺Fc RI⁺ neutrophils increased after vaccination and remained elevated throughout d168 with and without ALFQ (one-way ANOVA: p<0.0001 and p=0.04, respectively). Participants receiving ALFQ had increased frequencies of CD64⁺ activated neutrophils at d1 and d7 compared to baseline (baseline: 1.68% vs d1: 2.28% and d7: 2.51%; p=0.04 and p=0.04, respectively), normalizing to pre-vaccination levels at d14. Similar trends were observed without ALFQ. Neutrophil expression of B cell activating factor (BAFF) increased at d1 and peaked at d14 post-vaccination with and without ALFQ (one-way ANOVA: p=0.0002 and p=0.003, respectively). However, only in participants receiving ALFQ a transient increase of IL-21⁺ neutrophils at d1 was observed (baseline: 0.98% vs d1: 1.42%; p=0.02). Formation of NETs increased at d1 in both groups (with ALFQ: baseline: 4.39% vs d1: 9.96%, p=0.0007; without ALFQ: baseline: 2.91% vs d1: 3.30%, p=0.003) and remained elevated throughout d14 before normalizing to pre-vaccination levels at d168. Interestingly, in participants receiving ALFQ, BAb levels against IHV01 at d14 correlated with the frequency of IL-21⁺ neutrophils at d1 (r=0.53, p=0.05) and CD64⁺ neutrophils at d7 (r=0.56, p=0.04).

Conclusions: Overall, neutrophils are recruited early after vaccination potentially contributing to a transient inflammatory environment and providing B cell help, both required for induction of vaccine-specific antibody responses, further adjuvanted by ALFQ. These results warrant additional interrogations into the role of neutrophils during initial vaccine responses.

OA0306

Broadest binding antibody and cellular responses seen with a matched prime-boost polyvalent DNA plasmid vaccine in a comparative analysis of 13 HIV vaccine trials conducted worldwide

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Background: The HIV Vaccine Trials Network (HVTN) conducted numerous individual phase 1/2/3 trials following RV144 to assess delivery systems, immunogen sequences, doses, schedules and adjuvants. We compared immune responses across these trials to characterize regimens that elicited the strongest responses.

Methods: Validated assays were used to measure immune responses to 36 vaccine regimens from 13 clinical trials, conducted across four continents between 2003 and 2018, that enrolled healthy adults without HIV. HIV-specific CD4⁺ T-cell (IFN-g and/or IL-2) and binding antibody (IgG, IgG3) responses were measured 2 weeks post-last primary HIV immunization. Analysis included all participants who received the protocol-specified primary



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HIV vaccinations, excluding those diagnosed with HIV before immunogenicity assessment (n=1688). IgG and IgG3 breadth scores were the geometric mean of binding antibody responses to the 3 heterologous V1V2 antigens with the highest median responses among all participants by trial and vaccine regimen. CD4+ T-cell magnitude to any Env was the maximum over all Env pools tested. Positive response rates and breadth scores were compared between regimen pairs by Barnard's exact test and Wilcoxon rank-sum test, respectively.

Results: Highest median IgG breadth scores were elicited by the prime-boost and co-administrated regimens of polyvalent DNA with matched polyvalent protein adjuvanted with GLA-SE (HVTN 124) and the B/E ALVAC+gp120/alum prime-boost regimen (HVTN 097, RV144). The prime-boost HVTN 124 regimen induced significantly higher IgG3 breadth scores than all other regimens (median score>5.9-fold higher, all p<0.001) with robust IgG and IgG3 responses to a consensus gp120 Env protein (Con 6 gp120/B) and 100% CD4+ T-cell response rate to Env global peptides.

Vaccine Product(s)	Type of Regimen	Primary HIV Immunization* Schedule (Months)	Total Protein Dose	Trial (Arm)
ALVAC + AIDSVAX B/E gp120/alum	Prime-boost	ALVAC: 0, 1; ALVAC + protein:MF59: 3, 6	600 µg	HVTN 097 (T)
ALVAC + gp120/MF59	Prime-boost	ALVAC: 0, 1; ALVAC + protein:MF59: 3, 6	600 µg	HVTN 107 (T)
ALVAC + gp120/mme	Prime-boost	ALVAC: 0, 1; ALVAC + protein:mme: 3, 6	200 µg	HVTN 107 (T2)
ALVAC + gp120/AS01a	Prime-boost	ALVAC: 0, 1; ALVAC + protein:AS01a: 3, 6	200 µg	HVTN 100 (T)
ALVAC + gp120/AS01a	Prime-boost	ALVAC: 0, 1; ALVAC + protein:AS01a: 3, 6	40 µg	HVTN 107 (T1)
AD26 + gp140/alum	Prime-boost	AD26: 0, 1; AD26 + protein:alum: 6, 12	250 µg	HVTN 120 (T1)
Vaccinia + AIDSVAX B/E gp120/alum	Co-administration	NYVAC: 0, 1; NYVAC + protein:alum: 3, 6	600 µg	HVTN 096 (T)
Vaccinia + AIDSVAX B/E gp120/alum	Co-administration	NYVAC + protein:alum: 0, 1, 3, 6	600 µg	HVTN 096 (T2)
DNA + AIDSVAX B/E gp120/alum	Prime-boost	DNA: 0, 1; NYVAC + protein:alum: 3, 6	600 µg	HVTN 096 (T3)
DNA + AIDSVAX B/E gp120/alum	Co-administration	DNA + protein:alum: 0, 1; NYVAC + protein:alum: 3, 6	600 µg	HVTN 096 (T4)
DNA + MVA	Prime-boost	DNA: 0, 1, 2; MVA: 4, 8	-	HVTN 106 (T1)
DNA + MVA	Prime-boost	DNA: 0, 1, 2; MVA: 4, 8	-	HVTN 106 (T2)
DNA + MVA	Prime-boost	DNA: 0, 1, 2; MVA: 4, 8	-	HVTN 106 (T3)
AIDSVAX B/E gp120/alum + DNA	Prime-boost	Protein:alum: 0, 1; DNA: 3, 6	600 µg	HVTN 105 (T1)
DNA + AIDSVAX B/E gp120/alum	Prime-boost	DNA: 0, 1; protein:alum: 3, 6	600 µg	HVTN 105 (T2)
DNA + AIDSVAX B/E gp120/alum	Prime-boost	DNA: 0, 1; DNA + protein:alum: 3, 6	600 µg	HVTN 105 (T3)
DNA + AIDSVAX B/E gp120/alum	Co-administration	DNA + protein:alum: 0, 1, 3, 6	600 µg	HVTN 105 (T4)
DNA + gp120/MF59	Prime-boost	DNA: 0, 1; DNA + protein:MF59: 3, 6	200 µg	HVTN 108 (T1)
DNA + gp120/MF59	Co-administration	DNA + protein:MF59: 0, 1, 6	200 µg	HVTN 108 (T2)
DNA + gp120/AS01a	Prime-boost	DNA: 0, 1; DNA + protein:AS01a: 3, 6	200 µg	HVTN 111 (T2)
DNA + gp120/AS01a	Co-administration	DNA + protein:AS01a: 0, 1, 6	40 µg	HVTN 108 (T3)
DNA + gp120/AS01a	Co-administration	DNA + protein:AS01a: 0, 1, 6	200 µg	HVTN 108 (T5)
DNA + gp120/AS01a	Protein adjuvant	Protein:AS01a: 0, 1, 6	40 µg	HVTN 108 (T7)
gp120/MF59	Prime-boost	DNA: 0, 1; DNA(Biojector) + protein:MF59: 3, 6	200 µg	HVTN 111 (T4)
DNA + gp120/MF59	Co-administration	DNA(Biojector) + protein:MF59: 0, 1, 6	200 µg	HVTN 111 (T5)
Polyvalent DNA + polyvalent gp120/GLA-SE	Prime-boost	DNA: 0, 1, 3; protein:GLA-SE: 6, 8	400 µg	HVTN 124 (T2)
Polyvalent DNA + polyvalent gp120/GLA-SE	Co-administration	DNA + protein:GLA-SE: 0, 1, 3, 6, 8	400 µg	HVTN 124 (T3)

- Highest IgG and IgG3 median breadth scores
- 100% CD4+ T-cell response rate to Env global peptides
- Robust IgG and IgG3 responses to a consensus gp120 Env protein

Conclusions: DNA plasmids provided an immunogenic priming platform when followed by adjuvanted Env protein. Greatest binding antibody breadth and cellular responses were seen with the prime-boost polyvalent DNA-matched polyvalent protein/GLA-SE regimen.

Latin America in the spotlight: "Caminos" to zero

OA0402

SPrEP – Online PrEP and PEP: the first online platform for access to HIV prophylaxes in Brazil

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Background: In the city of São Paulo, the highest concentration of new HIV cases is among men and young people aged 15 to 29. Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PrEP) for HIV have been decisive in reducing the number of new infections. The STI/Aids Coordination of São Paulo has been diversifying strategies to break down access barriers to PrEP and PEP.

Methods: Through teleconsultations, SPrEP – Online PrEP and PEP is the first online service of its kind in Brazil. It operates with an alternative schedule in comparison to traditional services, from 6pm to 10pm, every day, including holidays and weekends. To access SPrEP, the user must be registered in the e-saúdeSP app. The PrEP request can be triggered by uploading an image or PDF file, which can also be an HIV self-test, with a negative result for up to 7 consecutive days.

In the case of PEP, an HIV test is not required. An appointment request is generated and the user is video called within a few minutes. Medication prescriptions can be sent by email, SMS or WhatsApp and can be collected in 45 units, 17 of which are available 24 hours a day.

Results: From June/2023 to April/2024, SPrEP had 622,000 accesses, with 1,232 appointments, 288 for PrEP, 365 for PEP, 126 follow-up appointments and 403 for other appointments.

Of the total number of appointments, 33% were for people aged 15 to 29; 57.2% for white people and 36.3% for black people. Regarding medication pick up, 65.7% did so in 24-hour units and 34.3% in units with regular hours.

Conclusions: With more than 40,000 PrEP registrations since 2018, the city of São Paulo has the largest distribution hub for this prophylaxis in Brazil. SPrEP is another option for the population to have access to prophylaxes in alternative times and at various medication pick-up points at any time of the day in São Paulo, at any time via teleconsultation, which offers access to a medical prescription and to online medical examination requests.

OA0403

Examining the impact of stigma on the PrEP cascade among indigenous gay and bisexual men in Guatemala

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Background: Indigenous gay and bisexual men (GBM) in Guatemala experience intersectional stigma based on their sexual orientation (SO) and Indigenous identity, which likely negatively impacts their engagement with HIV prevention services. We aimed to assess the relationship between different forms of stigma and the PrEP cascade among Indigenous GBM to inform PrEP programming.

Methods: Between June 2023 to March 2024, we administered a cross-sectional questionnaire to Indigenous GBM (n=348) in collaboration with two community-based organizations. We estimated prevalence of enacted SO stigma, internalized SO stigma, interpersonal racism, internalized racism, and systemic racism and the PrEP cascade (awareness, intent-to-use, uptake, adherence). We examined the relationship between stigma and the PrEP cascade using logistic regression.

Results: We found a high burden of SO stigma and Indigenous identity stigma: 93% of participants reported hearing that their SO was not normal; 53% reported losing a relationship with a family member; and 44% suffered physical violence for being gay/bisexual. Indigenous GBM reported high levels of interpersonal racism (71%) and moderate or high systemic racism (67%); 15% reported high internalized racism. 73% participants were aware of PrEP and a third (31%) had initiated PrEP. Among non-users, less than half (45%) found PrEP acceptable and 28% intended to use PrEP. Among PrEP users, 66% reported perfect 7-day adherence. In multivariable analyses, we found that for each one unit increase in internalized racism, participants were nearly twice as likely to be aware of PrEP (OR: 1.86, 95% CI: 1.04-3.36, p=0.04). For every one unit increase in enacted SO stigma (OR 2.43; 95% CI: 1.20-4.98; p=0.01), systemic racism (OR: 2.04, 95% CI: 1.30-3.26, p<0.01), and internalized racism (OR: 2.30, 95% CI: 1.29-4.17, p<0.01), participants were over twice as likely to use PrEP. Internalized SO stigma and interpersonal racism were not significantly associated with any PrEP outcomes.

Conclusions: Indigenous GBM experience high rates of stigma based on their SO and Indigenous identity which may contribute to greater awareness of their HIV vulnerability, leading to an increased use of PrEP. Future research should explore the role of self-assessed HIV risk on the relationship between stigma and PrEP use.

OA0404

Strategic alliance to reduce barriers to treatment of migrants with HIV and/or TB in Peru

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Background: At the end of 2023, 1.6 million Venezuelan migrants were living in Peru. The Peruvian's Ministry of Health reports that TB cases among migrants are exponentially on the rise since 2016. The HIV prevalence rate among Venezuelan migrants is 0.6 – 0.7%, double than the general population (0.3%). Between 2018 and 2022, there were 4,043 migrants living with HIV on antiretroviral treatment (ART) but total number of migrants with HIV is estimated in 8000. It is required that people with TB and HIV take medical tests before initiating treatment. For migrants in irregular situation, the out-of-pocket expense of these is very high and cant initiate treatment. This limits cure or control, increases risk of transmission and AIDS-related deaths.

Methods: An Steering Group was established in 2022 to develop a bill that incorporates migrants with HIV and/or TB into the National Health Insurance (SIS) while they obtain regular migration status. The group is comprised by USAID, UNAIDS, LHSS, VENEACTIVA, GIVAR, IOM, OPEMS UPCH, UNHCR, Social Observatory of TB of Peru and Partners in Health. The bill is evidence-based, states public health reasons and a cost-benefit analysis for the measure. The group held advocacy meetings with national authorities and legislators, an awareness raising event with the Ombudsman's Office, trained spokespersons from PLHIV and migrants groups, carried out political advocacy, and information material was distributed.

Results: In June 2023, the bill (5253) entitled "Law amending Legislative Decree 1164 for the health protection of refugees and migrants with HIV/TB" was submitted to the Congress, in January 2024 was unanimously approved by the Health and Population Committee and in March 2024, the Budget and General Account Committee of the Congress established an opinion in favour. The driving group is optimistic that it will be approved by the plenary before the end of the current legislature.

Conclusions: The strategic alliance between UN agencies, bilateral cooperation, academia, CSOs, PLHIV and migrants, has been key for the development of the bill and an advocacy strategy to close the gap in access to HIV and/or TB treatment by migrants, and thus reduce the risk of transmission and AIDS-related deaths.



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OA0405

Venezuelan migrant cisgender women sex workers in Lima, Peru: is time increased in Lima associated with less HIV-related vulnerability?

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Background: Peru is home to the second-largest Venezuelan migrant population. Lima hosts over 1 million Venezuelans, half of whom are women, with many engaging in sex work to earn income. To inform HIV prevention and care interventions tailored to migrant women vulnerable to HIV, such as sex workers, we explored how time since arrival in Lima, Peru was associated with HIV-related vulnerabilities.

Methods: Between February and March 2024, 198 Venezuelan migrant cisgender women sex workers in Lima participated in a bio-behavioral survey including testing for HIV, syphilis, gonorrhea and chlamydia. We compared participants reporting living in Lima for ≥ 4 years versus those in Lima < 4 years, using chi-square and fisher's exact tests to explore if less time living in Lima was associated with increased experience of HIV-related vulnerabilities.

	Arrived in Lima <4 years ago N = 87	Arrived in Lima ≥ 4 years ago N = 110	p-value
Difficulty finding a safe place to sleep (past 6 months)	36 (48.0%)	22 (23.2%)	0.001
Worried about not having enough food to eat (past 12 months)	78 (96.3%)	100 (96.2%)	0.767
Sex work is main source of income	56 (80.0%)	50 (63.3%)	0.038
Able to always choose own sex work clients	45 (66.1%)	64 (83.1%)	0.030
Any HIV/STI	8 (9.2%)	8 (7.7%)	0.911
Has health insurance	17 (20.5%)	27 (25.5%)	0.527
Intimate-partner violence (past year)	20 (27.0%)	32 (33.0%)	0.502
Mental Health:			
Anxiety	35 (45.5%)	37 (37.8%)	0.383
Depression		39 (39.0%)	0.630
Severe psychological distress	32 (43.8%)	17 (18.1%)	0.641
	16 (22.2%)		

Table. Relationship between time in Lima among Venezuelan migrant cisgender women sex workers.

Results: Among participants (median age 32 years, IQR 26-39), most (72.2%) had permanent or temporary residency, only 23% had health insurance and 76.3% reported earning less than half of Peru's monthly minimum wage.

Migrants in Lima for < 4 years were significantly more likely to report recent difficulty finding a safe place to sleep at night (48% vs 23%, $p=0.001$), difficulty paying rent this month (62.1% vs 38.2%, $p=0.001$), and sex work as their main source of income (80.0% vs 63.3%, $p=0.039$), compared to migrants in Lima for ≥ 4 years. STI prevalence (HIV, syphilis, gonorrhea or chlamydia) was similar between the two groups (9.2% vs 7.7%) as were other types of vulnerabilities including food/housing insecurity, mental health, and violence.

Conclusions: Increased time in Lima was associated with decreased reliance on sex work for income and increased autonomy in sex work practices. Though HIV prevalence was low, experiences of food and housing insecurity, intimate-partner violence, and mental health remained disproportionality high, which could which can increase their vulnerability to STIs, necessitating comprehensive interventions for this population.

OA0406

Needed policy reform and programmatic efforts to make Peruvian HIV prevention and care accessible for Venezuelan sexual and gender minority migrants: qualitative exploration

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Background: Latin America is currently facing its largest recorded mass migration due to the displacement of more than 7.03 million Venezuelans. Peru is the second largest recipient of Venezuelans, yet limited research has assessed health policy and responsiveness. Multi-level, systemic inequities perpetuate vulnerability to HIV and limit care, especially for Venezuelan sexual and gender minorities (SGM) migrants. There exists an urgent need to monitor SGM needs and strengthen HIV health systems to improve quality and accessibility.

Methods: Between January and March 2023, we conducted interviews with key informants from public institutions, international cooperation agencies, civil society organizations, and grassroots organizations working with migrants and refugees ($n=16$), and Venezuelan SGM migrants living in Lima, Trujillo, and Piura ($n=26$). Interviews explored health system access, HIV prevention and care, legal and policy barriers. Inductive and deductive analysis were informed by the Action Framework of the Working Group on Refugees and Migrants (GTRM) in Latin America.

Results: SGM participants had a median age of 39 years (IQR 26-37). Four barriers to accessing HIV prevention and care were described that affect Venezuelan SGM:

1. Health system constraints including underfunded and overburdened public systems that are ill-equipped to handle the influx of migrants and insufficient training on

SGM needs. Confusion among SGM migrants regarding if SGM services are available and where to access them;

2. Economic hardships experienced by SGM migrants increase vulnerability to HIV (eg., sex work, housing instability, exploitation), juxtaposed against needed HIV prevention and care not prioritized due lack of insurance and out of pocket expenses;

3. Social stigma and structural violence, including the multiplicative impact of xenophobia, homophobia, transphobia, limits trust in public health systems;

4. Shifting migration policies and heterogenous processes within health establishments limits access to health care and disproportionality impacting SGM migrants.

Conclusions: Several needs of SGM migrants are not addressed by the Peruvian health system, due to legal, procedural, and implementation barriers, leaving aside groups with high vulnerability to HIV. Considerable policy reform and programmatic efforts need to focus on the integration of this Venezuelan SGM into existing HIV prevention and care services and on the design of tailored interventions.

quarterly group FCs focused on exchanging knowledge, sharing implementation challenges, and identifying solutions across stages of the IJ to support CAB LA integration. Sixty-two monthly 1:1 FCs and six quarterly FCs were coded using the rapid qualitative analysis process described by Hamilton (2013) into five themes (barriers, facilitators, strategies, recommendations, and support provided).

Results: Clinics spent the most effort in the following stages: patient selection, benefits verification, injection visits, and continuation (Table).

Challenges across the IJ included insufficient staffing, increased clinic-pharmacy coordination, variable insurance coverage, CAB LA scheduling integration, and required labs. Facilitators across the IJ included prior injectables experience, pharmacy expertise with HIV-related medications, ease of physical storage, clinic effort to simplify scheduling, clinic-patient rapport, and patient enthusiasm to avoid pills. Helpful strategies across the IJ included clinic-specific adaptations to resource management (e.g., tracking logs), visits (e.g., transportation, integrated care), injection scheduling (e.g., injection days, drop-in appointments), and outreach through multiple mediums.

Early experiences with long-acting PrEP products

OA0502

Overcoming challenges integrating injectable PrEP into care: key strategies from the PILLAR study

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Background: Long-acting cabotegravir (CAB LA) for PrEP offers a new HIV prevention option to people who could benefit from PrEP. CAB LA has appealing features (e.g., less frequent dosing), but there may be challenges to introducing an injectable option into real-world settings. PILLAR is a Phase IV implementation science study evaluating strategies for integrating CAB LA into care at existing PrEP clinics across the US.

We present results on facilitators and strategies to address challenges across seven implementation journey (IJ) stages of integrating CAB LA into care.

Methods: Seventeen clinics were randomized 2:1 into dynamic implementation (DI) (treatment) and routine implementation (control). DI clinics (n=11) participated in monthly 1:1 implementation facilitation calls (FCs) and

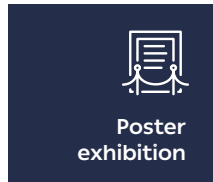
Implementation Journey Stages	Average Level of Effort*	Challenges	Facilitators	Strategies
Practice Preparation (Preparation)	Low	<ul style="list-style-type: none"> Staff turnover or insufficient staffing Increased patient volume Clinic-pharmacy coordination 	<ul style="list-style-type: none"> Prior experience with injectables Staff enthusiasm 	<ul style="list-style-type: none"> PILLAR injection training video PILLAR Spot® for centralized CAB LA materials Creating new staff roles and to manage injections Flexibility around patient scheduling
Patient Selection (preparation)	High	<ul style="list-style-type: none"> Patient hesitancy (needs, visit frequency, novelty) Structural influences 	<ul style="list-style-type: none"> Patient awareness and knowledge (influencers) Patient enthusiasm for a pill alternative 	<ul style="list-style-type: none"> Online advertising Social media (dating apps, mobile outreach, local events) Partnerships with community organizations
Benefits Verification (preparation)	High	<ul style="list-style-type: none"> Variable authorization requirements across and within insurance plans Benefit type (pharmacy vs. medical) More administrative time (paperwork, phone calls) 	<ul style="list-style-type: none"> Site learnings and familiarity Clinic-pharmacy coordination 	<ul style="list-style-type: none"> Consistent communication Designated point-person for insurance authorization
Inventory Management (initiation)	Low	<ul style="list-style-type: none"> Supply needs (product, needles) Developing new partnerships with pharmacies/alternative sites of administration 	<ul style="list-style-type: none"> Pharmacy expertise with HIV-related medications Physical storage (refrigeration is not required) 	<ul style="list-style-type: none"> Resource management (tracking/delivery logs) Site coordination re-supply ordering
Oral Lead-in (initiation)	Low	<ul style="list-style-type: none"> Oral CAB availability Insurance issues 	<ul style="list-style-type: none"> Patient enthusiasm to avoid pills 	<ul style="list-style-type: none"> Patient choice around initiation method Staff enthusiasm
Injection visits (initiation)	High	<ul style="list-style-type: none"> Injection scheduling Testing and lab requirements Variety of patient body types 	<ul style="list-style-type: none"> Positive patient experience with injection Patient flexibility with injection scheduling 	<ul style="list-style-type: none"> Clinic-specific injection scheduling (prescheduling, injection days/injection clinics, drop-in appointments) Clinic-specific visit adaptations (telehealth, integrated care)
Continuation (patient adherence, patient retention, patient persistence)	High	<ul style="list-style-type: none"> Injection scheduling within window, rescheduling Testing and lab requirements Increased patient volume 	<ul style="list-style-type: none"> Patient reminders sent across multiple mediums (text, phone, email, etc.) Patient rapport Extended/flexible hours 	<ul style="list-style-type: none"> Coordinated or integrated care Transportation services Telehealth Patient scheduling/tracking systems

*Average level of effort = cumulative effort contributed to that implementation stage throughout total time in study
Low effort: <=14% of cumulative effort
High effort: >14% of cumulative effort

[†]PILLAR SPOT is a CAB LA support hub for providers

Table. Challenges and successes across implementation stages for CAB LA.

Conclusions: Findings suggest the initial challenges with CAB LA integration into standard of care are surmountable. Flexible injection scheduling, resource management and coordination, and regular clinic discussion of implementation learnings are important strategies in CAB LA delivery.



OA0503

Low-barrier, rapid Cabotegravir PrEP initiation and retention within a U.S. municipal health system

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Background: Despite its potential to expand PrEP uptake, long-acting cabotegravir (CAB-LA) rollout needs to expand among underserved populations. The present study examines CAB-LA implementation in a clinic system serving publicly-insured patients.

Methods: The San Francisco Department of Public Health Primary Care Clinics is an integrated, municipal health system of 15 clinics. CAB-LA was offered on a drop-in basis, on the same day with a negative rapid HIV test and pending HIV viral load. On-time injections were defined as ± 7 days of target date. Logistic and Cox regression examined predictors of on-time injection and discontinuation, respectively.

Results: 96 participants (mean=37.6 years) taking CAB as PrEP from March 2022-March 2024 were included in analyses; 64% cisgender male, 16% cisgender female, 10% non-binary gender, 10% transgender female; 33% were Hispanic; 38% White, 14% Black, 7% Asian; 50% initiating PrEP for the first time. Most CAB-LA injections (85%) were on-time, and there were no differences in proportion of on-time injections by age, gender or race ($P > 0.116$). CAB-LA retention was 84.8% for the first six months (95%CI 80.9-88.9%), and mean time on CAB was 252 days (95%CI 210-293), Figure 1.

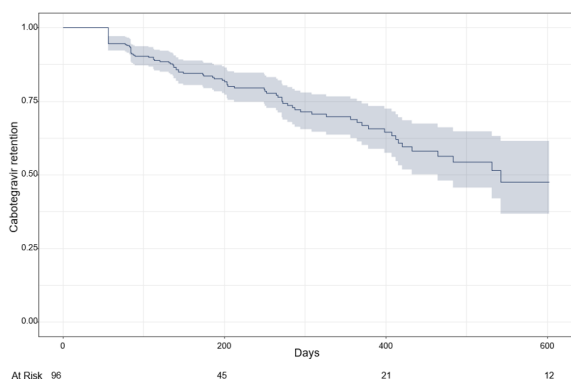


Figure 1.

In Cox regression, older age (scaled 10-years) was associated with retention (HR=0.73, 95%CI 0.60-0.89, $P=0.002$); cisgender men had higher retention than transgender women (HR=0.46, 95%CI 0.23-0.94, $P=0.032$), and non-binary people had higher retention than both cisgender women (HR=0.34, 95%CI 0.15-0.79, $P=0.012$) and transgen-

der women (HR=0.29, 95%CI 0.11-0.78, $P=0.014$). In addition, 8% of participants were also prescribed doxycycline post-exposure prophylaxis (doxy-PEP) for sexual health. No HIV seroconversions occurred.

Conclusions: Results provide evidence of the potential of CAB-LA to expand PrEP uptake for diverse participant populations in a low-barrier setting, with a high proportion initiating PrEP for the first time. Additional support may be needed for cisgender and transgender women CAB-LA users to ensure retention, such as navigation or case management.

OA0504

Long-acting injectable Cabotegravir (CAB-LA) pilot implementation at primary healthcare level in resource-limited settings: early real-world evidence from the USAID DISCOVER-Health Project in Zambia

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Background: Achieving the AIDS 2025 targets of less than 370,000 global annual HIV acquisitions from the baseline of 1.5 million in 2021 requires expanding combination HIV prevention choices beyond the currently existing arsenal. Long-acting injectable Cabotegravir for HIV pre-exposure prophylaxis (PrEP) has the potential to reduce the persistently high HIV incidence, although data on widespread implementation are scanty. John Snow Inc. through the DISCOVER-Health Project supports the Zambian ministry of health in implementing the PEPFAR CAB-LA pilot.

Methods: Following training of supervisors, health workers and community-based volunteers, health facility preparation for CAB-LA implementation and demand generation, CAB-LA was provided to eligible individuals in line with the national Implementation plan, in 2 health facilities participating in the demonstration from February 9th, 2024. Aggregates of client-level data were extracted from the electronic database housing clients records, and de-identified data by variables such as age, sex, population category for clients injected CAB-LA or discontinued (by reasons) were analyzed using WINPEPI

Results: By 5th April 2024, 609 clients accessed CAB-LA (median age = 24.4 years), with 425 (70%) of them being PrEP-naïve and 184 (30%) transitioning from oral PrEP. Females were more likely to be PrEP-naïve than males (OR = 1.36; 95% CI = 0.94-1.95; $p=0.051$). Of all clients, 340 (55.8%) were females, 198 (32.5%) were adolescent girls and young women, 131 (21.5%) were adolescent boys and young men, 42 (6.9%) identified as key populations and 238 (39.1%) were other high-risk populations. Additionally, 406/609 (67%) were due for second initiation injection and 371 (91%) were reinjected, 35 (9%) were pending reviews, 24 (3.9%)

discontinued CAB-LA, 22 (92%) of which were switched to oral PrEP while 2 (8.3%) commenced antiretroviral therapy after acquiring HIV. Discontinuation reasons included Hepatitis B virus 20 (83.3%), pregnancy 2 (8.3%), severe rash 1 (4.2%) and severe injection-site pain 1 (4.1%).

Conclusions: CAB-LA has potential to prevent HIV acquisition through expanding PrEP uptake and persistence among females, adolescents and young people and other high-risk populations. Robust laboratory support for eligibility screening is required in low-resource settings for smooth implementation

OA0505

HIV pre-exposure prophylaxis (PrEP) access preference among men who have sex with men in China: a discrete choice experiment

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Background: HIV pre-exposure prophylaxis (PrEP) is highly effective but not widely used by men who have sex with men (MSM) in China. This study explores PrEP access preferences among Chinese MSM.

Methods: An online cross-sectional survey with a discrete choice experiment (DCE) was distributed to MSM residing in Beijing and Chengdu in June 2023. Eligible study participants were above 18 years old, HIV-negative or unknown status, and were PrEP-eligible based on criteria from a Chinese consensus statement for PrEP.

The DCE explored attributes of PrEP modality (daily pill, on-demand pill, injections, implants), clinical care model (same-day, 2-visit, telehealth prescription), medication pick-up (clinics, pharmacy, home delivery), enhanced support (self-management, smartphone app, text reminder), and cost. Data were analyzed using mixed logit and latent class models.

Results: A total of 1013 MSM completed the survey with an average age of 31 years and a quarter (25%, 249/1013) had used PrEP. The most influential attributes were cost (relative importance = 65%), PrEP modality (28%), medication pickup (4%), enhanced support (4%), and clinical care model (0.2%).

The most preferred way to access PrEP was no-cost, on-demand pill, medication home delivery, self-management, and telehealth.

Four latent classes were identified. Men in Class 1 ("Modality matters", 30% of participants) were more likely to be influenced by PrEP modality, followed by cost.

Men in Class 2 ("All about cost", 29%) were more likely to be influenced by cost.

Men in Class 3 ("PrEP hesitant", 19%) were more likely to prefer not using PrEP.

Men in Class 4 ("Everything matters", 23%) were more likely to value all attributes and to prefer long-acting injectable PrEP.

Men in Class 2 were more likely to report lower income level (coefficient=-0.54, $p<0.05$) compared to referent men (Class 4).

Conclusions: MSM in China have strong and unique preferences regarding PrEP: cost is a critical variable, especially important because the medication and clinical care are currently entirely unsubsidized in China.

Preferences for on-demand PrEP and home delivery indicate methods the healthcare system can utilize to best meet the needs of MSM, and factors that should be incorporated into future interventions.

OA0506

Using stated preference methods to design gender-affirming long-acting PrEP programs among transgender and nonbinary adults

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Background: Integrating gender-affirming care with HIV biomedical prevention could help address the disproportionate HIV risk experienced by transgender and nonbinary (trans) adults. This discrete choice experiment (DCE) assesses and identifies the most important programming factors influencing the decisions of trans adults to use injectable long-acting HIV pre-exposure prophylaxes (LA-PrEP).

Methods: From March to April 2023 $n=366$ trans adults in Washington state chose between different 4 choice profiles that presented hypothetical programs (each comprised of 5 attributes with 4 levels). We analyzed ranked choice responses using a mixed rank-ordered logit model.

Results: Respondents preferred to receive LA-PrEP from a gender-affirming care provider and a co-prescription for oral and injectable hormones. Trans adults strongly favored 12-month protection and injection in the upper arm. No strong preferences emerged surrounding the type of health facility offering the gender-affirming LA-PrEP program.



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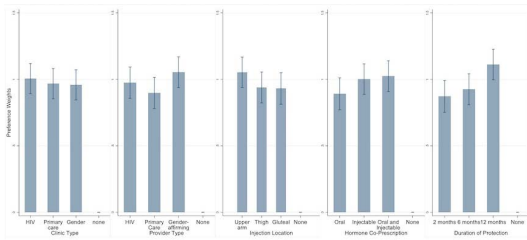
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Bars represent mean preference weights and error bars present 95% confidence intervals. Estimates are from conditional logistic regression models that included the primary (first) program choice vs all other program choices as the dependent variable and dummy-coded variables for each attribute level as the independent variables. Dummy coding estimates the preference weights of a given attribute level relative to the omitted level of that attribute. A more positive weight indicates a stronger preference towards a given attribute level.

Figure 1. Mean preference weights with 95% confidence intervals (CIs).

Conclusions: Our findings show that integrating and leveraging gender-affirming health systems, particularly medical services such as hormone therapy, with HIV biomedical products like LA-PrEP is strongly preferred and influential to trans adults' decision to use LA-PrEP. Leveraging choice-based design experiments provides informative results that hold promise for optimizing gender-affirming LA-PrEP programming for trans adults.

Monoclonals for prevention

OA0602

In vitro characterisation of mRNA-mediated delivery of multispecific bNAbS for HIV-1 immunoprophylaxis

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Background: HIV-1 broadly neutralising antibodies (bNAbS) show great promise at both reducing viraemia and preventing HIV-1 acquisition, however, their application may ultimately be limited due to high manufacturing costs and the requirement for combination-based therapies.

Here we describe the development of *in vitro* transcribed (IVT)-mRNA delivery of multispecific antibodies as a potential cost-effective, passive immunisation strategy for prevention of HIV-1 acquisition.

Methods: Previously described tandem single chain variable fragment (scFv) bispecifics (Bi-scFv and Bi-NAb) and heterologous heavy chain (knob-into-hole mutations) assembled tri-specific (Tri-NAb) antibodies combining VRC01/PGT121 and VRC01/PGT121/10e08 paratopes, respectively (>95% neutralisation coverage *in vitro* (208 pseudovirus panel), with geometric mean IC₅₀ titres <0.4 µg/mL), were selected for development. Antibody-encoding DNA plasmid constructs, including a novel single open reading frame (sORF) polycistronic Tri-NAb construct for com-

parison to Bi-NAb/10e8 co-transfection (Co-T) strategy, engineered with T7-IVT mRNA transcription compatibility were generated. Parental (PGT121, VRC01 and 10e08) and multispecific antibodies were expressed from DNA constructs by transient transfection in 293F cells, purified and biochemically characterised. Multispecific antibody-encoding mRNA transcripts were IVT from linearised DNA, purified of dsRNA, enzymatically capped (5' Cap 1 structure), and transfected into 293F cells. The functionality of the purified antibodies and mRNA-transfected cell culture supernatants were assessed *in vitro* against a panel of 17 HIV-1 tier 2 pseudoviruses with appropriate VRC01/PGT121 sensitivity/resistance profiles.

Results: Expression and conformational assembly of purified multispecific antibodies from DNA constructs were confirmed and demonstrated improved neutralisation coverage >70% coverage at IC₈₀ <1 µg/ml, compared to the parental monoclonal antibodies PGT121 (59%), VRC01 and 10e8 (24% coverage at IC₈₀ <1µg/ml), as expected. Encouragingly, unpurified mRNA-expressed multispecific antibodies matched the neutralisation coverage of purified antibodies (94%), with sufficient multispecific antibody titres to generate inhibitory dilution factors conferring 80% neutralisation (median ID₈₀) >150: Bi-scFv (1 427), Bi-NAb (655), Tri-NAb Co-T (327), and Tri-NAb sORF (166). Our data suggest that smaller, less complicated tandem scFv multispecific conformations (Bi-scFv and Bi-NAb) may be preferred for IVT-mRNA delivery.

Conclusions: These data support the preclinical advancement of IVT-mRNA encoding multispecific antibodies as a possible passive immunisation strategy against HIV-1 acquisition and require empirical determination of whether therapeutic titres are attainable *in vivo*.

OA0603

Biodistribution of intra-biliary injected Cu64 labelled HIV bNAbS in a non-human primate model

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Background: Copper-64 (Cu64) is being used for positron emission tomography (PET) imaging, as diagnostic or targeting tool in cancer. HIV broadly neutralizing antibodies (bNAbS) are currently being evaluated as therapeutics in patients. Yet, in humans, pharmacokinetics of therapeutic Ab is mostly followed in blood with limited insight into actual distribution. Using the rhesus macaque model we interrogated the distribution of isotope labelled HIV bNAbS using PET/CT.

Surprisingly we found rapid homing of specific HIV bNAbS to the liver and primarily the gall bladder following intravenous injection. Monitoring of feces did however not

show rapid elimination via the gastrointestinal tract. This prompted us to Cu64 labelled bNAbs directly into the biliary vesicle and follow their distribution over time.

Methods: Uninfected rhesus macaques were used for intra-biliary delivery of Cu64-DOTA or fluorescently tagged Ab via ultrasound-guided location of the biliary vesicle. After injection of antibodies VRC01 and VRC07-LS, several PET/CT scans were acquired between 5mins and 48h post injection. Plasma, urine and faeces were collected at the time of scans and radiation determined by scintillation. CT scans without contrast were used for anatomic localization and attenuation correction. MIM software was used to determine Cu64 signals. Tissues were also taken from macaques administered fluorescently tagged bNAbs and examined with deconvolution fluorescent microscopy.

Results: Intra-biliary delivery of Cu64-DOTA probes was successfully performed and radiation signal to evaluate biodistribution was determined. While the immediate signals were concentrated in the biliary vesicle, later time points showed transfer to the gut and uptake of the labelled bNAbs in small and large intestine walls. This was followed with rapid dissemination via lymphatic ducts at 4 hours post administration and beyond over time. Excretion via faeces or mucosal surfaces was limited over time. These data were corroborated with fluorescently tagged antibodies at the tissue level.

Conclusions: Our delivery system of Cu64 via biliary vesicle using NHP models was successful and illustrate a novel mechanism of antibody recirculation and persistence. This delivery approach can be used for a variety of targets in the field of infectious diseases and cancer and will facilitate furthering the HIV therapeutics field.

OA0604

In vivo protection by a combination of engineered bnAbs against repeated high-dose mixed-SHIV challenges

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Background: The HVTN703/HPTN081 and HVTN704/HPTN085 trials demonstrated that broadly neutralizing antibodies (bnAbs) can protect against HIV-1 infection but only if the infecting virus is neutralization-sensitive to the antibody. Indeed, the clinical trials failed to show protective efficacy because of the high frequency of neutralization-resistant isolates at the trial sites. Thus, a combination of bnAbs providing broader neutralization coverage is required to provide protection against the diversity of global isolates.

Methods: We sought to study the protection conferred by a cocktail of 3 enhanced bnAbs (ebnAbs) in rhesus macaques (RMs) from exposure to diverse Simian-Human Immunodeficiency Viruses (SHIVs). We selected ePGT121v1, ePGDM1400v9, and VRC01.23J1 that were engineered for increased half-life and improved neutralization breadth and potency. Three SHIVs were selected such that each ebnAb neutralizes 2/3 SHIVs, requiring all three mAbs for protection against a mix of all SHIVs. Starting at five days post-infusion, RMs were given a high-dose intrarectal challenge every three weeks, consisting of one or all three SHIVs. Animals were bled longitudinally to monitor infection and measure serum antibody concentrations, determined by ELISA. Long-reads sequencing was employed to identify breakthrough viruses and the acquisition of resistance mutations.

Results: The first group received one ebnAb and was challenged with one neutralization-sensitive SHIV. All animals except one were protected from 2-7 challenges. A second group of animals received one ebnAb but was



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challenged with all three SHIVs. In these animals, infection was established after one challenge in 75% animals, and seeded by the neutralization-resistant SHIV in the mixture. A third group of RMs received all three ebnAbs and challenged with all three SHIVs. Overall, animals receiving one ebnAb became more rapidly infected when challenged with multiple SHIVs than to one SHIV, but ebnAb cocktails delay infection from exposure to diverse isolates. We are currently analyzing breakthrough infections and ebnAb serum protective titers for the ebnAbs in cocktail. **Conclusions:** The triple ebnAb cocktail protects against repeated high-dose mixed SHIV challenges. Whether the concentration required for protection would be different for individual ebnAbs than for the cocktail is under assessment. These results will help inform future approaches to antibody-mediated protection strategies.

OA0605

Analytical treatment interruption (ATI) in Peru among MSM, trans & gender non-conforming (GNC) individuals with early ART initiation +/- VRC01 proximate to HIV acquisition: Stakeholder engagement & early clinical data

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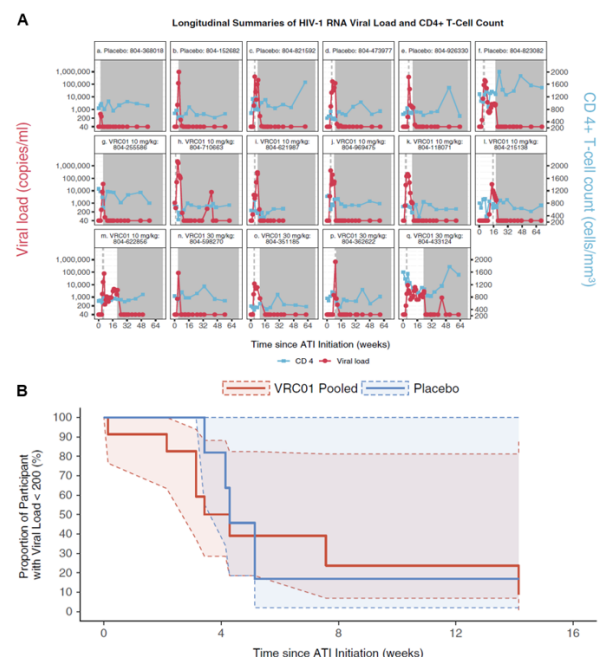
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Background: ART prevents and treats but does not eradicate HIV; viremia rebounds rapidly in most PWH upon ART cessation. Early ART initiation is associated with later ART-free virologic control, as observed in 10-15% of males

with Clade B HIV who initiated ART in early and acute infection. Broadly neutralizing anti-HIV-1 antibodies (bnAbs) may modulate immune responses to HIV. Our ATI was designed based on international consensus recommendations and in partnership with Peruvian community, investigators, healthcare providers, and other stakeholders, to evaluate whether early ART +/- the VRC01 bnAb, present at the time of HIV acquisition, is associated with post-treatment virologic control.

Methods: ATI eligibility includes former HVTN 704/HPTN 085 Peru participants with estimated HIV acquisition within 8 weeks of receiving VRC01/placebo and early suppressive ART initiation for ≥1 year. Participants stopped ART and received frequent viral load (VL), T-cell, and clinical monitoring. ART re-initiation criteria include confirmed CD4<250, VL>1,000 for 4 weeks (wks) without 0.5log₁₀ decline, [A1] [A2] HIV-related syndrome, or participant/clinician request.

Results: Fourteen MSM, 1 GNC, and 3 transwomen enrolled in Peru. No HIV transmissions or ATI-related SAEs or ≥Grade 3 AEs were observed. One ATI-related AE was reported, Grade 2 acute retroviral syndrome; the participant's VL rose rapidly from 1,450 to 679,000 and they immediately reinitiated ART. Nine STIs were diagnosed in 8 participants during ATI. One participant had tenofovir levels consistent with use during ATI. Among the remaining 17 participants, ART re-initiation criteria met included virologic (n=12), clinician request (n=1), participant request (n=4), and HIV-related syndrome (n=1). Median time to confirmed VL>200 was 4.1wks (range 0.1-14.1); median time to meeting ART re-initiation criteria was 7.9wks (range 2.7-23); these did not differ by VRC01 vs. placebo receipt (Figure).



Conclusions: An ATI developed with local stakeholder engagement in Peru, following international consensus recommendations, was safe; however, participants did not exhibit post-viral control.

OA0606

Pharmacokinetic interaction assessment of the HIV broadly neutralizing monoclonal antibody VRC07-523LS: a cross-protocol analysis of three phase 1 HIV prevention trials HVTN127/HPTN087, HVTN130/HPTN089 and HVTN136/HPTN092

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Background: VRC07-523LS is a safe, well-tolerated broadly neutralizing monoclonal antibody (mAb) developed for HIV prevention. Within individual trials, pharmacokinetic (PK) features of VRC07-523LS were not significantly different when administered alone or in combination with other mAbs. We combined data from three trials to increase the power to evaluate PK interactions and hypothesized that overall concentrations of VRC07-523LS would be similar when administered combined or alone.

Methods: This retrospective cross-protocol analysis assessed three phase 1, randomized, multicenter trials of participants without HIV aged 18–50 years in the United States and Switzerland. We included participants receiving intravenous or subcutaneous VRC07-523LS alone (HVTN127/HPTN087, n=100), combined with PGT121, PGDM1400 or 10-1074 (HVTN130/HPTN089, n=26), or combined with PGT121.414.LS (HVTN136/HPTN092, n=20). An open, two-compartment population PK model was used

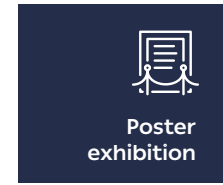
to describe serum concentrations of VRC07-523LS. We compared PK parameters estimated using the targeted maximum likelihood estimation method to account for potential differences in participants' characteristics between groups (combination versus single), including age, sex-at-birth, body weight and creatinine clearance.

Results: Median age was both 28 years for the combination and single groups, with 52% and 61% reporting female sex-at-birth, median body weight of 71kg and 76kg, and median creatinine clearance of 120mL/min and 122mL/min, respectively. No significant differences in VRC07-523LS clearance rate, inter-compartmental clearance, distribution half-life or area under the concentration curve were observed between combination and single groups. However, the mean covariate-adjusted central volume of distribution (V_c) was 1.25 times larger (4.66L vs. 3.74L, adjusted-p<0.001), peripheral volume of distribution (V_p) was 1.11 times higher (3.89L vs. 3.51L, adjusted-p=0.005), and elimination half-life was 1.11 times longer (53 days vs. 48 days, adjusted-p=0.002) for combination versus single administration.

PK features	Description	Single: Mean (95% CI)	Combination: Mean (95% CI)	Combination/Single: Ratio (95% CI)	Two-sided raw p-value	Two-sided adjusted p-value
CL (L/day)	Clearance from the central compartment	0.12 (0.11, 0.13)	0.13 (0.12, 0.13)	1.06 (1.00, 1.13)	0.056	0.17
V _c (L)	Volume of the central compartment	3.74 (3.26, 4.29)	4.66 (4.07, 5.34)	1.25 (1.14, 1.37)	<0.001	<0.001
Q (L/day)	Inter-compartmental distribution clearance	0.30 (0.22, 0.41)	0.30 (0.22, 0.41)	1.00 (0.91, 1.11)	0.97	0.97
V _p (L)	Volume of the peripheral compartment	3.51 (3.07, 4.01)	3.89 (3.45, 4.38)	1.11 (1.04, 1.18)	<0.001	0.005
Distribution half-life (day)	Length of time for serum concentration of the mAb to decrease by half in the distribution phase	3.71 (2.75, 5.01)	4.23 (3.15, 5.69)	1.14 (1.03, 1.27)	0.014	0.06
Elimination half-life (day)	Length of time for serum concentration of the mAb to decrease by half in the elimination phase	47.67 (45.46, 49.98)	52.84 (50.17, 55.66)	1.11 (1.05, 1.17)	<0.001	0.002
Dose normalized steady-state AUC (day/L)	Dose-normalized area under the curve assuming a single IV administration	8.42 (7.96, 8.9)	7.94 (7.52, 8.39)	0.94 (0.89, 1)	0.056	0.17

Table 1: Targeted maximum likelihood estimation (TMLE)-adjusted pharmacokinetic features of VRC07-523LS.

Conclusions: Biodistribution of VRC07-523LS differed when administered combined with other mAbs versus alone, but overall concentration-over-time was not impacted. This is important for planning future trials of VRC07-523LS with new mAb formulations.



The matrix reloaded: Disrupted immune responses, the way for HIV

OA0702

Dysregulation of intestinal CX3CR1+ macrophages homeostasis contributes to inflammation and viral persistence in SIV-infected cynomolgus macaques

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Background: Chronic HIV-1 and SIV infections are marked by persistent immune activation and inflammation, despite antiretroviral therapy (ART). In this study, we aimed to elucidate the contribution of intestinal CX3CR1+ macrophages (MΦs) to the immune dysregulation observed during chronic SIV infection and its implications for HIV-1 persistence following antiretroviral treatment interruption (ATI).

Methods: We investigated the dynamics of mucosal CX3CR1+ MΦs and T cell subsets in a cohort of Cynomolgus macaques during chronic SIV infection and subsequent antiretroviral treatment interruption (ATI).

Results: Analysis of mucosal specimens revealed a notable accumulation of pro-inflammatory MΦs in infected animals, which positively correlated with viral load levels. Interestingly, animals classified as post-treatment controllers (PTCs) exhibited restoration of MΦ homeostasis, suggesting a potential role in viral control post-therapy. Furthermore, our study unveiled significant alterations in mucosal T cell populations during chronic SIV infection. Total CD4+ T cells, particularly Treg cells, were depleted in the colonic mucosa of infected animals, with partial restoration observed in PTCs but not in non-controller animals. Conversely, Th1 CD4+ cells showed an increase in SIV-infected animals, while a trend toward reduction in Th17 cells was observed. Of interest, the accumulation of pro-inflammatory MΦs correlated with the depletion of Th17 cells.

Additionally, activated phenotypes were evident in CD4+ T cells from infected and non-controller animals, as indicated by the upregulation of PD-1, HLA-DR, and Ki67 markers. Neutrophils, recognized as key mediators of inflammation, also exhibited activation in SIV-infected animals, with a notable increase in CD66+CD32a+ cells. These

activated neutrophils were positively associated with the accumulation of pro-inflammatory MΦs and fecal calprotectin levels, indicative of intestinal epithelial damage.

Conclusions: Overall, our findings provide novel insights into the complex interplay between mucosal immune cell populations during chronic SIV infection, shedding light on the mechanisms underlying immune dysfunction and gut epithelial damage observed in progressive HIV/SIV infections and their contribution to viral rebound at ATI. As such, strategies able to preserve and/or regenerate the functions of CX3CR1+ macrophages are critically needed in future HIV cure research.

OA0703

Single-cell analyses reveal that monocyte gene expression impacts HIV-1 reservoir size in acutely treated cohorts

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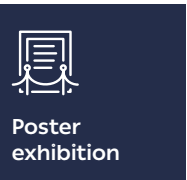
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Background: Host genetic variation impacts HIV-1 susceptibility and disease progression in antiretroviral therapy (ART)-naïve individuals. Similarly, HIV reservoir sizes can vary considerably between ART-treated people living with HIV (PLWH). Here, using unbiased single cell transcriptomics, we investigated if host gene expression differences in PBMC cell subsets from PLWH influence total reservoir size during suppressive ART.

Methods: Samples from 14 PLWH, diagnosed at Fiebig stage 3, from an acutely-treated cohort in Thailand demonstrated effective viral suppression and significantly different HIV-1 DNA reservoir sizes at 48 weeks after ART initiation. PBMC from week 48 samples were analyzed by single-cell RNA sequencing (scRNA-seq) to identify differentially expressed genes (DEG) that associated with reservoir size phenotype.

Significant findings were validated in an independent acutely-treated cohort, comprised of 38 participants from USA with different genetic backgrounds and HIV-1 subtype. Host factor effects on HIV-1 infectivity, proviral transcription, and memory CD4+ T cell population frequencies were studied using *in vitro* functional assays.

Results: DEGs and enriched pathways demonstrated increased monocyte activity in participants with lower HIV-1 cell associated DNA levels. *IL1B* expression in CD14+



monocytes showed the greatest fold-difference associating with smaller reservoir in independent cohorts. Modeling interactions with cell population frequencies showed that monocyte *IL1B* expression correlated inversely with reservoir size in the context of higher frequencies of central memory CD4+ T-cells suggesting an indirect *IL1B* effect via modulation of the cell population preferentially used for reservoir establishment.

Our *in vitro* results suggest that *IL1B* may contribute to decreased reservoir size *in vivo* during AHI via NF- κ B activation:

1. Induction of proviral transcription to 'flush-out' the reservoir via natural latency reversing activity;
2. Reduction of virus spread through activation of antiviral responses; and,
3. Reduction of the frequencies of specific CD4+ T-cell memory populations.

Conclusions: Collectively, unbiased high throughput scRNA-seq analyses identified an effect of monocyte transcriptomic variation on HIV-1 reservoirs in individuals initiating ART during AHI.

Specifically, *IL1B* expression in monocytes associated with lower HIV-1 reservoir size and this could be via activation of NF- κ B. Unbiased single-cell omics approaches can identify novel pathways that reduce the reservoir and have therapeutic implications for HIV-1 cure.

OA0704

Association of innate cells activation and mucosal homing potential with HIV acquisition in Thai HIV exposed individuals

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Background: HIV-exposed seronegative individuals (HESN) are a unique model to study immune factors impacting HIV-1 acquisition. Increased NK cell activity has been correlated with reduced HIV acquisition, suggesting involvement of NK cells in decreasing the risk of HIV-1 acquisition. Other studies have identified markers of HIV susceptibility such as the gut-homing integrin α 4 β 7, whose expression in memory CD4+ T cells is associated with increased susceptibility to HIV acquisition. Here we compare circulating innate and CD4 T cells phenotype in HESN and HIV-exposed seroconverted (HESC) participants prior to HIV-1 acquisition.

Methods: Cryopreserved PBMC from Thai participants in the Early Capture HIV Cohort (RV217), were used to characterize innate and CD4 T cells in 25 HESC and 75 HESN par-

ticipants. HESC pre-acquisition samples were matched for collection time, age, gender, and risk behavior with 3 HESN. Two flow cytometry panels were developed to investigate NK and T cells subsets.

Results: NK cells from HESN were less activated (HLA-DR+, $p=0.003$), showed a higher potential to migrate to the gut (α 4 β 7+, $p=0.010$) and lower expression of the inhibitory receptor ILT-2.

Moreover, we observed an increased frequency of α 4 β 7 expressing CD4+ memory T cells ($p=0.003$) and α 4 β 7 expressing invariant Natural Killer T (iNKT) cells in HESC ($p=0.003$), more specifically on the CD4+ subset. iNKT cells from HESC also had increased expression of T-bet. Random forest analysis showed that HLA-DR and α 4 β 7 expression by NK cells have the strongest association in predicting acquisition status.

Moreover, logistic regression model analysis including 4 variables: HLA-DR+ NK, CD16+ NK, α 4 β 7^{hi} memory CD4+ T and T-bet+ iNKT cells, showed a sensitivity of 64%, a specificity of 95.83% and an accuracy of 87.63% in identifying HESC and HESN.

Conclusions: Our data suggest that in addition to an increased frequency of HIV target cells such as CD4+ memory T and CD4+ iNKT cells expressing α 4 β 7, NK cells from HESC participants might have an exhausted and dysfunctional phenotype with a decreased ability to migrate to the gut mucosa.

It is possible that this dysfunctional phenotype increases the risk of HIV-1 acquisition relative to a more favorable quiescent NK cell profile as observed in the HESN participants.

OA0705

Single cell RNA sequencing analysis of human milk myeloid cells as potential vehicles of and defenders against vertical transmission of HIV

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Background: Approximately 150,000 HIV transmission events occur annually via human milk; yet, the risk of HIV infection via human milk-feeding is <15%, suggesting milk itself is partially protective. Infants ingest $\sim 10^5$ - 10^8 milk leukocytes daily, and our recent studies demonstrated that milk leukocytes, including unclassifiable CD14⁺ myeloid cells, perform antibody-dependent cellular phagocytosis (ADCP) of HIV, calling for their comprehensive analysis in the context of HIV transmission.

Methods: Cells were purified from milk pumped within the previous 12h by 9 HIV-negative donors in NYC. Live CD45+DRAQ5+ cells were sorted for scRNAseq. Single cells were encapsulated and cDNA prepared on a 10x Genomics Chromium instrument. Barcoded cDNA was amplified, fragmented and subjected to end-repair, poly A-tailing, adapter ligation, and 10x-specific sample-indexing. Data



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was processed using the v6.1 Cell Ranger Software Suite and v4.0 Loupe Cell Browser, prior to analytics using the Seurat single cell analysis R package (v4.0).

Results: 2179 milk myeloid cells were analyzed, and 10 populations were defined based on differential gene expression. Clusters were then categorically annotated, which indicated 5 distinct non-granulocyte myeloid subsets. Importantly, annotation with markers derived from PBMCs indicated milk myeloid cells are largely unique and do not align with those found in blood. Myeloid subsets were found to express CD4 (25%-75% expression by all 5 subsets) with highly dominant CXCR4 (50%-100% expression) compared to CCR5. Notably, Fc-gamma receptor 2A was expressed by ~100% of all subsets, alongside varying levels of FcGR 1A/2B/3A. Two subsets exhibited 50%-75% expression of Fc-alpha receptor, suggesting these cells may be elicited to perform Fc-mediated anti-viral functions not only by IgG isotypes, but also by monomeric (serum-derived) and secretory (mucosal) IgA (which comprises ~90% of milk antibody).

Conclusions: These data indicate that milk myeloid cells are unique and highlight the need for their comprehensive analysis among donors living with HIV, including assessment of HIV susceptibility, Env expression, and Fc-mediated functionality. This will facilitate design of a therapeutic vaccine aimed to eliminate HIV transmission via human milk-feeding that would effectively target infected milk myeloid cells (the vehicles of transmission), while eliciting antibody isotypes/subclasses that augment Fc-mediated function of protective milk myeloid cells (the defenders against transmission).

facilitator for this approach. This paper evaluated the performance of the SD Bioline HIV/syphilis Duo and Standard Q HIV/syphilis Comb in 30 health facilities in Uganda.

Methods: This was a cross-sectional study involving 18,924 pregnant women with a mean age of 25.8 years at 30 health facilities who were tested with the Standard Q HIV/syphilis combo to assess its field performance in comparison with the SD Bioline HIV/syphilis Duo in antenatal clinics. Sensitivity and specificity for HIV and syphilis were determined in comparison with the National HIV testing algorithm (Determine, Statpack, and SD Bioline), and the Treponema pallidum particle agglutination assay for HIV and syphilis respectively as the reference standards. Acceptability, ease of use, and feasibility were also assessed using self-reported questionnaires.

Results: For Standard Q, the HIV sensitivity was 96.1% (95%CI:86.5-99.5) and the specificity was 100%. Syphilis sensitivity was 100%, and specificity was 99.5% (95%CI: 98.6-99.9). For SD Bioline, HIV sensitivity was 89.4% (95%CI:86.1-92.0) and specificity was 96.3% (95%CI:95.3-97.1); syphilis sensitivity was 66.2% (95%CI:59.4-72.4) and specificity was 97.2% (95%CI:96.4-97.9). Therefore, Standard Q meets the diagnostic expectations with even better performance characteristics than the SD Bioline kits. Both rapid diagnostic tests were assessed as highly acceptable and feasible by health workers.

Conclusions: The excellent performance of the Duo Kits has facilitated the integration of syphilis testing and treatment into the already established HIV prevention program contributing to the dual HIV and syphilis elimination goal. This will enable more women to be diagnosed with HIV and syphilis so that they can access treatment and prevent transmission to their children.

STI prevention: We need to do more!

OA0902

Field performance evaluation of dual rapid HIV and Syphilis assays among pregnant women attending antenatal care at selected health facilities in Uganda

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Background: The Global Plan Towards Elimination of New HIV Infections in Children and keeping their mothers alive was launched in 2009 setting a series of ambitious targets with unprecedented investments in the Prevention of Mother to Child Transmission (PMTCT) of HIV. Uganda developed the triple elimination strategy to reduce mother-to-child transmission (MTCT) of HIV, syphilis, and Hepatitis B and innovative new approaches to service delivery that included triple testing for these infections. A novel point-of-care immunochromatographic test for dual diagnosis of both HIV and syphilis as well as hepatitis B became a

OA0903

Same day testing and treatment for STIs in adolescents: results of a pilot randomised controlled trial in South Africa

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Background: Laboratory-based testing for STIs is not routine in South Africa, but studies suggest that clients would prefer point-of-care (POC) sexually transmitted infection (STI) testing, and that same day testing may lead to better treatment completion and reduce STI transmission. We conducted a pilot randomised trial to evaluate whether same day testing and treatment for positive tests (SD) improved treatment completion rates.

Methods: The study was conducted in an adolescent-friendly primary health care facility in Johannesburg from August 2023 to February 2024. Participants 18 years or older, sexually active in the past three months, at elevated risk for STIs, and able to provide a means of contact were included. Randomisation was by day 1:1 to either SD

or standard laboratory testing with results return and treatment in 24-48 hours. Urine samples were tested for *C.trachomatis* (CT) and *N.gonorrhoeae* (NG) using GeneXpert™. The primary outcome of treatment completion within 30 days, was assessed by study arm using chi-squared tests. Time to treatment by study arm was assessed by log-rank test. Cox proportional hazards models assessed factors associated with time to treatment.

Results: Of 355 screened, 350 were enrolled, and 348 with valid tests were analysed. Median age was 21 years (IQR, 20-23), and 10% (33/348) had STI symptoms at that visit. Overall, 40% (138/348) had confirmed CT/NG; 79% (109/138) were asymptomatic. In the ITT analysis, 97% (65/67) in the SD group compared to 92% (65/71) in the standard group completed treatment within 30 days (risk ratio [RR] 1.06, 95% CI 0.98-1.15). In the per-protocol analysis, treatment completion rates were higher in the SD group (98% [63/67] SD vs 92% [49/71] standard; RR 1.36, 95% CI 1.15-1.61). Median time to treatment completion was significantly longer in the standard group (0 [SD] vs 3 [standard] days, $p < 0.0001$). Being asymptomatic prolonged time to treatment (adjusted hazard ratio 2.38; 95% 1.48-3.85).

Conclusions: Curable STIs were high and frequently asymptomatic or unrecognised in this adolescent population. With adequate counselling and follow up, treatment completion rates are high but can be improved with same day testing and treatment.

OA0904

The impact of expedited partner therapy on repeat STI positivity among adolescent girls and young women using oral PrEP in Johannesburg, South Africa

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Background: Adolescent girls and young women (AGYW) using pre-exposure prophylaxis (PrEP) for HIV prevention are at risk for sexually transmitted co-infection (STIs). In alignment with South African national STI treatment guidelines, syndromic STI management is implemented at PrEP visits. Asymptomatic AGYW miss treatment via this approach. The ARISE prospective cohort study is assessing point-of-care (POC) diagnostics, treatment, and expedited partner therapy (EPT) for STI management among AGYW using PrEP in Johannesburg.

Methods: Between February 2022-December 2023, HIV-negative, non-pregnant, sexually active AGYW aged 18-25 years interested in or already using PrEP underwent POC STI testing for *C. trachomatis* (CT) and *N. gonorrhoe-*

ae (GC) by GeneXpert; *T. vaginalis* (TV) by OSOM. Those testing STI+ received treatment and were eligible to enroll. Participants were offered EPT paired with counseling to support delivery. Decliners were offered partner referral cards. Participants returned for a test-of-cure (TOC) visit one month later. We summarize STI concordance (+ for the same STI at enrollment and TOC) among those who delivered EPT versus those who declined or were not able to deliver EPT by partnership type (primary versus non-primary).

Results: Among 305 AGYW enrolled, 271 (89%) had a primary or non-primary partner at enrollment and returned for the TOC visit. Median age was 21 years and baseline STI prevalence was 79% for CT, 19% for GC and 19% for TV, with 35% reporting STI-related symptoms. Among participants with a primary sexual partner, 226/256 (88%) accepted and delivered EPT. Among participants with a non-primary partner, 39/69 (57%) delivered EPT. Concordant STI+ results by EPT delivery status and partnership type are presented in the Table.

Positive STI result at enrollment	Concordant STI result at test of cure			
	EPT for primary partner (N=256)		EPT for non-primary partner(s) ¹ (N=69)	
	Accepted and delivered (N=226)	Did not accept, or accepted but did not deliver (N=30)	Accepted and delivered (N=39)	Did not accept, or accepted but did not deliver (N=30)
Chlamydia trachomatis, n/N (%)	19/179 (11%)	3/22 (14%)	4/26 (15%)	3/30 (10%)
Neisseria gonorrhoeae, n/N (%)	3/43 (7%)	0/4 (0%)	0/13 (0%)	0/3 (0%)
Trichomonas vaginalis, n/N (%)	4/46 (9%)	1/6 (17%)	1/10 (10%)	1/4 (25%)

Abbreviations: EPT=expedited partner therapy; STI=sexually transmitted infection.

¹For the non-primary partner analysis, acceptance was defined as accepted EPT with ≥ 1 non-primary partner(s) as intended recipient(s), and delivery was defined as delivered EPT to ≥ 1 non-primary partner(s). Participants who accepted and/or delivered EPT according to this definition, might not have accepted and/or delivered EPT to all their non-primary partners.

Conclusions: Among AGYW using PrEP and who received POC STI testing, EPT acceptance and successful delivery to primary partners was high; few were concordant STI+. Diagnostic STI testing and EPT should be considered as part of STI prevention packages for AGYW.





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OA0905

PrEP use and associations with STI incidence among young cisgender men and transgender women who sell sex in Bangkok and Pattaya, Thailand

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Background: Sexually transmitted infections (STIs) are an important consideration when it comes to implementing pre-exposure prophylaxis (PrEP), especially in young men who have sex with men (MSM) and transgender women (TGW). STI incidence has been associated with declines in condom use while on PrEP. Our analysis explores the relationship between STIs and these interventions among sex workers.

Methods: The Combination Prevention Effectiveness (COPE) study, an open-label combination HIV-prevention implementation trial, evaluated the effectiveness of PrEP in 846 participants between 2017 and 2020, accumulating 8671 person-years of follow-up. Participants had the option to start, stop, and restart TDF/FTC PrEP (Truvada®, Gilead Sciences, Inc.) at any point during follow-up. Routine testing was done for rectal *Neisseria gonorrhoeae* and *Chlamydia trachomatis* by nucleic acid amplification from rectal swab samples at study enrollment, 6-month-interval visits, and additionally at 3-month visits if optional testing was requested. Demographic and behavioral variables from the survey responses at each study visit were assessed for association with incidence of STI. Cox proportional hazards models were used to assess the association between variables and the time to first incidence of STI after baseline.

Results: At enrollment, 151 (17.1%) of the study participants were positive for at least one STI. The incidence rate of chlamydia and gonorrhoea was 22.76 per 100 person-years (95% CI:19.29-26.66) and 8.47 (95% CI:6.42-10.98), respectively. Participants who reported PrEP use had a higher incidence of STIs, while condom use showed a protective effect against incidents of STIs.

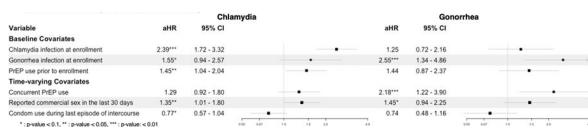


Figure. Differences in time-to-event analysis for outcomes of chlamydia and gonorrhoea in relation to baseline and time-varying behaviour factors among young MSM and TGW in Thailand (n = 846, observations = 1,632).

Conclusions: Our findings indicate high STI incidence and prevalence in Thai gender-diverse populations involved in commercial sex. Although PrEP use might suggest behavioral disinhibition, it's important to remember that STI risk behaviors is an indicator for PrEP use. Our data underlines the need for a comprehensive intervention package that includes targeted testing, safer-sex education, free condoms, and PrEP provision.

OA0906

Willingness and uptake of mpox vaccine among sexual minority men (SMM) in Latin America: examining differences by HIV serostatus

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Background: Sexual minority men (SMM) were disproportionately affected by the 2022 global mpox outbreak, and there is a growing concern about a possible increase in cases during summer 2024. Lessons learned from the recent outbreak highlighted the importance of vaccination strategies to mitigate the spread of the virus among at-risk populations, especially among subgroups with intersecting vulnerabilities, such as those living with HIV. The current study aims to describe differences in willingness and uptake of the mpox vaccine by HIV status among an online sample of SMM in Latin America.

Methods: Data were collected through Hornet, a geo-social networking application in late 2023. SMM residing in Latin American countries were invited to complete a self-report survey regarding the impact of the recent mpox outbreak. Descriptive statistics were used to present the rates of mpox diagnoses and willingness and uptake of the mpox vaccine. We conducted bivariate analyses to detect differences in these outcomes by self-reported HIV serostatus.

Results: Among the 5,141 SMM from 25 Latin American countries, the average age was 33.1 years (SD: 10.8), and 21.9% were living with HIV. A small percentage of study participants (3.8%) reported being diagnosed with mpox; 7.5% said they had been vaccinated for mpox. The majority (83.7%) of participants expressed willingness to be vaccinated if offered the vaccine. SMM living with HIV were more likely to report being diagnosed with mpox (10.7% vs. 2.4%, p < 0.001) and having been vaccinated (12.6% vs. 6.4%, p < 0.001). They were also more willing to receive the mpox vaccine (88.3% vs. 82.7%, p < 0.001). Lastly, those living with HIV were more likely to report perceived or experienced mpox stigma (14.4% vs. 7.9%, p < 0.001).

Conclusions: Our study reveals disparities in mpox diagnoses by HIV serostatus and highlights critical gaps in vaccine uptake among a high-risk population in Latin America. The findings emphasize the urgent need for tai-

lored vaccination strategies and targeted efforts to improve vaccine accessibility, especially among SMM living with HIV. Addressing these gaps is essential to meet the high willingness for vaccination and to promote global vaccine equity.

Integration for efficient PrEP delivery

OA1002

Pre-exposure Prophylaxis use, discontinuation and HIV seroconversion in a cohort of men who have sex with men in a Buenos Aires based non-governmental organization

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Background: HIV Pre-Exposure Prophylaxis (PrEP) is recommended as an effective biomedical intervention to address the HIV pandemic. This study aims to examine the use of PrEP and HIV seroconversion during the first 30 months of PrEP administration among men who have sex with men (MSM) from a Non-Governmental Organization (NGO).

Methods: This retrospective cohort included MSM who initiated PrEP (TDF/FTC) from July 2021 to December 2023 in Buenos Aires, Argentina. Treatment discontinuation was defined as users going over two months without medication. Data were analyzed using SPSS and R-Studio.

Results: During the cohort period, 2442 MSM underwent rapid HIV testing, with 78 being reactive (3.2%). Among non-reactive individuals (n=2364), 1043 (44.1%) initiated PrEP. Younger MSM and those who tested positive for syphilis were more likely to initiate PrEP (p-values<0.01). Of the 610 individuals on PrEP during the first 18 months, 83.6% (510) remained active after 6 months, and 69.3% (423) after 12 months.

Adherence to PrEP for 6 months was higher among older individuals (median age: 34 vs 32, p-value: 0.027) and those who tested positive for syphilis at baseline (92.6% vs 75.3%, p-value: 0.006). Before the second month on PrEP, 38.3% (210/549) reported adverse effects associated with lower adherence at 6 months (p-value: 0.008).

Although all individuals had a negative rapid test before initiating PrEP, 4 users seroconverted during prophylaxis: one after 1 month and three after 2 months. Only 1 of these individuals underwent confirmatory HIV testing, which revealed the presence of the M184V mutation associated with resistance to FTC.

Conclusions: A positive syphilis diagnosis was found to be correlated with higher adherence, likely due to increased risk perception. This underscores the importance of screening for other STIs, thus raising awareness among PrEP users. The lower adherence in young adults is consistent with other studies, reinforcing the need to develop strategies tailored to this group. Additionally, seroconversion highlights the need to re-evaluate screening methods before starting PrEP and to monitor resistance in HIV-positive cases.

OA1003

Unraveling PrEP persistence: mental health and substance use among South African adolescent girls and young women enrolled in a PrEP implementation program

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Background: PrEP implementation among South African AGYW is essential to ending the HIV epidemic. However, mental health and substance use disorders may hinder PrEP engagement. We explored how these factors relate to persistence of AGYW in a district-wide PrEP program.

Methods: We used data from FastPrEP, an ongoing youth-focused, decentralized PrEP implementation program with peer-navigator support. From April 2022, PrEP was offered to young people at four community-based mobile clinics and 12 health facilities near Cape Town. Females aged 15-29 years who received a one-month PrEP supply at enrollment were included. Log-binomial regression was used to estimate associations between moderate-severe depression/anxiety symptoms (PHQ-4 ≥ 6) and disordered drinking (AUDIT-C ≥ 3) at enrollment and persistence 1) in the program (i.e., retention) and 2) on PrEP at the first follow-up visit, adjusting for mobile vs. facility enrollment. Findings were stratified by age.

Results: Through April 2, 2024, 7,317 AGYW had PrEP dispensed through the FastPrEP program. The median age was 21 years (IQR=18-25) and most (78%) were enrolled at a mobile clinic. Further, 8% (316/4,008) reported moderate-severe depression/anxiety symptoms, which did not differ by age group (χ^2 p=.069), and 49% (1,984/4,015) reported disordered alcohol use, which varied by age (15-19 years = 44%; 20-24 = 54%; 25-29 = 51%, p<.001). Among all AGYW, 31% (2,264/7,317) were retained and 24% (1,741/7,317) had PrEP dispensed at their first follow-up visit. Moderate-severe depression/anxiety symptoms and disordered alcohol use were associated with a greater probability of persistence. When findings were stratified by age, associations were only present for AGYW aged 15-19 years. Specifically, those with moderate-severe depression/anxiety symptoms were more likely to be persistent in the program (adjusted prevalence ratio (aPR)=1.45, 1.15-1.82) and



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on PrEP (aPR=1.45, 1.10-1.93), and those who reported disordered alcohol use were also more likely to be persistent in the program (aPR=1.22, 1.04-1.43) and on PrEP (aPR=1.26, 1.04-1.53), at their first follow-up visit.

Conclusions: Our results reveal an unexpected relationship between mental health, substance use, and PrEP persistence among younger AGYW. Those facing these challenges may have found support within the PrEP program, enhancing their likelihood of continued engagement. Further mixed-methods investigations are warranted to elucidate these findings.

OA1004

A mixed methods implementation study of peer-led depression screening among transgender women with and without HIV in Thailand

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Background: Transgender women (TGW) experience high levels of depression, but access to mental health services remains limited. We assessed depressive symptoms and associated factors among TGW clients at the Tangerine Clinic, a transgender-led sexual health clinic in Bangkok, Thailand, and feasibility, acceptability, facilitators and barriers to peer-led depression screening.

Methods: Peer-led depression screening was implemented between October 2021- March 2022. TGW, aged >18 attending routine visits, answering "yes" to either or both Patient Health Questionnaire-2 (PHQ-2) questions were classified as positive, and further screened with PHQ-9. Factors associated with positive PHQ-2, and self-harm and suicidal ideation were analyzed using logistic regression. Self-harm and suicidal ideation were defined as those endorsing the PHQ-9 self-harm and suicidal ideation item.

TGW declining PHQ-2 screening (n=2), PHQ-9 score <7 (n=5) and PHQ-9 score >7 (n=5) were purposively recruited for in-depth interviews (IDIs) exploring feasibility, acceptability, facilitators and barriers to peer-led depression screening. Healthcare providers (n=12) were also interviewed. Two focus group discussions (FGDs) with TGW with different HIV status (n=16) were conducted. Qualitative data were analyzed using the Consolidated Framework for Implementation Research (CFIR) and Dedoose.

Results: A total of 317 TGW were screened, of which 167 (53%) had a positive PHQ-2 screening. Of these, 12 (7%) were with HIV, and 86 (51%) were taking HIV pre-exposure prophylaxis (PrEP). On PHQ-9 screening, 41(25%) had mild to moderate depressive symptoms (PHQ-9 score 7-18), and 3 (2%) severe depressive symptoms (PHQ-9 score≥19). In IDIs, rejection by family and friends, romance scams, financial hardship, school-based bullying, and multi-level intersectional stigma were believed to be associated with depressive symptoms in TGW.

FGD and IDI participants agreed implementing peer-led depression screening at the Tangerine Clinic was feasible and acceptable. Key facilitators included a peer-led service delivery model, stigma-free clinic setting with associated psychiatric treatment costs identified as a key barrier.

Conclusions: The prevalence of depression symptoms among TGW was substantial. Implementing peer-led depression screening using PHQ-2/PHQ-9 was feasible and acceptable to both TGW and healthcare providers. Multi-level barriers to peer-led depression screening were identified and should be addressed to facilitate improved access to mental healthcare services among TGW.

OA1005

Reducing HIV acquisition among clients on oral pre-exposure prophylaxis (PrEP) through the PrEP case-manager model: real-world evidence from the DISCOVER-Health Project PrEP program in Zambia

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Background: Oral Tenofovir-based HIV pre-exposure prophylaxis (PrEP) is an effective modality that was approved for use by the WHO in 2015 to prevent HIV acquisition in high-risk individuals. However, taking the daily oral pill is a significant challenge to adherence among clients on PrEP, explaining the 3% HIV incidence (Ambrosioni et al. 2020). To improve PrEP adherence and persistence, the DISCOVER-Health Project developed a case-manager model where clients on PrEP were assigned a trained community-based volunteer (CBV).

Methods: CBVs working in Project-supported health facilities were oriented in PrEP case-management using a training curriculum adapted from national HIV treatment guidelines. At each health facility, trained CBVs were assigned a defined number of clients on PrEP for adherence support through appointment reminders via text messages, phone calls or home visits. A list of clients due for PrEP follow-up visits was generated from the PrEP management system database every week for reminders within 3 days of the appointment visit. Individuals on PrEP were followed up for a year and de-identified client-level data were generated from the database for analysis using WINPEPI.

Results: Between 01/10/2022 and 30/09/2023, 55,940 clients were initiated on PrEP representing 55,940 person-years. Of these, 52% were males, 47% were adolescents and young adults aged 15-24 years and 23% identified as key populations. In the same period, new HIV acquisitions were recorded in seven individuals on PrEP ranging 18 to 52 years old (mean 32.6 years; median 37 years) for the

incidence rate of 0.013 (95% CI: 0.005 to 0.026) cases per 100 person-years and mean survival time of 372 days (95% CI: 14.2-730). Two individuals were identified within one month of PrEP initiation.

The risk of HIV acquisition was over 10 times higher in individuals in sero-discordant relationships than in the general population (odds ratio 11.87; 95% CI: 2.66 to 53.04; $p < 0.0001$).

Conclusions: Reinforcing adherence among individuals using PrEP through approaches like the case-manager model has potential to improve oral PrEP persistence and reduce HIV acquisition. Adoption of such models in real world settings may help contribute towards the reduction of new HIV acquisitions towards HIV epidemic control.

OA1006

HIV pre-exposure prophylaxis (PrEP) efficacy, adherence and persistence in an Italian multicentric access program (Sep2017-Nov2023): ItaPrEP study

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Background: PrEP implementation faced challenges until its reimbursement in 2023. National data are lacking. Aim is to report incidence rates (IR) of HIV, poor adherence and discontinuation (outcomes), along with their predictors.

Methods: PrEP program partially provided free drug supply. IRs were expressed as the number of new events/PYFU on PrEP. Poor adherence was defined as an incorrect intake for on-demand, temporary stop for daily PrEP, or reported sex without PrEP or a condom, and PrEP discontinuation as a definitive stop of or loss to FU for at least 1 year. Kaplan-Meier curves were fitted to estimate outcomes probability. A mixed-effect logistic model with a random intercept on the centre was used to explore the association between risk factors and outcomes.

Results: 1,758 PrUs with at least 1 FU visit were included. 98% men, 92% MSM, 88% Caucasian with a median age of 36 yrs (31-44). 66% had university degrees, and

19% used chemsex. 655 PrUs (38%) chose daily, 619 (36%) on-demand schedule, and 464 (27%) switched. 968 (55%) never had free supply. 6 HIV seroconversions were observed over 2,673 PYFU [IR 0.22/100 PYFU (95%CI:0.08-0.49)]. IR and 2-year probability for outcomes were 44/100PYFU (40.8-47.2) and 57.9% (54.8-61.0) for poor adherence and 22.1/100PYFU (20.2-24.2) and 37.1% (34.3-40.1) for discontinuation. Chemsex (OR 1.56; 95%CI 1.11-2.18) and switching schedule (3.21;2.38-4.33) were associated with poor adherence, unlike a high educational level (0.70;0.54-0.91). An age >40y (0.68;0.53-0.86), free drug supplies (0.73;0.54-0.99) and laboratory monitoring (0.40;0.29-0.53) were associated with a lower risk of discontinuation, while chemsex with a higher risk (1.80;1.30-2.48) (Fig.1).

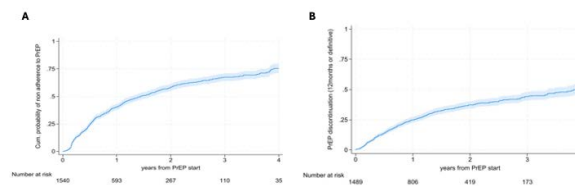


Figure 1. Kaplan-Meier curves.

A: The cumulative probability of poor adherence at 1,2,3 and 4 years was 40.2% (95%CI:37.5-43), 57.9% (54.8-61), 67.4% (63.9-70.9) and 75.4% (70.9-79.6).

B: The cumulative probability of poor discontinuation at 1,2,3 and 4 years was 24.8% (22.5-27.2), 37.1% (34.3-49.1), 44.3% (40.9-47.9) and 50.5% (46-55.2).

Conclusions: This Italian PrEP program, prior to reimbursement, showed an HIV seroconversion rate lower than in RCT control arms in high-risk populations. Younger age, low educational level, and chemsex, and barriers such as lack of free drugs and monitoring are key to targeting strategies to improve PrEP implementation.



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Host factors influencing vaccine responses

OA1102

Antibodies to HIV-1 CD4 induced epitope may evolve from B lymphocytes primed by antigens from human microbiome or infectious agents

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Background: Antibodies against the conformational CD4-induced (CD4i) epitope are frequently found in HIV-1 infected subjects. However, the mechanism of development of anti-CD4i Abs is unclear. We used anti-idiotypic (aID) monoclonal Abs (mAbs) of anti-CD4i mAbs as bait to isolate anti-CD4i mAbs from infected subjects and tracked the antigens that could have induced such Abs. Our preliminary results suggested that anti-CD4i Abs may evolve from B cells primed by microorganisms.

Methods: Anti-aID mAbs were isolated from HIV-1-infected subjects (Following up regularly at Kumamoto University Hospital, Kumamoto, Japan) using aID mAbs against anti-CD4i mAbs, 916B2 and 4E9C. Critical amino acid sequences for the binding of anti-aID mAbs, with shared idiotope to anti-CD4i mAbs, were analyzed by phage display. Peptides synthesized based on the identified sequences were used to examine reactivity to anti-aID mAbs and anti-CD4i mAbs by AlphaLISA. Germline-reverted anti-aID mAbs and anti-CD4i mAbs were constructed to estimate the ability of the peptides to prime these antibodies.

Results: Anti-aID mAbs, including that with the characteristics of anti-CD4i Abs, were isolated from HIV-1 infected subjects. Three amino acid sequences were selected from the phage library by anti-aID mAbs. The identified amino acid sequences showed similarity to proteins from members of human microbiota (*Caudoviricetes sp*) and infectious agents (*Vibrio vulnificus*). Peptides synthesized based on the identified sequences were reactive to most anti-aIDs and some anti-CD4i mAbs. These results suggest that anti-CD4i Abs may evolve from B cells primed by microorganisms. To confirm this hypothesis, we tested binding activity of the germline reverted anti-aID mAbs and anti-CD4i mAbs to the peptides from *Caudoviricetes sp* and *Vibrio vulnificus*. Comparison with the original mAbs revealed that the binding activity to the peptides were significantly stronger in most of the germline reverted mAbs than original mAbs. Moreover, the germline reverted mAbs are being examined for their recognition amino acid sequences by phage display.

Conclusions: The hypothesis of antibody evolution from

B cells primed by human microbiome may be attributed to antibody development and evolution against other viral antigens. Moreover, our data may provide important information for HIV-1 vaccine design strategies to induce Abs against conformational epitopes.

OA1103

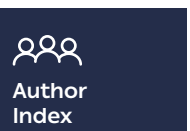
The vaginal microbiome pre-vaccination associates with local and systemic HIV vaccine immune responses

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Background: New vaccine strategies against HIV should induce protective mucosal immune response in the female genital tract which is a first site of HIV acquisition. The microbiome has been implicated in altered mucosal immunity, but its impact on vaccine-induced mucosal responses in the genital tract is not well understood. Here we assess the relationship between the vaginal microbiome and vaccine-induced binding antibody (BA_b) responses.

Methods: Cervicovaginal mucus samples were collected from participants (n=95) receiving the RV144 ALVAC-HIV/AIDSVAX B/E prime/boost vaccine regimen at baseline and 2 weeks post-RV144 prime/boost regimen. Vaginal microbiome data was generated by label-free tandem mass spectrometry. Mucosal and serum BA_b levels were measured using ELISA, and differences between microbiome groups were determined by *t*-tests.

Results: A total of 24 unique genus- and species-level taxa were identified. Participants clustered into 3 microbiome groups: *Lactobacillus (L.) crispatus* dominant (n=20, 21.1%), *L. iners* (n=40, 42.1%) and a polymicrobial group (PM, n=36.8, 36.8%). Relative to *L. crispatus* group, women with a PM microbiome showed increased activation of pathways involved in B and T cell receptor signaling, MHC class I/II antigen presentation, and neutrophil degranulation (Z score>5; P<0.0001). A subset of women had a consistent *Lactobacillus* dominant (LD, n=43) or non-*Lactobacillus* dominant (nLD, n=18) microbiome type across all time-points. These sub-groups were similar in age (avg_{LD}=29.6, avg_{nLD}=28.5, P=0.4). LD women showed significantly higher BA_b levels compared to nLD women at 2 weeks post-RV144 regimen, including those in the mucosa against A244 (IgG-gp120A244gD-D11, L2FD = 0.82, P=0.0393), and in serum (gp70V1V2-92TH023, L2FD=0.78, P=0.004; IgG-A244, L2FD=0.66, P=0.0153).



Conclusions: These data suggest an association between the vaginal microbiome and vaccine-induced BAb responses, with a more inflammatory polymicrobial environment being associated with lower vaccine-specific BAb levels. These results warrant further interrogations into the potential mechanisms by which the vaginal microbiome may impact vaccine responses and could inform interventional strategies.

OA1104

Similar meta clonotypes recognize HIV-1 Gag-KF11 across HLA-E*01:01/03 and HLA-B*57:01 with distinct functional profiles

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Background: A recombinant cytomegalovirus (CMV) vaccine that induces MHC-E restricted CD8 T cells has demonstrated 50% efficacy in preventing the establishment of SIV transmission. However, little is known about HLA-E restricted HIV-specific responses in people with HIV (PWH). Our previous work showed that CD8 T cells targeting a Gag epitope (KAFSPEVIPMF or KF11) were restricted by HLA-B*57:01 (B57-CD8s) and HLA-E*01:01 (E-CD8s) in PWH. This study aims to extensively compare the characteristics of KF11-specific CD8 T cells depending on their HLA restriction.

Methods: We obtained CD8 T cells from PWH, including 2 non-controllers (NC), 4 controllers (C), and 2 elite controllers (EC), and stimulated them with the KF11 epitope in the presence of HLA-B*57:01, HLA-E*01 or 03 antigen-presenting cells. We analyzed the resulting supernatants with a Luminex assay. We sorted antigen-specific CD8 T cells and assessed them using single-cell RNA and TCR sequencing. Select TCR clones underwent further analysis in a NFAT-driven luciferase-based TCR reporter assay.

Results: B57-CD8s secreted higher levels of conventional HLA-Ia cytotoxic cytokines like IFN γ , whereas E-CD8s produced more chemotactic cytokines, including RANTES, IP-10, and IL27. TCR α / β paired family analysis showed that despite these functional differences, most TCRs were dual-restricted by B*57 and E*01/03. Furthermore, we discovered an enriched cluster of TRAV5*01-TRBV19*01 clones, representing a tri-restricted metaclonotype in controllers. This tri-restriction was substantiated when TRAV5-containing clones triggered NFAT signaling in the presence of KF11-loaded B57-, E01-, or E03- cell lines. Deep sequencing of sorted KF11-specific CD8 T cells identified a significant increase in the TRAV5 cluster solely in controllers. We additionally identified another tri-restricted cluster of TRAV27*01- and TRAV29/DV5*01-TRBV2*01 clones

isolated to the elite controller. Moreover, within this antigen-specific CD8 subset, a dually E03-/B57- restricted cluster within this elite controller metaclonotype showed activation and stimulation, characterized by an IL15 signaling pathway signature like that in macaques which resisted SIV transmission post-vaccination with an MHC-E restricted CMV-based vaccine, exhibiting upregulation of both IL15 and IL15RA.

Conclusions: Our findings suggest that CD8 T cells, while dually restricted by HLA-B*57 or HLA-E, are functionally distinct depending on the presenting HLA. These dual-restricted CD8 T cells were predominantly observed in PWH who naturally control transmission.

OA1105

HLA-B*07:02 associated with higher vaccine efficacy in the phase 2b imbokodo trial among young cisgender women with increased likelihood of HIV acquisition in Southern Africa

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Background: The Phase 2b Imbokodo study (HVTN 705/HPX2008; NCT03060629) evaluated an investigational HIV-1 vaccine regimen, consisting of a vector-based vaccine (Ad26.Mos4.HIV) combined with clade C gp140 pro-





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tein, among young cisgender women behaviorally vulnerable to HIV in Southern Africa. While the trial demonstrated an estimated non-significant vaccine efficacy (VE) of 14% vs. placebo, analysis of HIV sequences isolated from study participants (i.e., sieve analysis) revealed higher VE against HIV-1 with non-proline (P) amino-acid residues compared to a P residue at position 364 in Env (30.1% 95% CI (-4.5%, 53.2%) vs -235.6% (-929.3%, -9.4%), $p=0.010$). We investigated whether host HLA genotypes, known to influence vaccine responses and HIV VE, modulated VE.

Methods: Between months 7 and 36 post-enrollment, 165 per-protocol participants acquired HIV-1. Of these, 115 participants acquired HIV-1 with a non-P residue at position 364. HLA class I and II typing was performed on the samples from all per-protocol participants who acquired HIV-1. HLA alleles with >5% frequency were selected for assessment of their association with overall and non-P residue VE. Associations were assessed using the case-only method. Adjusted p-values, controlling the family-wise error rate (FWER-adjusted p-value) and false discovery rate (FDR-adjusted p-value), were calculated using a resampling method. Associations with FWER-adjusted p-values <0.05 were considered significant (robust evidence of an association). Associations with FDR-adjusted p-values <0.20 were considered hypothesis-generating.

Results: HLA-B*07:02 was significantly associated with an increased overall VE (86% vs -3%, $p<0.001$) and non-P residue VE (97% vs 11%, $p<0.001$) (Table 1). HLA-DRB5*01:01 exhibited an increased non-P residue VE. HLA-A*30:01 exhibited a decreased VE. HLA-DPA1*02 exhibited a decreased non-P residue VE.

Type of Analysis	Allele	No. Cases (Vaccine vs. Placebo)	VE	95% CI	P-value	Differential VE		
						Unadjusted P-Value	FWER-adj P-value*	FDR-adj P-value*
VE Against All HIV-1 Viruses	B*07:02	74 vs 12	22%	(-0.1%, 25.7%)	0.069	<0.001	0.029	0.033
	B*07:02*	2 vs 17	5.7%	(-6.2%, 94.2%)	0.054	0.004	0.178	0.116
	A*30:01	55 vs 80	31.1%	(3.2%, 51.2%)	0.032	0.004	0.178	0.116
	A*30:01*	21 vs 9	-1.6%	(-35.7%, 32.5%)	0.056			
Non-P Residue Specific-VE	B*07:02	41 vs 53	11.2%	(-31.2%, 40.1%)	0.55	<0.001	0.009	0.009
	B*07:02*	0 vs 15	96.5%	(46.1%, 99.5%)	0.017	0.002	0.069	0.043
	DRB5*01:01	44 vs 48	9.2%	(-37.9%, 59.1%)	0.678	0.002	0.069	0.043
	DRB5*01:01*	9 vs 23	52.3%	(47%, 94.5%)	0.002			
	DPA1*02	6 vs 23	72.3%	(37.7%, 89.4%)	0.001	0.01	0.368	0.183
	DPA1*02*	0 vs 47	0.0%	(-36.2%, 40.1%)	0.663			

Table 1. Significant associations of HLA alleles with vaccine efficacy (VE) and non-P residue position 364 specific- VE among HIV-1 acquisitions post Months 7-36.

Conclusions: We demonstrate a VE of 86% among HLA-B*07:02 positive participants in the Imbokodo trial. HLA-B*07:02 was reported in association with a broad and potent response targeting Gag epitopes in the literature. Further epitope mapping will elucidate potential mechanisms of vaccine protection.

OA1106

Characterization of the B cell repertoire in African populations to inform HIV vaccine design

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Background: Developing an effective HIV vaccine remains key to HIV eradication. One new approach to vaccine design utilizes germline-targeting immunogens to target and expand broadly neutralizing antibody (bnAb) precursors, hence the success of this approach relies on the composition of the naïve B cell repertoire. Unfortunately, the human naïve B cell repertoire remains insufficiently characterized, particularly in African populations. More studies are therefore required to describe the allelic diversity in African populations, and to assess precursor frequencies for the various bnAb classes for which germline targeting immunogens are being developed. One example is the eOD-GT8 immunogen that primes the CD4 binding-site-specific VRC01-class antibody precursors.

We set up a study to characterize the African antibody repertoire and assess factors that may alter the repertoire, for instance, chronic pathogen exposure.

Methods: We recruited participants from three regions in Kenya experiencing varied malaria transmission intensities and collected PBMCs from each participant. Using single-cell RNA-Seq, we characterised B cell receptor sequences from isolated eOD-GT8-binding cells. Additionally, using bulk RNA-Seq we characterised the naïve immunoglobulin repertoire.

Analysis of the single-cell sequence data identified sequences with VRC01-class signatures in order to describe the precursor frequencies in this population.

Analysis of the overall antibody repertoire will define gene usage, identify novel alleles and assess the potential impact of malaria exposure on the antibody repertoire.

Results: Preliminary analysis indicates an average VRC01-class precursor frequency of 1 in 379,377 naïve B cells, in line with previous studies. We have also identified signatures linked to 11 other CD4 binding site bnAb sub-classes including the highly potent N6 sub-class.

Furthermore, previous malaria exposure does not seem to influence the precursor frequency. Preliminary analysis of naïve repertoire shows:

- dominance of the IGHV1-2*02 allele, among VH1-2 alleles, associated with higher usage of the VH1-2 gene that is a hallmark of VRC01-class precursors and;
- the presence of novel alleles in each participant's antibody repertoire.

Conclusions: Despite genetic diversity in the naïve B cell repertoire and varied levels of malaria exposure, VRC01-class precursors are present at similar frequencies to previous studies. This supports evaluating the germline targeting vaccine strategy for VRC01-class bnAb induction within this population.

Emerging data from recent human clinical vaccine trials

OA1202

Mutation-guided HIV vaccine design: a strategy for developing boosting immunogens for BnAb induction

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Background: A major goal of HIV-1 vaccine development is the induction of broadly neutralizing antibodies (bnAbs). While success has been achieved in initiating bnAb B cell lineages via vaccination, design of boosting immunogens that select for bnAb B cell receptors with improbable mutations required for bnAb affinity maturation remains a central challenge.

Methods: DH270 unmutated common ancestor (UCA) knockin mice were immunized with the CH848 10.17DT priming immunogen formulated as a ferritin nanoparticle and boosted with the 10.17WT Env trimer immunogen. Improbable mutations were mapped with the ARMADiLO computational program. Vaccine-induced monoclonal antibodies were isolated from immunized mice using antigen-specific single B cell sorting strategies. B cell repertoire single heavy or light chain next generation sequencing of immunized mice was performed to analyze the change in frequency of key mutations over time and in response to immunization regimens. Structural determination of vaccine-induced broadly neutralizing antibodies was performed by cryo-EM.

Results: We demonstrate a general process for designing HIV boosting immunogens and apply it to the design of a vaccine regimen targeting the V3-glycan bnAb DH270 lineage. First, we identified a set of key mutations

in the DH270 lineage that are sufficient for neutralization breadth. We then developed a boosting immunogen with a favorable binding profile for selecting these key mutations and tracked the selection of these mutations during affinity maturation in immunized bnAb precursor knock-in mice using antibody repertoire sequencing. We show that our prime-boost regimen elicited broadly neutralizing antibodies by selecting for the targeted functional improbable mutations. Structural determination of a vaccine-induced bnAb revealed that selected key improbable mutations make critical interactions with conserved elements within the V3-glycan epitope. Moreover, we show similar success in prime and boosting with nucleoside-modified mRNA-encoded HIV-1 envelope trimer immunogens with improved selection by mRNA immunogens of improbable mutations required for bnAb binding to critical envelope glycans.

Conclusions: These results demonstrate the ability of both protein and mRNA prime-boost immunogens to select critical improbable mutations in bnAb B cell lineages and induce antibodies with neutralization breadth after bnAb precursor expansion, a key proof-of concept and milestone towards the development of an HIV vaccine.

OA1203

RV 575 study: a phase 1 double blinded dose optimization study of ALFQ adjuvant with an HIV envelope vaccine containing A244 and B.63521... results of a blinded interim analysis

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Background: The Army Liposomal Formulation containing monophosphoryl lipid A (MPLA) and QS21 saponin (ALFQ), developed and patented by the U.S Army, is a safe and immunogenic adjuvant for vaccines. Prior studies used ALFQ with 100/50 and 200/100 µg MPLA/QS21. We conducted a Phase 1 study to further optimize ALFQ dosing.

Methods: We randomized sixty-five 18-55-year-olds without HIV to receive one of three ALFQ doses (200/100, 100/50, 50/25 µg MPLA)/QS21 and 300 µg each of HIV-envelope gp120 protein vaccines A244 and B.63521 at weeks 0, 4, and 8. We monitored post-vaccination reactogenicity, adverse events, and safety laboratory tests. We measured vaccine-specific antibody responses against a



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custom multiplex array of 30 HIV antigens by ELISA and Luminex, and peripheral antigen-specific CD4+ T-cell responses at weeks 2, 4, 6, and 10. Laboratory investigators were blinded to treatment. Unblinded statisticians conducted analyses.

Results: Mean (SD) age was 34 (8.5) years, 55.4% Caucasian, 30.8% Black, 50.8% female sex, 4.6% non-binary gender, 1.5% transgender. Fifty-seven (87.7%) participants each reported at least one local and systemic reactogenicity event respectively, main events: injection site pain 87.7%, fatigue 78.5%, headache 73.8%, myalgia 69.2%; thirty-nine (60%) reported at least one adverse event, 87.2% study product-unrelated. Binding and neutralizing antibody responses were detected following the 1st vaccination and increased after each subsequent vaccination.

Although, no significant differences in the magnitude of binding antibody responses to cognate vaccine immunogens or neutralization potency to a Tier 1 panel were observed between 100 and 200 µg MPLA ALFQ groups, binding antibodies were significantly higher compared to the 50 µg ALFQ group. Post-3rd vaccination, all arms showed equivalent levels of binding and neutralizing antibodies across all isotypes.

Similar results were observed with ELISAs examining antigen-specific antibodies against the vaccine immunogens with titers increasing at weeks 2 and 6 in all arms. Antigen-specific CD4+ T-cell responses, at 2-weeks post-2nd boost, showed significant increases ($p < 0.01$ for TNF-alpha and $p < 0.05$ for IL2, IFN-gamma, and CD40L) between low to high doses of ALFQ.

Conclusions: Preliminary blinded data show ALFQ-adjuvanted bivalent HIV-1 vaccine is safe and well-tolerated. Binding antibody titers and CD4+ T-cell responses were ALFQ dose-dependent and increased with the first two vaccinations.

OA1204

Vaccination with a novel fractional escalating dose strategy improves early humoral responses with a novel germline targeting HIV vaccine (426.mod.core-C4b): preliminary results from HVTN 301

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Background: Conventionally, vaccines are delivered through a single 'bolus' administration. In preclinical models, HIV vaccination strategies that mimic the sustained antigen load which the immune system experiences during acute infection improve the quality of humoral responses compared to traditional bolus administration. Here we report the results of a clinical trial testing the effectiveness and tolerability of a strategy based upon these concepts called fractionated escalating dosing.

Methods: HVTN301 is a first-in-human, double-blind, placebo-controlled trial evaluating a HIV immunogen nanoparticle (426.mod.core-C4b) adjuvanted with the TLR7 agonist 3M-052 AF/Alum intended to expand CD4-binding site bnAb lineage B cells. The trial compares 426.mod.Core administered as a single 100mcg "bolus" dose compared with a "fractional escalating dose" delivering 100mcg split into increasing doses given over three weeks in the priming phase (426.mod.Core dose of 2mcg, 5mcg, 10mcg, 15, mcg, 20mcg, and 48mcg). Outcomes include adverse events (AEs), antigen-specific CD4+ T cells and memory B cells (by flow cytometry), binding antibody (by binding multiplex assay), and serum neutralization (using a pseudovirus panel), all compared by Wilcoxon rank sum test.

Results: We enrolled 53 adults without HIV at six sites. The vaccine was safe, with no related serious AEs, related severe unsolicited AEs, or unplanned study pauses. Overall tolerability was similar with either fractional or bolus administration. Two weeks after the initial prime, fractional escalating doses led to increased frequency of CD4-binding-site specific memory B cells (median 0.050% vs 0.114%, $p < 0.001$), antigen-specific CD4+ T cells (median 0.005% versus 0.118%, $p < .0001$), increased total quantity of serum IgG that binds the vaccine (MFI 755 versus 3674 at

1:31250 dilution, $p < .0001$), and higher titers of neutralizing antibodies to HIV pseudovirus strains that identify CD4-binding-site antibodies (55 vs 284, $p < .001$).

Conclusions: Fractional escalating dose strategies of a nanoparticle HIV vaccine with a novel adjuvant was safe, tolerable, and enhanced antibody, B cell, and CD4+ T cell responses during the priming phase. HVTN 301 establishes proof-of-concept that sustained antigen/adjuvant exposure can improve immune responses for preventive HIV vaccines intended to elicit broadly neutralizing antibodies during the priming phase, supporting identification of strategies based upon this concept that can be more readily translated into clinical practice.

OA1205

Membrane-anchored HIV-1 Env trimer BG505 MD39.3 mRNA is immunogenic and can elicit tier 2 autologous neutralizing antibodies (HVTN 302)

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Background: Harnessing mRNA vaccine technology has the potential to accelerate HIV-1 vaccine development, but no published data are available on human immune responses to HIV-1 envelope (Env) delivered by mRNA. Here, we tested the immune response induced by the BG505 MD39.3 trimer expressed as mRNA in three forms: soluble (gp140), membrane-bound (gp151) and membrane-bound with a CD4-binding site knockout (KO) mutation. Both occluding the trimer base with membrane display and disrupting CD4 binding site-induced conformational changes via a KO mutation aim to reduce the elicitation of non-neutralizing antibodies.

Methods: HVTN 302 (NCT05217641) is a phase 1, open-label, randomized, multicenter trial evaluating the safety and immunogenicity of three mRNA-encoded HIV envelope trimers at two doses: 100 mcg and 250 mcg. Participants were vaccinated intramuscularly at months 0, 2 and 6. Immune assays quantified the response rate and magnitude of vaccine-specific binding antibodies, B cells, T cells, and serum neutralizing antibodies two weeks after the last vaccination.

Results: HVTN 302 enrolled 108 participants from February to August 2022. Robust vaccine-specific antibody binding titers, vaccine-specific IgG+ B cell responses, and vaccine-specific CD4 and CD8 T cell responses were observed in all groups without major differences between

soluble and membrane-bound groups. However, IgG+ B cell responses among positive responders to non-base epitopes were significantly increased in the membrane-bound group after 3 immunizations (250 mcg of gp151 vs gp140, median frequency: 2.0% vs 0.8%, $p = 0.013$). Autologous tier 2 ID50 neutralizing antibody titers were more frequent in the membrane-bound groups (100 mcg gp151 vs. gp140, 11/17 vs. 0/16, Fisher's exact test $p < 0.0001$; 250 mcg gp151 vs. gp140, 12/14 vs. 1/12, $p < 0.0001$). Epitope mapping of elicited antibodies determined the major target of the neutralizing response to be non-base epitopes (V1 and C3V5).

Conclusions: This study indicates that HIV-1 Env trimers delivered as mRNA are highly immunogenic and more capable of eliciting tier 2 autologous neutralizing antibodies when anchored in a membrane. Therefore, we conclude that strategies to reduce exposure to the immunodominant base of the HIV-1 Env trimer may help to improve the neutralizing antibody responses in vaccines aiming to elicit broadly neutralizing antibodies.

OA1206

Immunogenicity of fusion peptide and trimer vaccination: preliminary results from HVTN 303 part B, a phase 1 randomized clinical trial in adults without HIV

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Background: HVTN 303, a trial of HIV-1 fusion peptide-directed vaccine, was designed to prime with HIV envelope Trimer 4571, a fusion peptide conjugate (FP8-rTTHC), or their combination, with subsequent boosting with Trimers 4571 and 6931, all adjuvanted with Adjuvax (20%). In March 2023 vaccinations were permanently discontinued due to grade 3 solicited local and systemic reactogenicity (fever, injection site erythema and induration) and unsolicited adverse events (urticaria, rash, and serum sickness). Subsequently, boosting with Trimers 4571 and 6931 was stopped.

Methods: We evaluated peak immune responses of participants who had received one vaccination with Trimer 4571 (groups 5+6, n=13), two vaccinations with FP8-rTTHC (group 7, n=5), or two vaccinations with a combination of both immunogens (group 8, n=6). Sera were tested for binding antibodies to FP8 alone or with Trimer 4571 and two assays assessed percent related to trimer base bind-



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ing. Neutralization was determined by standard pseudo-virus neutralization assays. Immunogen-specific B cells were quantified by flow cytometry, sorted, and their antibodies were produced by the RATP-Ig protocol and tested for binding and neutralization.

Results: Serum antibodies to FP8 were elicited in all three study groups. The highest titers were elicited after two vaccinations with either FP8-rTTHC alone or in combination with Trimer 4571 (fold increase from baseline of 1.6 in groups 5+6, 27.9 in group 7, and 23.5 in group 8). Binding antibodies to trimer were detected after two immunizations with Trimer 4571; 65-75% of which was directed at the base. Serum neutralization was not detected in any group. Memory B cells expressing antibodies that bind FP8 in the context of native trimer were detected in 3/4 participants in group 7 and 4/4 in group 8. Some of the antibodies from these B cells can neutralize HIV.

Conclusions: Two vaccinations of FP8-rTTHC regimens induced FP8-binding antibodies in serum and B cells capable of recognizing FP8 in the context of native HIV envelope trimer. Evaluation of B cell responses and safety is ongoing. These findings may inform development of antigens to generate broad FP-directed responses that can protect against HIV infection.

Adapting PrEP for specific populations

OA1302

Pre-exposure prophylaxis (PrEP) modality and service delivery preferences among diverse populations in Malawi: results from a discrete choice experiment

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Background: As long-acting injectable cabotegravir PrEP is rolled-out globally, it is critical to understand preferences within and across populations for delivery. We compared PrEP modality and service delivery preferences through a discrete choice experiment (DCE) among diverse populations in Malawi.

Methods: Participants ≥ 18 years and potentially at-risk for HIV acquisition were recruited at public clinics and key populations (KP) drop-in centers within Lilongwe and

Blantyre, Malawi for a cross-sectional survey. KP groups included female sex workers (FSW, n=100), men who have sex with men (MSM, n=100) and transgender individuals (TG, n=50); non-KP groups sampled included adolescent girls and young women (AGYW, n=100), pregnant and breastfeeding women (PBFW, n=100), and heterosexual men with increased HIV acquisition risk (n=100). Two DCEs were designed (KP and non-KP). We assessed levels across six attributes to identify factors driving stated PrEP preferences: PrEP modality (oral vs. injection), visit frequency, side effects, PrEP service delivery location, costs, and waiting times* (*non-KP only). Effects were coded using a multinomial logit model.

Results: From August-September 2023, 550 participants were recruited. Among non-KP, injectable PrEP was strongly preferred to oral (Figure). Side effects and costs were both strong negative drivers of PrEP use among non-KP; preferences were similar between non-KP men and women. Among KP, injectable PrEP remained strongly preferred to oral PrEP, side effects were a less important driver, and there were strong preferences against PrEP delivery at government clinics vs. drop-in centers. Notably, side effects did not drive FSW preferences. Overall, PrEP-stigma was cited by >60% as the key barrier and <50% of participants found getting PrEP at HIV/STI clinics acceptable.



Figure: Strength of attribute preferences amongst Malawians: (A) Non Key Populations, including adolescent girls and young women, pregnant and breastfeeding women, heterosexual men at increased risk of HIV acquisition (n=300); (B) Key Populations, including cisgender female sex workers, men who have sex with men and transgender persons (n=250). Green bars indicate a statistically significant ($p < 0.05$) positive preference for an attribute as compared to the reference group; red bars indicate a statistically significant negative preference for an attribute as compared to the reference group; gray bars indicate a non-significant difference.

Figure.

Conclusions: Injectable PrEP largely and positively drove preferences, while costs were strong negative drivers. Reinforced counseling around side effects may be particularly important among non-KP; diverse delivery channels for PrEP are important across populations and recommended for roll-out in Malawi.

OA1303

Knowledge and acceptance of HIV pre and post-exposure prophylaxis among a cohort of cis and transgender female sex workers in Buenos Aires, Argentina

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Background: Combined strategies for HIV prevention include oral pre and post-exposure prophylaxis (PrEP and PEP). Sex workers are at high risk of acquiring HIV, however they face barriers to access healthcare services, including HIV prevention.

This study aimed to assess knowledge of PrEP and PEP, and the acceptance of PrEP in a cohort of female sex workers (FSW).

Methods: "MAS por Nosotras" is an ongoing prospective cohort of FSW recruiting at a non governmental organization in Argentina.

Medical and psychosocial information is obtained from consenting participants at baseline and each visit including structured questions on PrEP and PEP. Participants are tested for HIV and PrEP is offered for those who test negative. Baseline data is presented.

Results: From June-December 2023, 116 FSW were enrolled: 55 cisgender women (CGW) and 61 transgender women (TGW). Median age was 33.5 years (IRQ 26.8-44.3). Median years of sex work was 12 [IQR 6-19], with 51.7% of TGW and 26% of CGW with >20 sexual partners in the prior month and 59.5% reporting condomless anal/vaginal intercourse.

21/116 knew they were living with HIV and 3 other participants were diagnosed at baseline (23/24 TGW). Among those without HIV, 22.1% knew about PEP and 9.5% had used it before. 26.8% TGW were on PrEP at baseline.

Among those not receiving PrEP at enrollment, TGW had used PrEP in the past more frequently than CGW (20% vs 1.9%, p=0.008) and reported more knowledge on what PrEP was used for (53.3% vs 14.8%, p<0.001).

When PrEP was offered, acceptance was higher among TGW than CGW (66.7% vs 33.3%, p=0.003).

Reasons for not initiating PrEP included not feeling at risk, potential adverse events, not desiring taking medication and postponing PrEP for another time.

Conclusions: A quarter of FSW had previous knowledge of PrEP, lower in CGW than TGW. The acceptance was high among TGW but very low among CGW. Future research should focus on understanding barriers to access HIV prevention in CGW and TGW, in order to develop tailored HIV prevention policies.

OA1304

The persistent chasm between PrEP awareness and uptake: characterizing the biomedical HIV prevention continuum in a nationwide cohort of transgender women in the United States

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Background: Transgender women (TW) are disproportionately impacted by HIV, yet data on the biomedical HIV prevention continuum (HIVPC) among TW are limited. We characterized the HIVPC among a large, nationwide cohort of TW by PrEP modality (oral and long-acting injectable, LAI) and identified correlates of uptake and adherence.

Methods: From March 2023 to February 2024, we enrolled English and Spanish-speaking adult TW without HIV (laboratory-confirmed) into the ENCORE cohort. PrEP data were collected via self-reported surveys. Descriptive statistics characterized the HIVPC and modified Poisson regression models estimated adjusted prevalence ratios (aPR) and 95% confidence intervals (95% CI) for correlates of HIVPC progression (awareness-uptake-adherence). We assessed differences in proportions for each step of the HIVPC by modality.

Results: We enrolled 996 participants (mean age=35.6 years; range=18-80); 60% were Non-Hispanic White, 17% Black, 15% Latina/x, 6% Indigenous, and 5% Asian. Among the 62% who were sexually active (past 6-months), 91% had ever heard of PrEP, 36% had ever used PrEP, 25% recently used PrEP (past 6-months), and 20% were adherent. The largest proportional difference in HIVPC progression was from awareness to uptake (62% of sexually active,



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PrEP-aware TW had never used PrEP). This difference was significantly greater in the LAI continuum (96% of LAI PrEP-aware TW had never used LAI). Correlates of PrEP uptake included receiving health services at an LGBTQ clinic (α PR=1.5; 95% CI=1.2-1.9), current hormone use (α PR=1.8; 95% CI=1.2-2.5), and higher perceived HIV acquisition risk (α PR=1.5; 95% CI=1.1-2.2).

Correlates of non-adherence included higher anticipated discrimination (α PR=1.1; 95% CI=1.0-1.1). Among 14 TW who had used LAI PrEP, mean age was 37 years (range=21-59), 7% (1/14) identified as Black and 21% (3/14) Latina/x. 21% (3/14) were HPTN 083 participants and the remaining 79% (11/14) initiated LAI PrEP in 2023.

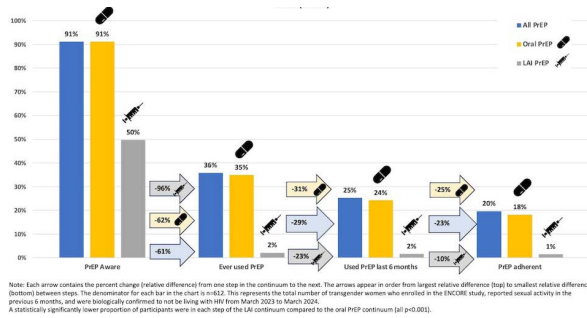


Figure. HIV prevention continuum among sexually active transgender women not living with HIV in the United States 2023-2024 (n=612).

Conclusions: Interventions to improve HIVPC outcomes -especially PrEP uptake- are needed to optimize PrEP among transgender women.

OA1305

At elevated risk within these four walls: expanding access to pre-exposure prophylaxis to incarcerated males in Zambia

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Background: HIV prevalence in Zambia among incarcerated populations is higher than the community outside. Once as high as 27% in 2009, it has decreased to 14.3%. Reasons for higher risk include poor access to health services, unsafe sex between incarcerated males, sexual assault, and the use of contaminated needles for tattoos. In 2019, the provision of pre-exposure prophylaxis in prisons was introduced, expanding access to effective biomedical prevention to incarcerated populations.

Methods: The introduction of PrEP in prisons was initially hampered by the restrictive legal environment around homosexuality in Zambia.

Through quiet advocacy and emphasis on other risk factors, authorization was provided in 2019 for PrEP to be provided to incarcerated populations as part of HIV services offered in 26 Zambia Correctional Services (ZCS)

facilities supported by the USAID DISCOVER-Health project. ZCS officers were trained as HIV/AIDS coordinators to oversee HIV/AIDS activities in prisons. Influential incarcerated males are nominated to work as peer educators. These peer mentors, 30 per facility, provide key messaging to other inmates and generate demand for PrEP. Peer mentors hold small group discussions and individual counselling sessions on combination HIV prevention and linkage to PrEP.

Peer mentors are also equipped to provide psychosocial support to fellow incarcerated males to improve continuation on PrEP, including safekeeping of PrEP drugs and providing reminders to those on PrEP.

Results: In 2019, ZCS facilities supported by USAID DISCOVER-Health initiated 62 male inmates on PrEP. In 2023, expansion to additional correctional facilities resulted in 3,815 inmates initiated on PrEP. In total, from 2019 to 2023, 8,392 inmates have been initiated on PrEP. Of the 8,392 inmates initiated on PrEP, 514 were 15-19 (6%), 1,833 were 20-24 (22%), 5,523 were aged 25-29 (67%) and 422 (5%) were aged >50 years old.

Conclusions: PrEP provision is critical in averting HIV acquisition during incarceration. Empowering incarcerated individuals to be peer mentors who are equipped as sources of key messaging on PrEP ensures that incarcerated males have access to accurate information on HIV prevention to help avert HIV acquisition.

Safeguarding the health of incarcerated populations in turn ensures gains made in reducing HIV transmission in communities are maintained.

OA1306

Greater PrEP use in a community-based needle and syringe program versus facility-based medication for opioid use disorder program for people who use drugs in Uganda

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Background: HIV pre-exposure prophylaxis (PrEP) is critical for people who use drugs in high HIV-burdened settings and could be integrated into existing harm reduction services - needle and syringe (NSP) and medication for opioid use disorder (MOUD) programs. In Uganda, we integrated oral PrEP into a community-based NSP and facility-based MOUD program and compared PrEP refills and adherence.

Methods: PrEP delivery was integrated into Uganda's only public MOUD program (within Butabika Mental Health Hospital) and a non-profit community-based NSP. Harm reduction providers were trained on PrEP, programs received HIV testing commodities, and PrEP trainers provided continuous technical assistance.

All HIV-negative people accessing each harm reduction program were offered PrEP. Those initiating had PrEP dispensing data abstracted from medical records for 12 months and the opportunity to enroll in research procedures (quarterly blood draws for tenofovir [TFV] quantification and behavioral questionnaires).

In age-adjusted Cox proportional hazards models, we compared time to first PrEP discontinuation (using definitions for strict and real-world discontinuation) among people within each program.

Results: Among 417 participants (325 from NSP, 92 from MOUD), 91% were male, median age=31 (IQR 25-40), and cannabis, cocaine, and street opioids were drugs most commonly used. Injection was the most common route for opioid use and 19.9% of participants had shared injection equipment.

After the first visit, 83% had a subsequent refill, after the second, 79%; subsequent visits had a 67% refill rate. TFV was detected in 54% of visits after PrEP dispensing (28% had TFV >40ng/ml) and similar among NSP and MOUD. The median time to 1st discontinuation was 1 month (IQR 1-3) for MAT and 4 (IQR 1-6) for NSP participants.

Using a real-world definition based on 2 consecutive months without PrEP coverage, the discontinuation rate was statistically lower among people in the NSP versus MOUD (hazard ratio 0.16, 95% CI 0.12-0.21). Results using a stricter definition had higher discontinuation rates and similar difference between the programs ($p < 0.001$).

Conclusions: Initial PrEP use was good to modest among people accessing harm reduction services in Uganda. While both programs delivered PrEP to this high-risk population, the community-based NSP may yield better PrEP continuation than the MOUD program.

Support matters: You are not alone!

OA1402

"They are not HIV treatments drugs; they are preventive drugs (PrEP)". Experiences of using PrEP among vulnerable adolescent girls and young women in Tanzania

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Background: HIV poses a significant global health concern, affecting adolescents among other populations. This is attributed to various vulnerabilities including biological factors, gender inequalities and limited access to comprehensive sexual and reproductive health services in sub-Saharan Africa. In Tanzania, adolescent girls, and young women (AGYW) face double the risk of HIV infection compared to their male counterparts.

The introduction of pre-exposure prophylaxis (PrEP) brought hope for changing the HIV cascade in the country.



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However, numerous challenges still hinder PrEP uptake. Therefore, this study explores experiences of PrEP uptake among vulnerable AGYW in Tanzania.

Methods: This study employed a phenomenological qualitative approach; 52 semi-structured interviews were carried out between May to November 2022 in the selected healthcare facilities in Tanzania. The study adopted inductive-deductive thematic analysis guided by the Social Ecological Model (SEM) to elicit the views of AGYW aged 15–24. Nvivo software was utilised to organise data.

Results: This study has uplifted barriers and facilitators on PrEP uptake among AGYW in Tanzania. The barriers are categorized at individual, interpersonal, and institutional levels. The individual level barriers included pre-requisites for initiating PrEP, disbelief in the effectiveness of PrEP, interference of refill hours with working hours, financial constraints, and adherence to the pills. The interpersonal level barriers included misconceptions about PrEP pills, and labelling of PrEP users. The institutional level barriers included inadequate privacy, PrEP drug stockout, being turned away by health care facilities (HCF), long waiting times, and distance to the HCF. Facilitators included factors at individual level (experienced benefit of PrEP, adequate PrEP knowledge, having multiple partners, perceived risk due to the nature of the work, PrEP ensuring privacy), interpersonal level (support from social networks), and institutional level (accessibility of PrEP, receiving refill reminders).

Conclusions: To overcome barriers to PrEP uptake among AGYW, it is crucial to develop multi-level interventions that consider personal, social, and structural factors hindering PrEP uptake. Implementing strategies like prioritizing off-site PrEP delivery and expanding community outreach for PrEP awareness can help dispel misconceptions and enhance uptake.

OA1403

The impact of the 'Le Kip Kip' Social Influence Campaign on PrEP knowledge, attitudes, and perceptions among women in South Africa

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Background: Strategies addressing PrEP stigma are needed to facilitate PrEP uptake and persistence among women, including adolescent girls and young women (AGYW)

and female sex workers (FSW). We evaluated the effect of the 'Le Kip Kip' social influence campaign, implemented as part of a cluster randomized trial (CRT), on PrEP knowledge, attitudes, and perceptions in South Africa.

Methods: We conducted cross-sectional baseline (May-June 2022) and endline (October-November 2023) surveys among AGYW and FSW receiving decentralized HIV prevention services from TB HIV Care in 6/10 programme districts involved in the CRT. Outcomes included PrEP knowledge (dichotomous), negative PrEP-user stereotypes (mean of 6 Likert scale items), and anticipated PrEP approval by others (mean of 3 Likert scale items).

We conducted difference-in-differences analyses using modified Poisson and linear regression models to quantify potential impacts of the intervention on each outcome, adjusting for age and education.

Results: Among 1,201 women (601 baseline; 600 endline) surveyed (42% AGYW, 58% FSW), PrEP knowledge, PrEP-user stereotypes, and PrEP approval improved over time, but changes were not statistically significant (Figure 1). PrEP knowledge significantly increased over the study period in intervention districts relative to control districts among AGYW (PRR: 4.72, 95%CI: 3.17,7.05), but not FSW (PRR: 1.20, 95%CI: 0.28,5.14). Expected PrEP approval from social networks increased in intervention districts relative to control districts in unadjusted analyses among FSW (b:0.26, 95%CI: 0.04,0.47) but not AGYW (b:0.32, 95%CI: -0.58,1.23).

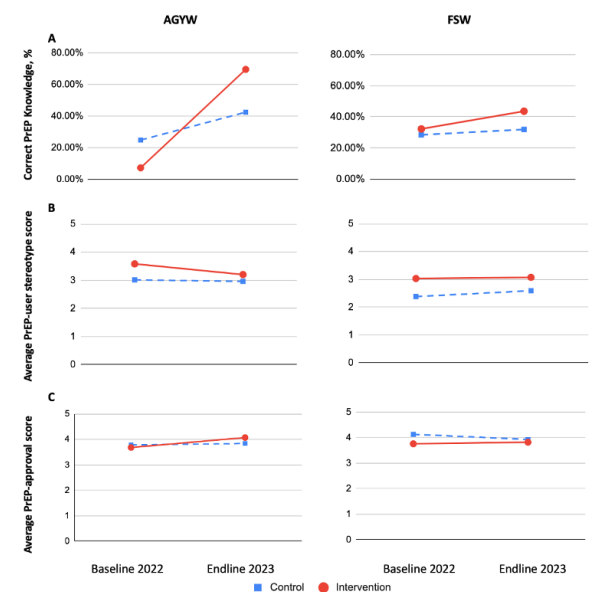


Figure 1. Crude study outcomes among AGYW and FSW by study group and survey round. (A) Correct PrEP knowledge, (B) Average PrEP-user stereotype score, (C) Average PrEP-approval score.

Conclusions: The 'Le Kip Kip' campaign increased PrEP knowledge for decision-making among AGYW, and positively nudged attitudes towards PrEP within FSW's social networks overall. PrEP-stereotype scores among FSW and AGYW within communities were not affected. Persistent PrEP stigma manifesting in negative stereotypes warrants complementary interventions enabling PrEP uptake and persistence among women with sustained HIV vulnerabilities in South Africa.

OA1404

The influence of male partners on pregnant women's participation in HIV prevention trials: experiences from the MTN-042 Dapivirine Vaginal Ring and oral PrEP study in Kampala, Uganda

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Background: Male partners are key health decision-makers in their families, yet their perceptions about the participation of their pregnant partners in research are not widely known. The MTN-042/DELIVER study assessed the safety, adherence, and acceptability of the monthly dapivirine vaginal ring (DVR) and daily oral tenofovir/emtricitabine when used during pregnancy. Considering the delicate nature of pregnancy and participants' socio-cultural settings, MTN key stakeholders recommended that researchers engage with male partners to the extent possible. Recruitment started with third-trimester cohort, followed by second and first-trimester cohorts. Here we describe male partners' perceptions and influence on pregnant partners' decisions to participate in HIV prevention research.

Methods: Potential participants were asked whether they had engaged their male partners about the DELIVER study and what their partners' reactions were, whether they approved participation or not. For enrolled participants, partners were invited to participate in two of four engagement sessions. The session's objective was to explore perceptions and the influence of male partners on pregnant women's interest in research participation. The content was coded, summarized, and thematically analyzed. Male partner responses were quantitatively captured from the participant appointment tracking logs and updated regularly.

Results: A total of 1183 potential participants were pre-screened; 344 male partners were approached by their spouses for permission to participate in DELIVER. The majority (88%) were unsupportive; 39.5% (n=136) refused participation, and 48.8% (n=168) switched off phones denying their pregnant partner's participation. Only 11.6% (n=40) accepted study participation and engaged in the male partner sessions.

Reasons for male partner refusal included:

1. Safety concerns about study products causing stillbirths, abortions, and congenital anomalies, especially during early and late trimesters;
2. Rumors, and misconceptions about the depopulation of Africans through HIV prevention research;
3. Lack of PrEP awareness; and
4. Low HIV risk perceptions. Male partners who perceived themselves to be at high risk, accepted participation, and wanted to know about PrEP and to have HIV-free babies.

Conclusions: Awareness about PrEP is urgently needed among male partners to facilitate uptake among pregnant women who need HIV prevention methods but lack the autonomy to protect themselves and their babies from acquiring HIV.

OA1405

Impact of community – health facility electronic bidirectional client referral services in Ethiopia

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Background: Effective bidirectional referral between health centers and communities is crucial for ensuring the continuity of HIV care. To improve the speed and quality of referral services in Ethiopia, Project HOPE integrated a bidirectional referral system into the unified data system (UDS) for data collection via CommCare. We summarized the electronic exchange of patient information and its application in Ethiopian community HIV care and treatment activities.

Methods: Project HOPE developed a bidirectional referral application on the CommCare platform for the exchange of patient information. The application runs on mobile devices, such as smartphones and tablets. User accounts were created for community and facility health workers. They received bidirectional CommCare data entry training, tablets for data collection, and ongoing technical support. Over 30 implementing partners were involved. Trained health facility and community health workers conduct two-way electronic referrals based on client needs. This includes feedback about services. A retrospective analysis summarized the outcome of the bidirectional electronic referral system from 2020 to 2023. The analysis focused on 772 selected high-load health facilities in Ethiopia.

Results: A total of 130,000 client data were exchanged among the community and health facility care providers including interruption in treatment, contacts of HIV positive index cases, high viral loads among people living with HIV, cervical cancer referrals, community care and support, and 95 % of the clients have got the service with confirmed feedbacks. The referral system improved communication and feedback between community and health facility workers, alerted users with notifications, provided a job aid guide, and used validations to improve the quality of healthcare services to people living with HIV. All implementing partners used the UDS on a regular basis to monitor their performance, report to USAID and PEPFAR's DATIM system, and make timely decisions at all levels.

Conclusions: The electronic bidirectional referral system improved the community health facility collaboration to provide holistic care and timely and consistent HIV



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services at all levels, strengthen program data quality, and promote data use and real-time communications. Therefore, we recommend the wider scaleup of digital platforms for bidirectional referral services to strengthen and support community-based HIV service delivery in resource-limited settings.

OA1406

Factors leading to viral load non-suppression after Intensive adherence counseling among HIV patients in TASO Mbale Eastern Uganda. A cross-sectional study

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Background: Globally, 37.7 million people are living with HIV and of these, only 66% on ART are suppressed. According to the United Nations Program on HIV/AIDS through the ambitious 95-95-95 target, 95% of people living with HIV (PLHIV) on antiretroviral treatment (ART) should be virally suppressed by 2025 to eliminate HIV as a public health problem by 2030. Viral load (VL) non-suppression is associated with poor adherence, and intensive adherence counseling (IAC) has shown to improve suppression.

Methods: This was a Cross-sectional study, conducted in TASO Mbale. Data were abstracted for all clients with non-suppressed viral load between Jan 2018 to August 2021 from the TASO Mbale program database and various parameters were considered. These parameters included the IACs done, the time the repeat VL was done, presence of an opportunistic infection, sex, age, and the current regimen. A client was considered to have a non-virological status if there were >1000 copies/ml. The clients were followed for a maximum period of 43 months. A total of 13428 person months was observed for different periods. The data were then analyzed using statistical software Stata version 14. Bivariate analysis was done for all covariates. Hazard ratios (HRs) were estimated as a degree of association between viral non-suppression and client features, via a Cox proportional hazards regression.

Results: A total of 442 PLHIV with unsuppressed VL were enrolled and underwent IAC of whom 60 (13.6%) had VL non-suppression after IAC. The overall rate of VL non-suppression was 4.47 (3.41-5.75) per 1000 person-months (PM) of observation after IAC. ART regimen was statistically significant with viral load suppression especially DTG-3TC-LPV/r based regimen had (AHR=5.78, 95%CI, 1.137-29.384, p=0.034). Poor adherence level to ART had a significant contribution to viral load non-suppression (AHR=4.88, 95%CI: 1.607-14.836, p=0.005).

Conclusions: Virological non-suppression after IAC was found at 13.6% and associated with patients' poor adherence levels. Viral load suppression was associated with good adherence, to ART drug regimens specifically DTG-3TC-LPV/r and AZT-3TC-LPV/r-based regimens. The findings lead to a huge boost towards the third UNAIDS target of 95%.

The great escape: Antibody efficacy against viral evolution and diversity

OA1502

Defining the contribution of HIV-1 subtype C CD4 binding site mutations to VRC01 resistance and viral fitness

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Background: Human Immunodeficiency virus type 1 (HIV-1) continues to be a threat to the public health globally with about 36.7 million people living with the virus. The development of a preventive vaccine is a challenge to the public health.

Individuals from the Antibody Mediated Trial (AMP) [HVTN 704/HPTN 085 and HVTN 703/HPTN 081] were infused with VRC01, a bNAb targeting CD4 binding sites, every 8 weeks. While it did not decrease HIV-1 acquisition, highly sensitive isolates showed successful bNAb prophylaxis.

In this study features of the envelope gene associated with VRC01 neutralization resistance were mutated to generate VRC01 sensitive viruses and sensitivity was regarded as a confirmation of the resistant sites.

Methods: Putative VRC01 novel mutations were generated by identifying VRC01 resistant HIV-1 subtype C envelope sequences. VRC01 sensitive pseudovirus mutants were generated by site directed mutagenesis. Neutralization assay was performed to measure VRC01 inhibition of the sensitized viruses compared to wildtypes.

Results: Neutralization of double (F717L/I646L) and triple mutations (F317I/646L/K683R) was tested. The H703_0842 (F717L/I646L) became neutralization sensitive to VRC01, 3BNC117, PG9 & PGT151 compared to their H703_0842 wild type.

The triple mutation was introduced in the H704_0482 virus (F317I/646L/K683R) was resistant to VRC01 and sensitive to 3BNC117, PG9 and PGT151, compared to its wild type.

Conclusions: Neutralization resistance of subtype C strains against VRC01 was identified with possible HIV-1 escape sites in the V3 region, gp41 transmembrane and the C2 region.

The study confirmed that some mutations found in gp120 significantly contribute to neutralization by the VRC01. Thus investigating resistance mechanisms against VRC01 may shed more light on antibody neutralisation escape of HIV-1.

OA1503

A higher proportion of recent compared to historic HIV viruses are resistant to antibody dependent cellular cytotoxicity mediated by monoclonal antibodies

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Background: HIV diversity represents a significant barrier to effective prevention and treatment strategies; including to the use of monoclonal antibodies (mAbs) which are currently being assessed in clinical trials.

Methods: Phylogenetic analysis of 1380 subtype C envelope sequences sampled from 1988-2021 shows that later sequences (2015-2021) are significantly more diverse than earlier sequences. To determine if increased diversity impacted antibody-dependent cellular cytotoxicity (ADCC) mediated by mAbs, we constructed infectious molecular clones (Env-IMCs) containing 11 historic (1998-2008) and 15 recent (2017-2021) env sequences that best represented global diversity in C1C2, V1V2 and CD4 binding site regions. ADCC susceptibility was tested against 16 neutralizing and non-neutralizing mAbs targeting V2 apex, V3 glycan, CD4 binding site, MPER, fusion peptide, and CD4-induced epitopes.

Results: Overall, only PGT121 had significantly less ADCC activity against recent viruses compared to historic ones ($p=0.004$, FDR $q=0.06$). However only 1/11 (9%) historic viruses versus 5/15 (33%) recent viruses were resistant to ADCC mediated by the mAb panel ($pAUC>50$ for <2 mAbs; binomial $p=0.009$). Phylogenetically corrected signature analysis showed that 379R and 496V were significantly associated to ADCC sensitivity, whereas 379G and 496I were associated to ADCC resistance (the latter not significant after multiple testing correction). Interestingly, both 379G and 496I increase in frequency over time when comparing historic Envelopes to the more recent ones, whereas the sensitive residues, 379R and 496V, become less prevalent over time.

Conclusions: These data suggest that HIV is evolving to become more resistant to ADCC. Consequently, careful selection of mAb combinations and vaccine immunogens will be needed to successfully prevent and treat HIV-1 acquisition.

OA1504

Neutralisation sensitivity of currently circulating HIV-1 India clade C to broadly neutralising antibodies targeting CD4bs and V3 glycan supersite

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Background: The disease burden of HIV-1 is quite high and currently no preventive vaccine is available. Broadly neutralizing antibody have proven to be an effective modality in controlling infections as observed in the preclinical studies.

Hence for the clinical application of bnAbs as preventive or therapeutic intervention, it is imperative to study the effectiveness and the efficiency of relevant bnAbs against the currently circulating HIV-1 variants. This would not only help optimize best bnAb combination but also the vaccine approach for a given population.

Thus, this study was carried out with the aim to examine the neutralization phenotype of contemporary circulating HIV-1 India clade C virus across different regions and risk groups by a panel of clinically relevant bnAbs. A comparative and comprehensive analysis was also carried out with the historical viruses collected prior to 2015.

Methods: For this study, samples were collected from ($n=161$) people living with HIV (PLHIV) across 5 different clinical sites in India, for the year 2019-2023. The HIV-1 envelope gene could be amplified, cloned and pseudoviruses were generated successfully from the 88 of the samples. These 88 pseudoviruses were assessed *in vitro* with different classes of bnAbs for neutralization sensitivity. A comparative study with historical viruses focusing on CD4bs and V3 directed bnAbs was also carried out to study the phenotype evolution.

Results: The neutralization assessment of contemporary HIV-1 viruses exhibited most sensitivity to CD4bs and V3 glycan supersite directed bnAbs amongst all the classes. Although comparative analysis with historical virus neutralization data revealed increasing resistance to the 3BNC117 (CD4bs) and BG18 (V3 glycan) bnAbs. Several broadly resistant viruses were also identified which were resistant to all but one class of bnAbs ($IC50>25\mu g/ml$).



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Conclusions: Although the neutralization assessment revealed most sensitivity to the CD4bs and V3 directed class of bnAbs yet increasing resistance was also observed to certain individual bnAbs. This neutralization assessment along with identification of broadly resistant viruses warrants continual virus surveillance amongst PLHIV to optimize bnAb combination with highest coverage and multiple specificity. Thus, a single preventive/therapeutic combination may not a gold standard rather, population specific intervention needs to be strategized.

OA1505

Neutralisation sensitivity of African HIV-1 isolates from diverse clades to clinically relevant bNAbs

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Background: Broadly neutralising antibodies (bNAbs) are a major focus for HIV vaccine design and passive immunisation for HIV prevention. Given the significant genetic diversity of the African HIV-1 epidemic, assessing which bNAbs will be most effective against circulating strains in each region is essential.

Studies have shown that over the course of the maturing clade C and B epidemics, recently transmitted viruses show reduced sensitivity to bNAbs. However, it is not known if this is the case for the A1 and D clades, and A1D recombinants, which predominate in East Africa.

Methods: We characterised the neutralisation sensitivity of 183 African, recently transmitted viruses, from the IAVI-ADVANCE network, isolated between 2005-2020, against potent CD4bs (N6 and 1-18), V2-Apex (CAP256, VRC26.25 and ePGDM1400.V9) and V3-glycan directed (ePGT121.V1 and BG18) bNAbs. We next identified the ten most difficult-to-neutralise isolates from each clade, and assessed these against a larger panel of ten bNAbs in clinical development, both individually and in combination.

Results: We observed subtle, but significant, changes over time in bNAb sensitivity at different epitopes, however, this varied by clade. The N6, 1-18 and ePGDM1400.V9 bNAbs showed reduced potency against later clade A1 isolates (significant for N6), while CAP256.VRC26.25 had reduced potency against later clade C isolates. In contrast, BG18 had increased potency against later isolates from

both clades (significant for clade C). Overall patterns in neutralisation sensitivity over time could not be evaluated for clade D and A1D recombinants due to sparse sampling coverage in later years. With the exception of clade D, the combination of VRC07-523-LS, ePGDM1400.V9 and ePGT121.V1 had the best coverage (80-100%) of the ten most difficult-to-neutralise isolates per clade, at a concentration of 1 µg/ml. Of concern, 20-70% of difficult-to-neutralise isolates were only sensitive to one bNAb in the best clade-specific combination.

Conclusions: Although there was high overall coverage of difficult-to-neutralise isolates with bNAb combinations, we identified isolates in all clades that showed complete resistance to multiple classes of bNAbs. Such viruses with intrinsic resistance represent a challenge to bNAb-based strategies, but could be valuable for isolating novel bNAbs, which may be more effective at constraining the emergence of resistance mutations.

OA1506

Diminished sensitivity of historical and contemporary HIV-1 strains to fusion peptide broadly neutralizing antibodies (bnAbs) may call for a reassessment of bnAbs efficacy

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Background: Recognising the global demand for an HIV-1 vaccine, numerous broadly neutralising antibodies (bnAbs) targeting vulnerable epitopes on the HIV-1 envelope have been isolated. Fusion peptide-targeted bnAbs have been shown in non-human primates and human trials to inhibit viral entry by blocking the required conformational changes in Env-gp120 and gp41 subunits.

We tested the hypothesis that continual genetic evolution resulting in emerging HIV-1 envelope diversity may alter envelope glycoproteins, reducing binding and neutralization by existing Fusion Protein bnAbs.

Methods: We assessed the neutralising capability of ten fusion peptide-targeted bnAbs (DFPHA, DF1Wa.01, ASC02, VRC07.01, VRC01.23, VRC34, OPVa, OPVb, OPVc and PGT151) against historical (>10 years) and contemporary (< 3 years) HIV-1 pseudoviruses in a TZMBL neutralization assay to assess the potency and breadth of the antibodies using IC₅₀/80 values at concentrations of 100 g, 2 g, and 0.1 g against 226 HIV-1 pseudotyped viruses, comprising 150 historical and 80 contemporary strains across 8 clades. Proportions of neutralized historical and contemporary viruses were compared using the Wilcoxon rank test.

Results: At a concentration of 0.1µg/ml, 70% (7/10) bnabs exhibited greater sensitivity to historical than contemporary viruses, with PGT151, VRC01.23, showing the highest potency at IC₅₀, neutralising 65% and 58% of historical viruses, respectively. Sensitivity at IC₈₀ was higher for historical viruses (39% of 146) than for contemporary viruses

(19% of 80), Significant variations occurred across clades, with A1 and C showing the highest sensitivity, while regional clades D and AD were notably underrepresented, highlighting need for focused research on locally prevalent strains.

Conclusions: This study highlights the dynamic change in HIV-1's vulnerability to fusion peptide-targeted bnAbs over time. The reducing sensitivity of contemporary HIV-1 strains to bnAbs than their historical counterparts, suggests evolutionary shifts in the virus that might impede current bnAbs-driven interventions. The better inhibitory effects of PGT151 and VRC01.23, further strengthens the necessity for a tailored approach in antibody-based therapies. The differential sensitivity observed across clades, and the underrepresentation of clades D and AD data, emphasizes the importance of regional-specific studies. This study reinforces the need for continued surveillance and adaptation in bnAbs-driven prevention strategies to remain abreast of HIV-1's evolutionary trajectory and resistance patterns.

Prevention advances: PrEP, DoxyPEP and MPTs P;

OA1602

Project PEACH: offering HIV and STI prevention options to men who have sex with men in Atlanta, Georgia, USA

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Background: In the United States, the HIV epidemic disproportionately impacts men who have sex with men (MSM), especially Black MSM. With the emergence of new sexual health prevention methods including HIV pre-exposure prophylaxis (PrEP) and doxycycline post-exposure prophylaxis (doxy-PEP) for STI prevention, there is a need to better understand preferences in utilizing these strategies in combination with structured support, including Motivational Interviewing (MI).

Methods: Between November 2021 and September 2023, we enrolled 240 HIV-negative MSM in Atlanta to be followed for 2 years in a prospective, observational cohort to evaluate preferences for HIV prevention options.

We offered participants the option to use daily or on-demand oral PrEP and/or doxy-PEP alone or in combination with PrEP. In March 2023, injectable cabotegravir (CAB-LA) became locally available and linkage to CAB-LA services

was offered. All participants also received a mobile application (app) to monitor prevention product use, sexual behaviors, desire to change prevention products, and risks of PrEP or PEP discontinuation. 4-monthly surveys, monthly/weekly in-app quiz, and quarterly HIV/STI testing were completed. Targeted MI sessions were offered based on survey responses.

Results: The median age among 240 participants was 30; 63% self-identified as Non-Hispanic Black and 12% as Hispanic. At baseline, 219 participants chose PrEP (166 Daily, 43 On-Demand, 10 Injectable), 177 of whom also requested doxy-PEP. 16 participants selected doxy-PEP alone, and five chose the app alone. There were 34 changes in prevention products over 17 months, which occurred on average 286 days from enrollment. 11 changes occurred following an MI where participants opted to change from Daily to On-Demand PrEP rather than discontinuing PrEP. In six changes, participants added doxy-PEP to daily PrEP. Among those who changed prevention methods, 88% did so once. Preliminary HIV incidence is low (0.52/100 person years).

Conclusions: In an ongoing study of prevention preferences among MSM, we found high rates of HIV PrEP and doxy-PEP uptake with persistence over study follow-up. Some participants opted to change from daily to on-demand PrEP or add doxyPEP after MI sessions. Future analyses will examine differential HIV and/or STI incidence based on prevention choice and motivators for prevention method adherence, discontinuation, and change.

OA1603

Doxycycline post-exposure prophylaxis (DoxyPEP) real-life effectiveness in a cohort of men who have sex with men in Milan, Italy

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Background: Aims are to evaluate the uptake of doxycycline post-exposure prophylaxis (DoxyPEP) among MSM and its effectiveness against bacterial STIs [syphilis (Tp), chlamydia (Ct) and gonorrhea (Ng)].

Methods: Retrospective study on MSM in care for HIV or PrEP at San Raffaele Hospital, Milan, Italy, who received DoxyPEP counselling and prescription between August 2022 (first DoxyPEP prescription, baseline-BL) and March 2024 (freeze date). DoxyPEP was offered to people with an STI history or who reported condomless sex with ≥ 1 partner. DoxyPEP with doxycycline 200mg within 72h from potential exposure was suggested for intense sexual activity (>5 partners). All individuals with ≥ 1 follow-up visit after BL and ≥ 1 before BL were included. DoxyPEP uptake was self-reported during routine visits (users: ≥ 1 intake). Among DoxyPEP users, %-changes in incidence rate (IR; 95% confidence interval, 95%CI) of bSTIs (Tp, Ct, Ng) before and af-



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ter DoxyPEP prescription were estimated with a pre-post intra-patient analysis based on mixed-effect Poisson regression (with random slope). DoxyPEP use was quantified as days-of-therapy (DOT) per 1000-patient-days (1000-PD).

Results: Overall, 444 MSM (67 PLWH, 377 PrEP users) received DoxyPEP counselling and prescription; 121 (27.5%) reported DoxyPEP uptake during follow-up. Median months of follow-up in DoxyPEP users were 14.3 (IQR=10.3-16.9) and 9.11 (7.04-11.6) before and after prescription, respectively. Comparison of characteristics by DoxyPEP uptake in Table.

	Overall n=444	Non-users n=323	DoxyPEP users n=121	p-value
Age (years, IQR)	37.3 [32.5;43.1]	37.3 [32.3;43.0]	37.4 [33.5;43.3]	0.553
Living with HIV	67 (15.1%)	42 (13.0%)	25 (20.7%)	0.063
PrEP user	365 (82.2%)	270 (83.6%)	95 (78.5%)	0.268
4CMenB vaccination	66 (14.9%)	37 (11.5%)	29 (24.0%)	0.002
At least 1 concomitant STI at BL	93 (20.9%)	58 (18.0%)	35 (28.9%)	0.016
At least 1 previous STI	337 (75.9%)	229 (70.9%)	108 (89.3%)	<0.001

Among users, 247 bSTIs (Tp:39, Ct:83, Ng:125) were detected before BL and 88 (Tp:14, Ct:19, Ng:55) after.

Regression models among users showed a significant reduction of -79% (IRR=0.21,95%CI=0.16-0.27, p<0.001) in bSTIs' IRs after DoxyPEP prescription compared to before: Tp:-78% (IRR=0.22,95%CI=0.12-0.4, p<0.001), Ct:-86% (IRR=0.14,95%CI=0.08-0.23, p<0.001), Ng:-74% (IRR=0.26,95%CI=0.19-0.36, p<0.001), even among individuals not vaccinated with 4CMenB.

Overall DOT per 1000-PD was 4.02 (median DOT=2.79) among users.

Conclusions: DoxyPEP uptake among MSM was relatively low but more frequent among those at higher STIs risk. A reduction in all expected bSTIs was observed among DoxyPEP users. With proper counselling, low-level DoxyPEP use retained prophylactic effectiveness.

OA1604

Community-based organizations providing health services: nPEP, an emerging response to HIV reduction in Ecuador

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Background: Corporación Kimirina, a community-based organization, provides health services for the prevention of HIV/AIDS in Ecuador, being a national reference in the detection and response to the epidemic in key populations. Considering that non-occupational post-exposure prophylaxis (nPEP) is considered the only strategy to reduce the risk of contracting HIV, Kimirina established an nPEP program.

Methods: The post-exposure prophylaxis program was developed within the framework of combined prevention; medical care was provided telematically and in person: for

the delivery of medication, users had the option of going to the community centers or through the field promoters, ensuring access to medication for people living in areas far away from the community centers. Medication was always available for delivery.

Results: During 2023, the program covered 19 of the country's 24 provinces, with a total of 299 beneficiaries, who were found to have a negative HIV diagnosis at the end of the program's follow-up and control. The epidemiological profile of nPEP beneficiaries is that the vast majority (93%) are men, with an average age of 29.7 years; 38.8% did not use a condom; 9% have been diagnosed treated or have had symptoms of an STI; 2% have shared needles and syringes; 9% knew they had an HIV-positive sexual partner; of these, 61.5% are on ARV treatment and 42.3% have an undetectable viral load.

Conclusions: Of the total number of people who were tested for HIV in 2023, thanks to the access of nPEP in Kimirina services, prevented 8.5 people per thousand from getting HIV. The hybrid care modality was innovative and has allowed greater coverage for the initiation of treatment and linkage of these people to prevention programs such as pre-exposure prophylaxis.

OA1605

Are women interested in a nonhormonal Multipurpose Prevention Technology (MPT) vaginal ring? Results from a national online survey with US women

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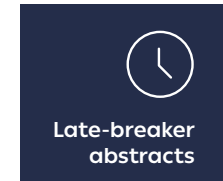
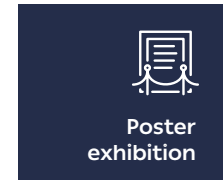
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Background: Many US women have an unmet need for/ are unsatisfied with their current pregnancy/HIV/STI prevention method(s). We assessed end-users' preferences to inform a novel non-hormonal multipurpose prevention technology vaginal ring (MPT-ring) for contraception and HIV/STI prevention in development, and to learn more about women's interest in vaginal rings – the most common form of MPTs in development.

Methods: We conducted a cross-sectional online survey with sexually active US women (Dec2023-Jan2024) currently/interested in using contraception, recruited via Prime Panels. We asked women about interest in a non-hormonal ring that prevents pregnancy, HIV, and STIs (at varying levels of protection); prevents bacterial vaginosis; and does not affect menstruation. We used multivariate logistic regression to examine factors associated with high product interest.

Results: 2,105 women completed the survey (mean age, 31 years; range 18-49) from all 50 states. 53% were married/cohabiting; 57% had ≥1 child; 43% ever had an unintended pregnancy. 61% said it is important their contracep-



tion be non-hormonal. 17% ever used a contraceptive ring (4% currently using). Most said they would be very likely (33%) or likely (40%) to use the MPT-ring at moderate levels of protection (80% for pregnancy, 50% for HIV/STIs); 76% would use it for both pregnancy and HIV/STI prevention. 33% would prefer using the ring continuously (its 1-month duration); 31% at each sex act; 36% intermittently (a few days/weeks at a time). 73% would remove it during menses. 71% of all participants felt confident about ring insertion/removal, but some were concerned about placement/expulsion (56%) and/or cleaning (47%). Being "very likely" to use the MPT-ring was associated with older age, having child(ren), perceived HIV risk, perceived STI risk, preference for nonhormonal contraception, history of heavy menses, and experience using a ring or knowing others who have. Among women unlikely to use the MPT-ring, reasons included happiness with their current method(s) (55%) and/or wanting higher pregnancy (42%) or HIV/STI (21%) effectiveness.

Conclusions: We found strong interest in a nonhormonal MPT-ring, with heterogeneity in use preferences (e.g., indication; regimen). Women most interested in this product were older, had children, perceived HIV/STI risk, preferred nonhormonal methods, and had experience with vaginal rings.

OA1606

An HIV-1 risk assessment tool for men aged 15-59 years: a pooled analysis across 13 nationally representative African surveys

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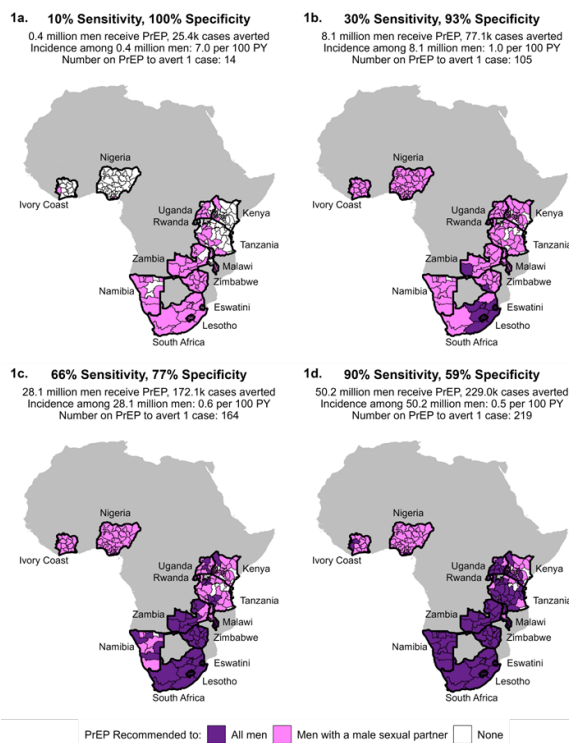
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Background: Southern, Eastern, and West African countries host 15% of the global population, yet account for more than half of new global HIV-1 acquisition events. Tools for identifying adults at greatest risk of HIV-1 can guide focused HIV prevention with pre-exposure prophylaxis (PrEP). Although considerable attention has been devoted to which women are most likely to acquire HIV-1, similar assessments are lacking in men. We sought to identify men at highest risk of HIV-1 and estimate potential PrEP reach and efficiency.

Methods: From 2015-2019, nationally representative surveys were conducted in Cote d'Ivoire, Eswatini, Kenya, Lesotho, Malawi, Namibia, Nigeria, Rwanda, South Africa,

Tanzania, Uganda, Zambia, and Zimbabwe. Lasso regression models were fit with 27 individual, partner, household, and epidemiologic variables to predict recent HIV-1 diagnosis among men 15-59 years. Models were trained and internally cross-validated. Performance was evaluated using area under the receiver-operating-characteristic curve (AUC), sensitivity, specificity, and number needed to treat (NNT).

Results: Among 167,121 participants, 112 had recent HIV-1, representing 122 million men and 256,000 new annual cases. Only two variables were retained: 1) living in a sub-national area with high prevalence of HIV-1 viremia (the product of adult HIV-1 prevalence and non-suppression among adults living with HIV) and 2) having a male sexual partner. Full-population AUC was moderately high (0.80); cross-validated AUC was slightly lower (0.76). When targeting a sensitivity of 33%, 8.1 million men were predicted to have an elevated risk of HIV-1 acquisition; NNT was 105. When sensitivity was 67%, 28.1 million men were predicted to have an elevated risk of HIV-1 acquisition; NNT was 164.



Conclusions: This parsimonious risk assessment tool was generalizable to the region and had good performance. Our findings emphasize the importance of offering PrEP in areas of highest population HIV-1 viremia and to men who have sex with men, with tradeoffs between reach and efficiency.



Social determinants and HIV vulnerability factors among men

OA1702

Money, jobs or schooling? A model-based evaluation of the potential health impact of economic strengthening in South Africa

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Background: High incidence rates of HIV, sexually transmitted infections (STIs) and teenage pregnancy are major challenges facing South Africa. The role of socio-economic drivers is complex, with high socio-economic status protecting against some risk behaviours (condomless sex, early sexual debut and casual/transactional sex in females) but increasing others (e.g. male engagement in transactional/commercial sex). Consequently, the impact of economic strengthening interventions is unclear.

Methods: We extended a previously-developed agent-based model of HIV, STIs and fertility in South Africa, to reflect effects of education, employment and per-capita household income on sexual behaviours. Effects were estimated from literature and from calibration of the model to African randomized controlled trials of economic strengthening interventions. Population attributable fractions (PAFs) were calculated. We considered three intervention types, targeting households with per-capita income below the national average: school support to reduce dropout; vocational training for unemployed adults; and unconditional cash transfers.

Results: Low socio-economic status accounted for 17% of new HIV infections, 12% of incident STIs (gonorrhoea, chlamydia and trichomoniasis) and 11% of teenage births in South Africa, over 2000-2020. However, because of uncertainties regarding effect sizes, confidence intervals around these PAFs were wide (-11-44%, -11-35% and 0-26% respectively), with uncertainty in the effect of education on condom use being the most significant correlate of the HIV PAF ($r=0.95$) and the effect of schooling on sexual debut being the most significant correlate of the teenage birth PAF ($r=0.79$).

	New HIV infections			New STIs			Births to
	Total	Males	Females	Total	Males	Females	teenage girls
School support	0.5%	-0.4%	1.1%	1.7%	1.6%	1.8%	1.6%
	(-2.8-3.9)	(-4.4-3.6)	(-2.0-4.2)	(-0.8-4.1)	(-0.9-4.1)	(-0.5-4.0)	(0.0-3.2)
Vocational training	2.2%	2.2%	2.2%	1.5%	1.5%	1.4%	0.4%
	(-4.1-8.5)	(-4.5-8.9)	(-4.0-8.2)	(-3.6-6.5)	(-3.8-6.8)	(-3.3-6.1)	(-5.3-6.1)
Cash transfers	1.1%	0.6%	1.5%	1.8%	1.8%	1.8%	0.7%
	(-4.4-6.7)	(-7.3-8.4)	(-3.0-6.0)	(-2.5-6.2)	(-2.7-6.4)	(-2.1-5.7)	(-2.3-3.7)

Over 2025-2040, vocational training would achieve the greatest reduction in HIV incidence (2.2%, 95% CI: -4.1-8.5%), cash transfers would achieve the greatest reduc-

tion in STI incidence (1.8%, 95% CI: -2.5-6.2%) and school support would achieve the greatest reduction in teenage births (1.6%, 95% CI: 0.0-3.2%).

Conclusions: Structural interventions to reduce poverty could modestly improve several reproductive health outcomes in South Africa. However, ambiguity regarding causal pathways precludes a precise quantification of impacts, and there is a small risk of negative outcomes.

OA1703

The role of identity worth, mistrust in science, PrEP stigma, and PrEP acceptability as a predictor of PrEP self-efficacy: a structural equation model

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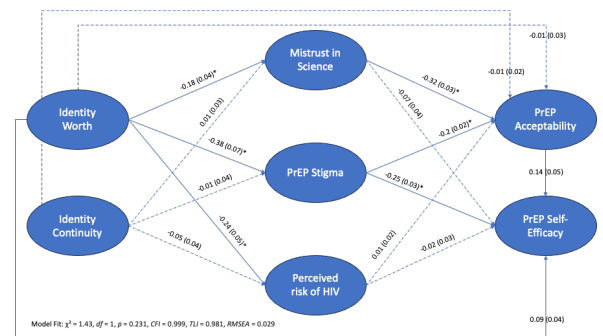
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Background: Pre-Exposure Prophylaxis (PrEP) is medication used to prevent the spread of Human Immunodeficiency Virus (HIV). Populations with increased need of HIV prevention (e.g., Men who Have Sex with Men (MSM)) are eligible for PrEP for free in the UK. However, HIV surveillance reports indicate stagnated uptake of the drug, alongside increasing rates of HIV acquisition. As such, psychosocial research is needed to explore social barriers to PrEP uptake.

This study aimed to explore the role of identity resilience as a predictor for PrEP usage. It was hypothesised that PrEP self-efficacy would be positively predicted by PrEP acceptability. This would be mediated by mistrust in science, PrEP stigma, and perceived risk of HIV.

Methods: 500 MSM participated in an online cross-sectional, psychometric study between June and September in 2023. Participants had to be based in the UK but could either be PrEP or Non-PrEP users. Structural Equation Modelling (SEM) was used to explore a model of best fit to test the hypotheses.

Results: A significant model was found. Model Fit: $\chi^2 = 1.43$, $df = 1$, $p = 0.231$, CFI = 0.999, TLI = 0.981, RMSEA = 0.029.



Conclusions: This model indicates the indirect effects of identity worth on PrEP acceptability and PrEP self-efficacy. Interestingly, identity continuity provides no predictive power amongst this sample of participants, nor does perceived risk of HIV (PRHS). This may indicate that

the decision to take PrEP is primarily associated with the constructs of identity worth (i.e., self-esteem, self-efficacy, and distinctiveness). Identity worth was positively associated with PrEP self-efficacy. The association of identity worth with predicting PrEP acceptability is mediated through mistrust of science and PrEP stigma.

When trying to develop interventions for PrEP uptake for those who feel efficacious at taking PrEP but are hesitant to take it, addressing specific parts of identity resilience may be beneficial.

OA1704

Group by time outcome differences from baseline to month 3: findings from a couples-based, HIV serostatus neutral digital intervention (P3) with 74 cisgender male couples in Lima, Peru

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Background: No efficacious, couples-based HIV serostatus neutral interventions exist for cisgender male couples in Lima. Epidemiological evidence estimates a significant proportion of sexual minority men acquire HIV from their primary sexual partners. In response, we developed and are currently evaluating a theoretically guided, couples-based, HIV serostatus neutral digital intervention to examine changes over time regarding communication, decision-making, and alignment of sexual agreements with using evidence-based HIV strategies (e.g., routine testing, PrEP, ART/U=U) (i.e., preliminary efficacy).

Methods: We conducted a 6-month, pilot randomized controlled trial with 74 cisgender, sexual minority male couples living in Lima. Assessments occurred every 3 months post baseline. A 3-month waitlist control condition was used to compare outcome differences between the two groups of couples over time (i.e., immediate intervention vs. waitlist).

We conducted generalized linear models (GLMs) to detect changes from baseline to month 3 between the two intervention conditions for individual-level outcomes regarding communication, decision-making, and alignment of sexual agreements with using evidence-based HIV strategies (e.g., routine testing, PrEP, ART/U=U).

Results: Output from the GLMs found significant improvements over time for the immediate intervention condition. Men's beliefs improved over time about whether their sexual agreement and its permitted behaviors matched their use of evidence-based HIV strategies ($b=0.27$, $SE=0.11$, $p=0.02$).

The same group of participants also believed this type of matching had improved over time for their primary partners ($b=0.22$, $SE=0.13$, $p=0.11$). Men communicating with their primary partners about having a detailed sexual

agreement and using evidence-based HIV strategies in their relationship also improved over time ($b=0.25$, $SE=0.13$, $p=0.05$). Lastly, men making decisions with their partners about having a detailed sexual agreement and using evidence-based HIV strategies in their relationship also improved over time ($b=0.30$, $SE=0.14$, $p=0.03$).

Similar types of improvements from baseline to month 3 were not observed among couples / partnered men in the waitlist intervention condition.

Conclusions: Compared to participants in the waitlist condition, our findings highlight important improvements among men in the immediate intervention condition.

These findings signal that couples in the immediate intervention condition are communicating and making decisions about their sexual agreements and what evidence-based HIV strategies to use in their relationship.

OA1705

Food and housing insecurity among cisgender men who have sex with men in the United States and associations with social, behavioral, and psychological HIV transmission vulnerabilities

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Background: Socio-economic disparities pose a critical challenge to preventing the transmission of HIV among key populations. This study investigates the prevalence of food and housing insecurity among cisgender men who have sex with men (MSM) in the United States and explores associations between these insecurities and social, behavioral, and psychological vulnerabilities related to HIV transmission.

Methods: We used cross-sectional data from 2021 American Men's Internet Survey (AMIS), an annual survey among MSM in the United States. Participants self-reported food and housing insecurity, substance use, condomless anal intercourse and transactional sex with male partners, STI diagnoses, and depression symptoms. Log-binomial regression was used to determine if the prevalence of HIV transmission vulnerabilities was associated with food and/or housing insecurity, adjusting for confounding by age, race/ethnicity, income, and HIV status.

Results: Among 9,061 MSM, the median age was 44 years (IQR=32-57), the majority were non-Hispanic white (65%) and had a college degree or higher education (62%), and 14% reported HIV positive status.

Additionally, 14% (1,213/8,979) reported any food insecurity, 7.5% (674/9,012) any housing insecurity, 3.8% (343/9,022) both food and housing insecurity, and 83% (7,425/8,969) neither insecurity in the past 12 months.



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Figure 1 depicts associations between food and housing insecurity and HIV transmission vulnerabilities. Insecurities were significantly associated with a higher prevalence of depression symptoms (PHQ-9 ≥ 10), as well as substance use, transactional sex, and an STI diagnosis in the past 12 months. Food insecurity was associated with a lower prevalence of disordered alcohol use (AUDIT-C ≥ 4).

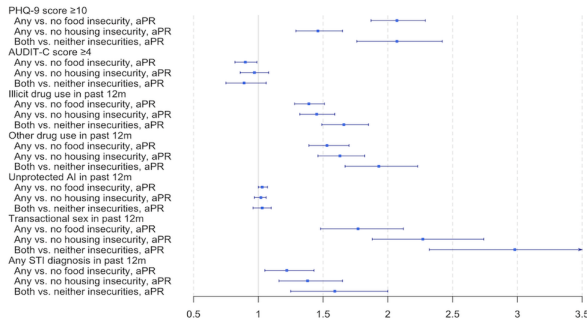


Figure 1. Forest plot for associations between food and housing insecurity and HIV transmission vulnerabilities. aPR = adjusted PR; AI = anal intercourse; other drug use = any drug use other than marijuana; models adjusted by age category, white vs. other race/ethnicity, income category, and HIV positive status

Conclusions: Our study reveals that US MSM have concerning prevalence of food and housing insecurity that is significantly associated with increased vulnerabilities to sexual health and mental health. Addressing these insecurities is critical to mitigating HIV transmission risks and improving overall health outcomes in this population. Future interventions should prioritize addressing socio-economic disparities to enhance HIV prevention efforts.

OA1706

Factors associated with retention and adherence on Pre-Exposure Prophylaxis among men who have sex with men in Kigali, Rwanda: a cross-sectional study

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Background: Pre-Exposure Prophylaxis (PrEP) is recommended as an HIV prevention measure for men who have sex with men (MSM). We assessed factors associated with PrEP retention and adherence among MSM in Kigali, Rwanda.

Methods: We undertook a cross-sectional study and used a questionnaire to obtain PrEP retention and adherence history from MSM enrolled that attended follow-up visits from four (4) health facilities between April 2021 to June 2021. We used multivariable cox regression to determine

factors associated with 3-month retention and principal component analysis (PCA) to determine factors associated with self-reported adherence. Data were analyzed using STATA (version 16.0).

Results: We interviewed 439 MSM aged 18 years and above that were initiated on PrEP. Majority were employed (57%, n=251), between ages 25-34 years (49%, n=217), close to half completed primary level education (47%, n=206), were involved in sex work (42%, n=184), and over a half lived in household of 1-2 members (55%, n=241). Ninety percent of the MSM respondents (n=393) were retained on PrEP at 3 months and among those retained, 287 (73%) had good adherence.

Multivariable cox regression revealed that MSM more likely to be retained on PrEP, were those that are sex workers (adjusted Hazard Ratio (aHR)=4.139; 95% Confidence Interval (95%CI): 1.569, 10.921), had more than one (1) regular sexual partners (aHR=3.949; 95%CI: 2.221, 7.022), lived in households of 3-5 members (aHR=3.755; 95%CI: 1.706, 8.261), completed secondary school education (aHR=2.154; 95%CI: 1.130, 4.108), and were circumcised (aHR=2.218, 95%CI: 1.232, 3.993).

Employed MSM had a 66% decreased likelihood to be retained on PrEP (aHR=0.345; 95%CI: 0.168, 0.707). Similarly, MSM that used condoms consistently had an 85% decreased likelihood to be retained on PrEP (aHR = 0.149; 95%CI: 0.035, 0.632).

Principal component regression analysis showed that the component with MSM with higher numbers of regular sexual partners had increased odds of adhering to PrEP (Crude Odds Ratio (cOR)=1.32; 95%CI: 1.144, 1.530).

Conclusions: Our study highlighted that MSM using PrEP as the main method of HIV prevention were more likely to be retained and adherent to PrEP. There is need to emphasize PrEP use alongside other HIV prevention methods like condoms.

Planet of the Apes: Learning immunogenicity from animal models

OA1802

Short-term combination immunotherapy with broadly neutralizing antibodies and CCR5 blockade mediates ART-free viral control in infant rhesus macaques

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Background: In 2022, there were 1.5 million children living with HIV (CLWH), only half of whom had access to antiretroviral therapy (ART). Even when ART is available, lifelong daily adherence can be challenging for CLWH, emphasizing the need for alternative strategies to durably suppress HIV replication. Here we evaluated whether a triple combination of early ART initiation with HIV broadly neutralizing antibodies (bNAbs) and the CCR5-blocking mAb Leronlimab could mediate virus clearance in simian-HIV (SHIV)-infected infant rhesus macaques.

Methods: A total of 16 four-week-old infant rhesus macaques were orally infected with SHIV-SF162P3 and placed into the following treatment groups, with all treatments beginning at 72 hours after infection: 1) ART + bolus doses of the bNAbs PGT121-LS and VRC07-523-LS (n=2), 2) ART + Leronlimab for 8 weeks (n=6), or 3) ART + bolus doses of the bNAbs PGT121-LS and VRC07-523-LS + Leronlimab for 8 weeks (n=8). ART was maintained for 27 weeks, at which time an analytical treatment interruption (ATI) was performed and the kinetics of virus rebound compared between the groups. Untreated infected infants (n=8) served as additional controls.

Results: Following ATI, both animals in group 1 (ART + bNAbs) rebounded rapidly, while 4/6 in group 2 (ART + Leronlimab) rebounded with viremia by week 10 post-ATI, with two remaining aviremic currently through week 20 week post-ATI. In contrast, 0/8 animals in group 3 (ART + bNAbs + Leronlimab) have rebounded at the time of abstract submission (15 weeks post ATI). Assessment of the viral reservoir is ongoing.

Conclusions: Finding a treatment that can prevent reservoir establishment and spread after the first 48 hours has been elusive. The results of this study suggest that the combination of ART, bNAbs, and CCR5 blockade via Leronlimab synergize in an undefined mechanism to prevent further seeding of of the reservoir early after infection, and may even permanently reduce it. Further studies are warranted to study this combinatorial effect in more detail.

OA1803

Induction of precursor CD4 binding-site targeting broadly neutralizing antibodies in infant macaques following immunization with germline-targeting SOSIP trimers

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Background: A vaccine that can establish protective immunity before sexual debut is crucial to prevent the estimated 410,000 new cases of HIV that occur annually among adolescents. The time between weaning and sexual debut is a period of relatively low risk for HIV acquisition, thus early childhood is an opportune window for implementation of a multi-dose HIV immunization strategy to elicit protective immunity prior to adolescence.

As the elicitation of bNAbs will be critical for an effective HIV vaccine, the goal of our study was to assess the ability of a B cell lineage-designed HIV envelope SOSIP to induce precursor CD4bs-targeting bNAbs in early life.

Methods: Infant rhesus macaques (RMs) received either the wild-type (WT) BG505 SOSIP or the CD4bs germline-targeting BG505 GT1.1 SOSIP (n=5/group) with the 3M-052-SE adjuvant at 0, 6, and 12 weeks of age. All infant RMs were then boosted with the WT BG505 SOSIP at weeks 26, 52 and 78, mimicking a pediatric immunization schedule of multiple vaccine boosts within the first two years of life.

Results: Both immunization strategies induced durable, high magnitude binding antibodies and plasma autologous virus neutralization. Most notably, three GT1.1-primed infants exhibited a plasma HIV neutralization signature reflective of VRC01-like CD4bs bnAb precursor development. Negative stain electron microscopy-based polyclonal epitope mapping (nsEMPEM) of IgG in plasma demonstrated that only GT1.1-primed infants developed plasma antibodies targeting the CD4bs.

High resolution CryoEMPEM mapping of polyclonal antibodies in one GT1.1-primed infant with the bnAb precursor signature, revealed N276 glycan accommodation of CD4bs-directed responses. In characterizing the GT1.1 vaccine-elicited B cell repertoire in the three infants exhibiting a CD4bs bnAb precursor response, we isolated one



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autologous virus neutralizing mAb with epitope specificity for the CD4bs and moderate heterologous virus neutralization activity.

Conclusions: Thus, a multi-dose immunization regimen with bnAb lineage designed SOSIPs is a promising strategy for implementation in early childhood, and the induction of early B cell responses with the potential to mature into protective HIV bnAbs prior to adolescence when sexual HIV exposure risk begins.

OA1804

Induction of V3 glycan-directed responses post CH848 gp160 mRNA-LNP vaccination in infant rhesus macaques

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Background: A major goal in a successful HIV vaccine is the induction of a broadly neutralizing antibody (bnAb) response. BNabs need years to develop in adults, whereas infants living with HIV induce bnAbs early and at higher frequency. We hypothesize that a multi-dose HIV vaccine started during infancy would allow for the necessary time to mature B cells towards the production of bnAbs and could be easily implemented by incorporation into the global pediatric vaccine program.

Methods: Six infant rhesus macaques (RMs) were intradermally immunized at weeks 12, 24, and 52 with the CH848 10.17DT gp160 mRNA-LNP priming immunogen (50 g), which lacks the N133 and N138T V1 glycans and can engage the unmutated common ancestor (UCA) of the DH270 V3 glycan bnAb lineage and boosted with 50 g CH848 10.17 wildtype (WT) gp160 mRNA-LNP, with the V1-glycans restored (wks 86, 90, 96). Tier 2 neutralizing antibodies and SOSIP trimer binding were measured and compared between the DT prime and WT boost vaccine regimen.

Results: Two weeks post 3rd DT priming immunization, all infants developed tier 2 autologous neutralizing ID₅₀ titers against the DT vaccine-matched pseudovirus, with a geometric mean ID50 titer (GMT) of (78,422 ± 6.41). Two infants showed a 3-fold decrease to the N332 glycan knockout pseudovirus in sera, indicating a potentially V3 glycan-directed response. CH848 V3-specific B cells were also detectable by flow cytometry.

Two weeks post 3rd WT boost, titers were maintained against the DT vaccine-matched pseudovirus (GMT ID50 44,237 ± 2.76), but the V3 glycan-directed neutralizing responses were no longer detectable in the sera. Nonetheless, 4 of 6 infants showed plasma antibody cross-reactivity to other Env trimers, especially to 92RW020, at 6 months post WT boost, although antibody binding was not dependent on the N332 glycan.

Conclusions: We plan to boost with heterologous 92RW020 mRNA-LNP to promote further antibody maturation and breadth. Our studies demonstrate that mRNA-LNP vaccines can induce V3 glycan-directed responses in infant RMs, but further optimization, specifically with the shaping boost immunogen, is needed to induce precursors to bnAbs.

OA1805

Immunogenicity of HIV BG505 germline-targeting GT1.1 SOSIP envelope trimer immunization in infant and juvenile rhesus macaques

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Background: HIV is a highly mutable virus, therefore a vaccine that induces protective, broadly-neutralizing antibodies (bnAbs) before sexual debut is critical to eliminate the ~410,000 new cases annually among adolescents worldwide. Recent work has established that children living with HIV develop bnAbs earlier and at a higher frequency than adults.

In this study we compared the ability of a CD4 binding site (CD4bs) germline-targeting SOSIP trimer immunization strategy to induce precursor bnAbs in infant and juvenile rhesus macaques (RMs).

Methods: Infant (n=5) and juvenile (n=4) RMs received 3 immunizations of the germline-targeting BG505 GT1.1 SOSIP trimer (50ug) with the 3M-052-SE adjuvant 6 weeks apart. All RMs were then boosted 12 weeks later with the BG505.664 WT SOSIP trimer 3 times in 6-month intervals.

After an over one-year follow-up, all animals received two boosts with a mixed Clade B SOSIP nanoparticle. Vaccine-elicited antibody responses were monitored through 2.5 years after the 1st vaccination.

Results: BG505 GT1.1 SOSIP trimer immunization consistently induced higher magnitude vaccine-specific IgG binding and tier 1 neutralization responses in infants compared to juvenile RMs. Plasma tier 2 autologous virus neutralization responses were similar between the groups, yet nsEMPEM demonstrated that the infant response generally targeted more epitopes. Notably, after the 5th immunization, three of five GT1.1 SOSIP-immunized infants exhibited a plasma neutralization signature indicating CD4bs bnAb precursor development, compared to only one of four juvenile RMs.

Additionally at this time, two infants and one juvenile exhibited low level heterologous tier 2 virus neutralization activity. By week 150, two weeks post-2nd nanoparticle boost, an additional infant developed the CD4bs precursor bnAb signature, whereas and this response was not maintained in the one juvenile. Nanoparticle boosting also improved the breadth of heterologous neutralization in 4 out of the 5 infants and 2 out of the 4 juveniles.

Conclusions: Our data indicates that sequential immunization with germline-targeting BG505 SOSIP trimers may induce neutralizing antibodies and CD4bs bnAb precursors more frequently in infant compared to juvenile. Our results highlight the potential for an HIV immunization strategy in early life to induce protective bnAb responses and can inform approaches for future human pediatric clinical trials.

OA1806

Anti-SIV Env RhmAbs +/- CD8a depletion and N-803 in ART-suppressed rhesus macaques leads to post-treatment control of viremia associated with transcriptomic changes in CD8+ and CD4+ T cells

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Background: Building upon robust latency reversal seen after CD8a-depletion and IL-15 superagonist treatment in SIV-infected, ART-suppressed rhesus macaques (RMs), here we combined these agents with four rhesus-derived anti-SIV Env-specific rhesus IgG1 monoclonal antibodies (RhmAbs) with the goal to reduce reservoirs and/or modulate viral rebound dynamics after ART interruption.

Methods: 28 RMs were infected with SIV_{mac239}; ART was initiated 8 weeks post-infection. Groups were assigned after 96-weeks on-ART: Group 1 (n=7): ART-only; Group 2 (n=7):

ART+RhmAbs; Group 3 (n=14): ART+RhmAbs+CD8a-depletion+N-803. Analytical treatment interruption (ATI) of ART was performed when SIV RhmAb were no longer detected (for 3/4 RhmAbs) or well below the IC90 (for 1/4 RhmAbs).

Results: Latency reversal (defined as on-ART viremia >60 copies/ml) was achieved in 11/14 Group 3 RMs versus 0/14 Group 1+2 RMs. Median CD4+ T cell-associated SIV-DNA and intact provirus levels were lower post- versus pre-intervention in all Groups, with the greatest change seen in Group 3 RMs (p<0.0001 for both reservoir measures in blood; p=0.0003 and p<0.0001 for total and intact SIV-DNA in lymph nodes, respectively).

By ATI day 21, all RMs rebounded to >60 copies/ml with no intergroup difference in time-to-rebound. A greater fold reduction in viral setpoint 3 months post-ATI compared to pre-ART was seen in Group 2 (p=0.018) and Group 3 (p<0.008), but not Group 1. Post-treatment viral control off-ART (PTC, defined as ≥3 consecutive viral loads <10³ copies/ml) was observed in 8 RMs from Groups 2 and 3 and none from Group 1.

Transcriptomic analyses revealed a post-intervention increase in immune activation and metabolism pathways in CD8+ T cells from RMs with PTC. CD4+ T cells from RMs with PTC had increased interferon pathway and decreased TGFbeta signaling genes post-intervention. Similar changes were not found in RMs with typical rebound viremia.

Conclusions: Time-to-viral-rebound was not impacted by SIV RhmAbs+CD8a-depletion+N-803 despite robust latency reversal and evidence of reduced infected cell levels. PTC was observed only in animals receiving SIV RhmAbs and SIV RhmAbs+CD8a-depletion+N-803, likely explained by treatment-induced changes in the T cell transcriptome towards an activated and antiviral state.



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Leveraging technology to accelerate testing and prevention

OA1902

Mission (NOT) impossible: digital intelligence guided care cascade management to eliminate mother to child transmission of HIV. Results from Ahana project supported by The Global Fund 13 states of India

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Background: Evidence suggests access to HIV testing remained low at 36% in the 13 Plan India project states during 2016-17 with an estimated annual pregnancy of 14 million (48% of total in the country) per year. Complementing Govt. of India's EMTCT of HIV strategy, Plan India has been implementing Ahana project supported by The Global Fund towards attaining Elimination of Mother to Child Transmission in 13 priority states of India.

Methods: Care cascade monitoring and management has been guided through a digitally operated intelligent approach:

1. A digital MIS application has been developed,
2. All 330 field workers have been provided with tablets to:
 - a. Manage and monitor early identification and linkages to ART treatment,
 - b. Follow-up of PPWs with care and support services towards drug adherence through digitally guided intelligence,
 - c. Due management and proofing of leakages to ensure viral suppression.

Results: With expansion in the PMTCT service coverage, HIV testing among pregnant women increased from 36% during 2016-17 to 89% during 2022-23 resulted in increasing identification of HIV positive pregnant women. More than 25,000 pregnant women identified as HIV positive during April-16 to Sept, 23 were linked to ART. Linkage to ART services improved from 86% during 2016-17 to 99.7% during 22-23. Institutional deliveries among PPW increased from 90% during 2016-17 to more than 94% in April- Dec, 23. While linkages of HIV exposed infants with EID services within 60 days improved from 55% during 2016-17 to 90% in 22-23, HIV testing among spouses of PPWs increased from 74% during 2018-19 to 97% during 22-23. More than 87% babies followed up till 18 months and 13 thousand babies confirmed as negative at confirmatory testing.

Conclusions: The result suggests that digitally guided outreach has enabled to early linkages to treatment, follow up for adherence and management of EID algorithm. Intelligence guided prioritization enabled successful due management and improved cascade. Plan India's Ahana project shows the application of digital platform and intelligence guided cascade management as an effective tool in the journey to achieve EMTCT.

OA1903

Findings from the Todurujo na Kadurok (Empowering Youth) HIV self-testing and edutainment comic randomized controlled trial with refugee youth in a humanitarian setting in Uganda

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Background: HIV vulnerabilities among refugee youth are shaped by structural and social factors in humanitarian settings that constrain access to HIV prevention and testing. Although HIV self-testing (HIV-ST) is particularly promising among youth, humanitarian contexts are underserved by HIV-ST. Comic books, a form of graphic medicine whereby images are juxtaposed by text reflecting internal and external narratives to share health information (known as 'edutainment'), are understudied in the context of HIV-ST. Uganda is African's largest refugee hosting nation with over 1.5 million refugees.

We evaluated the effectiveness of HIVST and edutainment comics in increasing HIV testing with refugee youth in Bidi Bidi refugee settlement, Uganda.

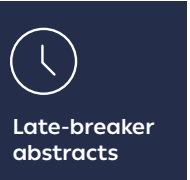
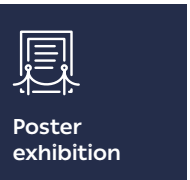
Methods: We conducted a qualitative formative phase with focus groups with refugee youth to create an edutainment comic about HIV testing barriers and facilitators in Bidi Bidi. We then conducted a randomized controlled trial in Bidi Bidi with a purposive sample of refugee youth aged 16-24.

Arms included:

1. HIV-ST;
2. Comics;
3. HIV-ST with comics; and,
4. Standard of care (SOC).

Intervention effects on primary (HIV testing uptake) and secondary (e.g., HIV knowledge) outcomes at 3-month follow-up (T2) were assessed using generalized estimating equation (GEE) models.

Results: There was 98% retention (n=117/120) of participants (n=120; mean age: 20, standard deviation: 2.3) at T2. In adjusted analyses, in comparison with the SOC at T2, HIV testing odds were highest in Arm 3 (adjusted odds ratio [aOR]: 8.46; 95% confidence interval [CI]: 2.87-24.97) followed by Arm 2 (aOR: 4.14; 95%CI: 1.58-10.87), with no significant differences with Arm 1 (aOR: 2.81; 95%CI: 0.96-8.16). Arm 1 at T2 reported lower HIV-related stigma (ab: - 0.95, 95%CI: -1.9, -0.03), reduced condom use at last sex (aOR: 0.21, 95%CI: 0.07-0.65), and lower consistent condom use compared to the SOC (aOR: 0.010, 95%CI: 0.02-0.58). In secondary analyses including all participants, there were statistically significant T1 to T2 increases in HIV testing



(aOR: 21.79; 95%CI: 4.57-103.93), HIV knowledge (ab: 1.45; 95%CI: 0.93-1.97; p<0.001), and safer sex efficacy (ab: 3.64; 95%CI: 2.09-5.19; p<0.001).

Conclusions: HIV self-testing is feasible with youth in a Ugandan refugee settlement and can be supplemented with edutainment comics to advance HIV prevention.

OA1904

Use of WhatsApp chatbot Technology to support effective use of HIV Self-testing among men and young adults in the private sector in Kenya

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Background: The evolution of social media has impacted health programs in unique ways. A lot of people have access to and use various social media differently. WhatsApp has 2 billion users making it the most popular app in over 100 countries including Kenya. This paper seeks to illustrate the role of a digital counselor (WhatsApp chatbot) in promoting the effective use of HIV self-testing (HIVST) kits in Kenya.

Methods: PS Kenya developed a WhatsApp chatbot to promote access to HIVST information and products. The chatbot content was reviewed by the target audience to make it desirable. 120 pharmacists were trained to support HIVST users in land on chatbot and access information. We conducted pharmacy activations where trained sales agents engaged HIVST users on the chatbot. Clients landing on the chatbot were assisted to register and access the main menu with information on where to find HIVST kits, how to test, HIVST self-reporting, and risk assessments. The client's data were captured electronically as they navigated the chatbot and analyzed.

Results: Out of 722 clients who landed on the WhatsApp chatbot, 384 (53.2%) were male, 283 (39.2%) were females, and 55 (7.6%) did not reveal their identity in the 10-month time. 83.5% (603) of the chatbot users were aged 16-30 years while 16.5% of the users were people above 30 years. 170 of the users reported having never tested for HIV while 230 mentioned having tested more than 12 months ago with the rest of the users tested with thin the last 12 months. Of the total users who landed on the chatbot, 386 (53.5%) wanted to find HIVST kits while 344 (47.6%) reported to have performed HIVST screening. On the self-reporting menu, 697 (96.5%) users reported to have not tested before using the chatbot while 73 (10.1%) reported to have accessed HIVST kits before. On whether the test results were reactive, 36 users reported positive results while 17 users reported to have conducted confirmatory testing at a facility indicated on the chatbot.

Conclusions: WhatsApp Chatbot is a viable solution in promoting the effective use of HIVST kits among young people hence sustaining HIV prevention programs globally.

OA1905

Home based STI self-testing and diagnosis to trigger PrEP restart among adolescent girls and young women in South Africa

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Background: Intermittent adherence and poor persistence on oral pre-exposure prophylaxis (PrEP) for HIV prevention are common among adolescent girls and young women (AGYW). Discrete mechanisms for AGYW to accurately self-identify periods of heightened risk and trigger PrEP initiation are lacking.

We report on preliminary effectiveness of home-based STI self-testing and a self-administered behavioral risk tool to trigger PrEP restart.

Methods: PALESA, a pilot randomized controlled trial, was launched in June 2023 at a clinical research site in Johannesburg, South Africa and is due for completion in June 2024. HIV-negative, non-pregnant, sexually active, cisgender AGYW, aged 16-18 years who previously used PrEP with discontinuation within the last 6 months were enrolled and randomized to one of two study arms:

1. STI self-testing (using the Visby Medical Sexual Health Test) coupled with a self-administered behavioral risk tool and;
2. Self-administered behavioral risk tool only.

Participants were followed for six months through a combination of virtual (Months 1, 2, 4, and 5) and in-person visits (Months 3 and 6) to collect data on sexual behavior and experiences with the STI self-testing kits, and self-administered behavioral risk assessment. We used a negative binomial model to compare PrEP restart between study arms at 3 months.

Results: Of 55 AGYW enrolled in PALESA (median age=18; IQR 17-18), 25.5% reported never using condoms with their current partner and 45.5% reported inconsistent condom use. During the first 3 months of follow up, *Chlamydia trachomatis* was diagnosed in 39.3% in the self-testing arm and 33.3% in the comparator arm and *Neisseria gonorrhoeae* was diagnosed among 10.7% in the self-testing arm and 11.1% in the comparator arm. By 3 months of study follow-up, 71.4% of participants in the STI self-testing arm and 44.4% in the comparator arm restarted oral PrEP use (adjusted RR 2.27, 95% CI 0.98-5.24).

Conclusions: In this pilot study to collect preliminary data on novel tools to trigger PrEP re-start among AGYW, STI self-testing may have a higher impact on PrEP restart.





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Further research with a larger cohort is warranted to confirm these findings and further explore the potential for STI self-testing to impact PrEP use in AGYW.

OA1906

Scaling up HIV self testing through different distribution channels in Myanmar

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Background: Myanmar is one of 35 countries accounting for 90% of global new HIV acquisitions with concentrated epidemic among key populations (KPs). HIV testing coverage was 31% among men having sex with men (MSM), 41% among Female Sex Workers (FSW), and 28% among People Who Inject Drugs (PWID). Access to HIV testing is impeded by ongoing political unrest, limited public health sector, movement restrictions, and armed conflicts.

The study was done to demonstrate the feasibility of HIV Self-Testing (HIVST) distribution through different channels using client-centered approaches.

Methods: From May 2022 to Dec 2023, the program distributed HIVST in 3 States and Regions through the multi-level strategy that included 5 KP-led CSOs at the community level, 3 implementing partners at the facility level, and online through the Facebook chatbot linked with 16 private pharmacies. A descriptive analysis of the distribution data was done.

Results: 4261 HIVST were distributed through 3 channels. 98% (n=4174) of HIVST were received by KPs including 2727 MSM, 178 TGW, 823 SW, and 446 PWID. The result return rate was 97% (n=4137): 100% (n=2687) with the facility, 98% (n=1156) with the community, and 76% (n=294) with online. The reactive rate was 4% (n=156): 3% (n=81) with facility, 7% (n=69) with community, and 2% (n=6) with online. 156 HIVST were reactive, 86 of them received confirmation testing and received ART, and 172 received PrEP. 330 KPs used HIVST for index testing with a reactive rate of 5% (n=15) and 1385 KPs were used for PrEP follow-up. 2876 case-finding HIVST (excluding PrEP follow-up) distributed: 49% (n=1415) with facility, 38% (n=1080) with community, and 13% (n=381) with online.

Reactive rate of case-finding HIVST was 5% (n=141): 6% (n=78) with facility, 6% (n=57) with community, and 2% (n=6) with online. 1871 (47%) first-time testers and 1005 (53%) subsequent testers received case-finding HIVST with reactive rates of 6% (n=106) and 3% (n=35).

Conclusions: HIVST can be scaled up in Myanmar through three distribution channels: facility, community, and online. This approach can help the country achieve the first 95 targets by reaching more KPs with HIV testing services. Access to HIV self-tests (HIVST) can also increase demand for PrEP and other HIV services among KPs.

Tailored approaches to improve PrEP uptake and persistence

OA2002

PrEP uptake and adherence among transgender women: findings from a randomized clinical trial of a multicomponent intervention (HPTN 091)

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Background: Transgender women (TW) have the highest HIV prevalence of any key population, yet experience sub-optimal PrEP engagement. HPTN 091 assessed a novel, multicomponent, integrated service delivery strategy to enhance daily oral PrEP uptake and adherence.

Methods: The study enrolled 303 TW, ≥18 years, at 4 US sites (Houston, New York, Philadelphia, San Francisco) and 1 Brazil site (Rio de Janeiro). Participants were randomized 1:1 to Immediate (IA) or Deferred Arms (DA). All were offered Truvada® or Descovy®. The IA was offered co-located gender-affirming hormone therapy (GAHT) and 6 structured peer health navigation (PHN) sessions after enrollment, while the DA was linked to external GAHT until transition to IA interventions at week 26. Socio-behavioral surveys and biomarkers were collected at baseline and week 26. PrEP adherence was assessed via intraerythrocytic tenofovir diphosphate (TFV-DP) concentrations. PHN implementation was assessed via focus group discussions (FGDs) with all 8 peer navigators.

Results: Median age at enrollment was 28 years (IQR: 25-35). Over half (54%) identified as Hispanic/Latina; 31% Black, 35% White, and 28% another race. At enrollment, 11% and 42% reported ongoing PrEP and GAHT use, re-

spectively, with no difference by arm. Acceptance of study-provided PrEP at enrollment was 73% (71% IA, 75% DA). 99% in the IA completed ≥ 1 PHN session (median: 6 sessions). At week 26, retention was similar across arms (85% IA, 89% DA). PrEP uptake (IA 86%, DA 88%, $p=0.65$) and adherence (IA 44%, DA 48%, $p=0.48$) rates were similar between arms based on drug concentrations consistent with ≥ 4 doses/week.

The frequency of quantifiable TFV-DP concentrations was comparable across arms (IA 70%, DA 76%, $p=0.25$). While structured PHN sessions were limited to the IA, FGDs indicated that PHNs provided psychosocial support and referrals regardless of arm.

Conclusions: PrEP engagement was high among all participants, likely due to peer support and referrals to needed services in both study arms. Co-location of PrEP/GAHT with structured PHN sessions was not associated with higher PrEP uptake nor adherence.

Findings highlight the flexibility available to PrEP programs to co-locate PrEP/GAHT or facilitate access to external GAHT to promote PrEP engagement in the context of peer support for TW.

OA2003

Acceptability of semiannual HIV pre-exposure prophylaxis (PrEP) dispensing with interim HIV self-testing for streamlined PrEP delivery in Kenya

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Background: In Africa, the delivery of oral HIV pre-exposure prophylaxis (PrEP) within already strained public health facilities has resulted in prolonged waiting times and suboptimal experiences for clients.

We sought to explore the acceptability of dispensing PrEP semiannually supported with interim HIV self-testing (HIVST) versus quarterly to optimize clinic-delivered PrEP services.

Methods: We conducted a qualitative study within a randomized controlled trial testing the effect of six-months PrEP dispensing supported with interim HIVST (semiannual clinic visits) compared to the standard three-months PrEP dispensing (quarterly visits) on PrEP clinical outcomes in Kenya (NCT03593629).

Eligible participants were ≥ 18 years, refilling PrEP for the first time, and were either in an HIV sero-different couple (men and women) or singly enrolled (women). We conducted serial in-depth interviews (IDIs) with participants

in the intervention arm at enrolment, six months, and 12 months. We applied thematic analyses of participants' perceptions of the intervention and mapped themes to acceptability constructs outlined in the Theoretical Framework of Acceptability (TFA).

Results: Between May 2018 and June 2021, 55 participants completed 120 serial IDIs; 64% (35/55) of participants were in sero-different couples, 64% (35/55) were women, and the median age was 32 years (IQR 27-40 years). Overall, participants perceived this novel PrEP delivery model as highly acceptable; it was well-liked (TFA: affective attitude) and less burdensome than the standard quarterly PrEP refill visits (TFA: burden).

Participants also valued the increased privacy and confidentiality that came with HIV testing at home (TFA: ethicality) and were confident in their ability to participate in the intervention (TFA: self-efficacy).

Some participants, however, highlighted potential disadvantages of the model, including fewer opportunities for counselling with providers and potentially less accurate HIV testing (TFA: opportunity costs). Ultimately, most participants reported that the intervention allowed them to achieve their HIV prevention goals (TFA: perceived effectiveness) and discussed increased confidence in HIVST and PrEP use after each visit.

Conclusions: Semiannual PrEP clinic visits supported with six-months dispensing and interim HIVST was perceived as highly acceptable among PrEP users who experienced the intervention in Kenya. More comprehensive pre-intervention counselling and HIV self-test training may help address the concerns presented.

OA2004

Integrating strengths from various sources through a digital health platform: an online-to-offline service model for PrEP

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Background: Over the last decade, global evidence has shown PrEP's high efficacy, reducing HIV acquisition risk by over 90% in MSM. China approved TDF/FTC for PrEP in 2020. However, PrEP services, primarily in HIV ART hospitals, face low utilization due to complex clinic procedures and limited LGBT friendliness. In Guangzhou, a prominent city in China, the proportion of MSM seeking PrEP services in 2022 was merely 4.9% compared to PEP cases in these HIV ART hospitals, emphasizing the need for convenient, LGBT-friendly, and complementary services.

Methods: The HIV digital health platform ("Chabei"), developed by our team, serves as a central hub connecting organizations to create an online-offline PrEP service model. Initially, LGBT community-based organizations (CBOs) provide online/offline MSM-friendly consultation and assessments. Guangzhou center for disease control



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and prevention, in collaboration with third-party testing facilities, conducts offline testing for HIV, HBV/HCV/STIs, and creatinine. Physicians familiar with ART medicines review, prescribe, and facilitate the delivery of PrEP medications to MSM through online medical platforms. Subsequent follow-up is managed by CBOs. The HIV digital health platform acts as a unified portal for online/offline services, integrating processes and data from different organizations to enhance efficiency, user experience, and data flow. Consultation, assessment, testing, and follow-up services are provided free of charge, with MSM responsible only for medication costs.

Results: Launched in Guangzhou in December 2021, our model provided PrEP consultations for 920 MSM by June 2023. Of them, 223 underwent pre-medication testing. 4 with positive HIV antibodies were unsuitable, and 6 with positive HBV antigen were referred. 27 had abnormal creatinine levels, but none precluded PrEP.

Ultimately, 207 MSM initiated PrEP, 3.6 times more than all HIV ART hospitals in Guangzhou. 99.5% percent opted for event-driven PrEP, with 50.7% in follow-up. No HIV seroconversions occurred.

Conclusions: Our model integrates strengths from various sources through the HIV digital health platform, combining online convenience with standardized, safe, and MSM-friendly procedures. It serves as a distinctive complement to HIV ART hospitals. The model enhances the applicability of PrEP and holds potential for adaptation in other Chinese cities. Subsequent stages will explore streamlined processes and adaptable follow-ups in line with WHO guidelines.

OA2005

Promoting access to combined HIV prevention services by mobile populations (truck drivers) using health hub vans equipped with virtual health platforms at Kasumbalesa border in Zambia

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Background: Kasumbalesa boarder is the busiest border of Zambia due to the volume of trucks transporting commodities from East, Central, and Southern Africa to the Democratic Republic of the Congo. Every day, between 1300 and 1500 long-haul trucks are cleared in both directions. Most of the time, truck drivers are stranded at the border and must wait in enormous lines to be cleared. Due to security issues and the distance to the health facilities, truck drivers who spend the most of their time on the road have difficult or no access to health care, particularly combined HIV prevention treatments.

Methods: In June 2023, the USAID DISCOVER-Health project implemented by JSI, introduced innovative health hub vans equipped with virtual health platforms to enhance mobile populations' (truck drivers') access to combined

HIV prevention services. The virtual health platform leverages technology to generate demand for combined HIV prevention services, while the health hub vans employ person-centered concepts by converting a modified Landcruiser into a mobile clinic. The virtual health platform supports multiple languages that are utilized by truck drivers. At the baseline and endline, quantitative data was gathered and analyzed using Microsoft Excel.

Results: Before the innovation, the data reveals that, out of the 32,753 new pre-exposure prophylaxis (PrEP) clients in Fiscal Year 2022, 0% were mobile population (truck drivers). Following the innovation, truck drivers accounted for 2749 (5%) of the 55,257 PrEP New clients by September of Fiscal Year 2023. By March 2024, 202174 condoms had been delivered, and 15,834 truck drivers had received various integrated HIV prevention messages and services, of which 6207 had accessed PrEP and 101 had accessed ART.

The mobile population's access to PrEP increased by 126% between September 2023 and March 2024. In the same period 2259 truck drivers accessed treatment for various sexually transmitted diseases as the service was integrated.

Conclusions: Health hub vehicles installed with virtual health platforms facilitated easier access to integrated HIV prevention services. The invention has thus been extended to key population such as female sex workers and other border regions like Sakania in Ndola. This innovation is recommended for mobile population.

OA2006

Uptake of pre-exposure prophylaxis among out-of-school girls aged 15-19

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Background: In Uganda, adolescents make up a quarter of the population, yet they encounter a multitude of challenges that hinder their well-being. Factors such as poverty, HIV/AIDS, early marriage, and limited educational opportunities significantly impact their lives. Notably, Adolescent girls bear a disproportionate HIV burden, accounting for two-thirds of new acquisitions.

Despite the increasing recognition of Pre-Exposure Prophylaxis (PrEP) as an effective tool in HIV prevention, there exists a substantial gap in understanding its accessibility and acceptance, particularly among those who are out of school.

Methods: This was a cross-sectional study involving 4,185 Adolescent Girls and Young Women (AGYW) aged 15 to 19 years who were enrolled in the DREAMS program between September 1st and February 30th, 2024 in Kampala Uganda. Information regarding socio-demographics, initiation of Pre-Exposure Prophylaxis (PrEP), and factors contributing to HIV risk was obtained from an electronic medical

records system. A root cause analysis was conducted to understand the factors underlying the low adoption of PrEP. Descriptive data analysis was performed using SPSS version 26.

Results: There was a low uptake of PrEP among adolescents aged 15-19 years, with only 2.9% (125) initiated on the regimen. Patterns of risky sexual behaviours were evident, with 45.6% (57) reporting irregular condom use, 10.4% (13) acknowledging multiple sex partners, and 32.0% (40) engaging in transactional sex. Additionally, a considerable proportion of adolescent girls, totalling 55.2% (69), were found to be sexually active. A root cause analysis revealed various concerns contributing to the low uptake of PrEP among girls, including challenges with pill size and dosing, fear of stigma due to packaging resembling antiretroviral medication, and side effects such as nausea and headaches.

Conclusions: Despite the majority of AGYWs being sexually active, the low uptake of PrEP persists. Overcoming barriers necessitates the development of youth-friendly formulations that address concerns related to pill size and dosing. Strategies aimed at mitigating stigma surrounding PrEP, including educational campaigns and community engagement to foster acceptance and uptake among adolescent girls. Additionally, healthcare providers should offer comprehensive information, counseling, and support to PrEP users to ensure optimal utilization and effectiveness of the intervention.

Policy and legal barriers to HIV services

OA2102

A descriptive analysis of rapid response social and legal support activities on HIV prevention service delivery among LGBTQI+ clients in Uganda following passage of the 2023 Anti-Homosexuality Act

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Background: Uganda's Anti-Homosexuality Act 2023 (AHA)—passed by Parliament on March 21, 2023 and largely upheld by the Constitutional Court on April 3, 2024—poses grave threats to HIV epidemic control and LGBTQI+ human rights. It stipulates harsh penalties for “homosexual behavior” and its “promotion,” ranging from 10 years up to the death penalty.

USAID/Uganda's HIV/TB team collaborated with the Democracy, Human Rights, and Governance team to co-fund and manage three Ugandan LGBTQI+-led AHA rapid emergency response support awards in May 2023, recognizing that structural determinants were likely to impact HIV prevention uptake and continuity among LGBTQI+ people.

Methods: We analyzed rapid response awards data (June 2023-February 2024), PEPFAR Key Population (KP) Tracker HIV dashboard data (March 2023-July 21, 2023), and triangulated it with USAID HIV partner reports for referrals to rapid response mechanisms to identify any trends.

Results: PEPFAR data demonstrates a sharp increase in human rights incidents among LGBTQI+ clients following the passage of AHA, with a decrease of up to 60% in HIV service uptake at 84 PEPFAR-supported KP drop-in centers during that same period. Emergency activities responded to 2,323 incidents, mostly among gay men or lesbians (62%) and transgender individuals (19%). The bulk of these incidents were eviction/forced relocation (42%), threats/discrimination (24%), and assault (17%). HIV prevention uptake among KPs largely rebounded to near normal levels beginning in June 2023. Data limitations prevent us from attributing HIV service delivery improvements solely to rapid response services, as USAID worked with the Ministry of Health (MOH), partners, and LGBTQI+ civil society to develop concurrent HIV service delivery adaptations, while the MOH issued a helpful June 5, 2023 circular calling for non-discriminatory client care in Ugandan health facilities regardless of sexual orientation.

Conclusions: Despite limitations, our analysis from Uganda suggests that working closely with LGBTQI+ leaders to provide emergency social and legal support, in combination with LGBTQI+-led HIV service delivery adaptations, is a critical strategy for maintaining HIV prevention service continuity among LGBTQI+ people in the six months following passage of anti-gay laws. These findings may inform policymakers in the rising number of African countries considering similar laws.



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OA2103

Hierarchical cluster analysis reveals a sub-group of persons who inject drugs living with HIV that are more likely to experience sub-optimal HIV care in Kenya

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Background: In Kenya, persons who inject drugs living with HIV (PWID-LH) struggle with suboptimal HIV care, defined as: >6 months without care, not on ART, or virally unsuppressed (>1000 copies/ml). PWID-LH are often referenced as a monolithic group, which overshadows underlying subgroups needing additional support. We conducted hierarchical cluster analyses (HCA) to subdivide a population of PWID-LH in Kenya and determined subgroups more likely to experience suboptimal HIV care.

Methods: Our analysis uses baseline data of 783 PWID-LH enrolled in an HIV cohort study from 2017 to 2021 in Nairobi and Coastal Kenya. Recruitment occurred through harm reduction organizations, with eligibility criteria: age ≥18 years, HIV-positive, and injected drugs (previous year). We conducted an HCA for men and women that included 66 variables spanning demographic, HIV risks, drug use, and violence. Logistic regression identified clusters of PWID-LH associated with HIV suboptimal care, adjusting for recruitment region.

Results: Of the 783 PWID-LH, nearly half were women (48.7%) and 33% experienced sub-optimal HIV care. Among men, the median age was 38 years (IQR: 33-44 years), most injected heroin (91%) multiple times per day (83%), and engaged in transactional sex (48%). Among women, the median age was 35 years (IQR: 30-40 years), most injected heroin (92%) multiple times per day (76%), and engaged in transactional sex (81%). HCA revealed four clusters among men, with no significant associations between clusters and suboptimal HIV care; however, HCA identified four clusters among women and showed a cluster of young women (Cluster 2) twice as likely to experience sub-optimal HIV care compared to a cluster of older women (Cluster 4) [AOR: 2.49; 95% CI: 1.21-5.13]. Women's cluster characteristics are presented (Table 1).

Clusters:	1 n=83 (21.8%)	2 n=85 (22.3%)	3 n=124 (32.5%)	4 n=89 (23.4%)
Demographics	Median age: 32 yrs Marital status: Single (54%) Marital status: Married (12%) Living w/ children (8%) Informal employment (12%) Informal illegal employment (55%) Unstable housing (16%) Temporary housing (8%) Living outside in open (11%) Reduced/mobility (10%)	Median age: 33 yrs Marital status: Single (74%) Marital status: Married (12%) Living w/ children (10%) Informal employment (21%) Informal illegal employment (7%) Unstable housing (17%) Temporary housing (9%) Living outside in open (7%) Reduced/mobility (13%)	Median age: 35 yrs Marital status: Single (87%) Marital status: Married (10%) Living w/ children (8%) Informal employment (29%) Informal illegal employment (8%) Unstable housing (11%) Temporary housing (9%) Living outside in open (8%) Reduced/mobility (12%)	Median Age: 39 yrs Marital status: Single (7%) Marital status: Married (12%) Living w/ children (84%) Informal employment (38%) Informal illegal employment (46%) Unstable housing (9%) Temporary housing (1%) Living outside in open (1%) Reduced/mobility (13%)
HIV	3+ HIV barriers to care (15%) Barrier to care: Cost (1%) Barrier to care: Transport (1%) Barrier to care: Admin (2%) Barrier to care: Stigma (8%) Poly substance use (6%) Concomitant drug use (4%) Personal CD4 (46%) Current methadone use (9%)	3+ HIV barriers to care (44%) Barrier to care: Cost (2%) Barrier to care: Transport (1%) Barrier to care: Admin (1%) Barrier to care: Stigma (8%) Poly substance use (9%) Concomitant drug use (4%) Personal CD4 (37%) Current methadone use (12%)	3+ HIV barriers to care (8%) Barrier to care: Cost (1%) Barrier to care: Transport (1%) Barrier to care: Admin (1%) Barrier to care: Stigma (8%) Poly substance use (5%) Concomitant drug use (2%) Personal CD4 (19%) Current methadone use (12%)	3+ HIV barriers to care (2%) Barrier to care: Cost (1%) Barrier to care: Transport (1%) Barrier to care: Admin (2%) Barrier to care: Stigma (8%) Poly substance use (5%) Concomitant drug use (1%) Personal CD4 (19%) Current methadone use (9%)
Injection drug use	3+ 4 years IDU (39%) IDU Location: Unshaded building (17%) Injected alone (26%) Rushed injection (48%) Shared needles (8%) MSP use partners (8%) MSP use solo (8%) No condom use during last sex (48%) Received gonorrhoea for sex (82%) Sex w/ PLWH (48%)	3+ 4 years IDU (42%) IDU Location: Unshaded building (9%) Injected alone (40%) Rushed injection (79%) Shared needles (13%) MSP use partners (10%) MSP use solo (10%) No condom use during last sex (60%) Received gonorrhoea for sex (49%) Sex w/ PLWH (21%)	3+ 4 years IDU (36%) IDU Location: Unshaded building (29%) Injected alone (39%) Rushed injection (45%) Shared needles (9%) MSP use partners (19%) MSP use solo (19%) No condom use during last sex (40%) Received gonorrhoea for sex (27%) Sex w/ PLWH (12%)	3+ 4 years IDU (42%) IDU Location: Unshaded building (9%) Injected alone (15%) Rushed injection (48%) Shared needles (9%) MSP use partners (18%) MSP use solo (17%) No condom use during last sex (33%) Received gonorrhoea for sex (82%) Sex w/ PLWH (43%)
Sexual Behaviors	Physical violence (12%) Sexual violence (1%) Fear for safety (8%)	Physical violence (17%) Sexual violence (8%) Fear for safety (11%)	Physical violence (28%) Sexual violence (7%) Fear for safety (11%)	Physical violence (26%) Sexual violence (8%) Fear for safety (7%)
Violence (past year)	1.64 (0.79-3.41)	2.40 (1.17-4.90)**	1.11 (0.59-2.11)	1.00 (Ref)
OR (95% CI)	1.88 (0.85-4.16)	2.49 (1.21-5.13)**	1.15 (0.60-2.18)	1.00 (Ref)
AOR (95% CI)				

Conclusions: HCA highlighted a subgroup of women more likely to experience suboptimal HIV care in Kenya, which is fundamental for developing tailored HIV prevention interventions.

OA2104

The transgender scorecard: ensuring representation in HIV prevention research

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Background: The field of HIV prevention research has begun to recognize transgender and gender-diverse (TGD) people as a key population in the global HIV response. Though limited, estimates suggest that global HIV incidence is 66 times higher for transgender women, 7 times higher for transgender men, and unknown for gender nonbinary people (relative to cisgender people). Despite these stark disparities, TGD people remain underrepresented in HIV research, resulting in a data desert for HIV prevention in TGD communities. To address the underrepresentation of TGD people in HIV prevention research, HANC and AVAC sought to design an evidence-based policy and advocacy tool to ensure that TGD people and priorities are considered in the design and implementation of all HIV prevention clinical trials.

Here we present the TGD Scorecard and findings from our analysis of TGD representation in HIV research over the past 35 years.

Methods: We undertook a project to synthesize global TGD HIV-related priorities into a series of scorecard indicators of TGD representation in HIV clinical trials. We then pilot-tested the Scorecard, assessing 41 milestone HIV studies that took place from 1991-2023. Source documents for this assessment included study protocols, study publications, and study records on clinicaltrials.gov.

Results: Only 12 out of the 41 studies in our analysis included TGD people. From 1991-2006, there was no TGD representation in milestone HIV trials. Out of the 174,944 participants in the 38 completed studies, less than 1% were TGD (n=1,663). Among the TGD participants that were in-

cluded, 90% were transgender women; transgender men and gender nonbinary participants represented only 3% and 7% of TGD participants, respectively. Only 6 studies reported the gender of participants in primary publications, and research systems to support TGD enrollment are underutilized.

Conclusions: Findings from our analysis of 41 milestone HIV clinical trials over the past 35 years confirm that TGD people remain underrepresented in HIV prevention research. Albeit, a trend toward greater inclusivity in recent years has been observed.

These findings support our recommendation to utilize our TGD Scorecard as a policy and advocacy tool by researchers and advocates alike to operationalize our commitment to TGD representation in HIV prevention research.

OA2105

Age of access policy reform needed for adolescents and PrEP in some sub-Saharan African countries

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Background: Adolescents are at increased risk of HIV acquisition, and account for 10% of all the new HIV infections in 2022. Pre-Exposure Prophylaxis (PrEP) is an effective prevention method that vastly reduces the risk of HIV acquisition among high-risk vulnerable populations. In this study, we examine national age of access (AOA) policies by evaluating if adolescents can access PrEP without parental consent.

Where inconsistent with WHO recommendations, such policies, guided by the legal definition of adulthood, curtail adolescents' sexual and reproductive rights, and risk limiting access to vital HIV services by requiring them to obtain consent from a parent or guardian.

Methods: The HIV Policy Lab, a collaboration between the O'Neill Institute for National and Global Health Law, UNAIDS, and the Global Network of People Living with HIV (GNP+) tracks the adoption status of 33 globally recommended laws and policies for 194 countries. To evaluate the Age of Access (AoA) for adolescents, we conducted a review of national policies to determine age restrictions on adolescents' access to PrEP without parental consent.

Results: In our preliminary analysis, we found relevant PrEP guidelines for 28/46 countries in sub-Saharan Africa (SSA).

In SSA, the region with the highest number of children and adolescents living with HIV (CALHIV), only 14/28 countries do not require parental consent for adolescents aged 12 years and above for PrEP. Among them, 65% (9/14) are PEPFAR-supported countries, 50% (7/14) also have optimal AOA guidelines for HIV testing, and 57% (8/14) also have optimal AOA guidelines for HIV treatment.

Out of the 28 countries where relevant guidelines were found: 4 (14%) require parental consent for individuals <15 years; two countries (7%) require parental consent for individuals <16 years, 3,5% (1/28) requires parental consent for individuals <17 years, 11% (3/28) require parental consent for individuals ≤18 years and 7% (2/28) lack age-specific parameters for access.

Conclusions: Countries still need to review and update their age consent policies to be in alignment with WHO testing guidelines for adolescents. Tracking and analyzing the age of consent policies should be considered an important part of expanding adolescents' access to HIV testing, prevention, and care services.

OA2106

Impact of public insurance expansion on equitable HIV pre-exposure prophylaxis (PrEP) coverage in the United States: a staggered differences-in-differences approach

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Background: Despite growing availability over the last decade, pre-exposure prophylaxis (PrEP) coverage in the United States (US) remains suboptimal and insufficient for population-level HIV incidence reductions. Beginning in 2014, through a provision in the Affordable Care Act, US states could elect to expand public insurance (Medicaid) coverage to low-income adults who were previously ineligible for this coverage.

We evaluated the impact of Medicaid expansion on state-level PrEP prescribing outcomes.

Methods: We abstracted HIV surveillance data from 50 US states (2012-2022) to assess the impact of Medicaid expansion on two state-level PrEP indicators: PrEP coverage (the number of individuals prescribed PrEP per 100,000 residents) and the PrEP-to-need ratio (PnR, the number of individuals prescribed PrEP per new HIV diagnoses). To quantify the effects of Medicaid expansion on state-level PrEP coverage and PnR, we used the Callaway-Sant'Anna differences-in-differences method for staggered policy adoption, accounting for state-level variations in the timing of Medicaid expansion. We assessed outcomes for the overall state population and across population strata (age, sex, race/ethnicity).

Results: We observed increases, albeit non-significant, in PrEP coverage attributable to Medicaid expansion (average treatment effect on treated states (ATT)=37.7, 95% confidence interval (CI): -25.4-100.7). Medicaid expansion was associated with significant increases in the PnR (ATT=4.45, CI: 2.45-6.45), with treatment effects growing over calendar time (Figure). In subgroup analy-



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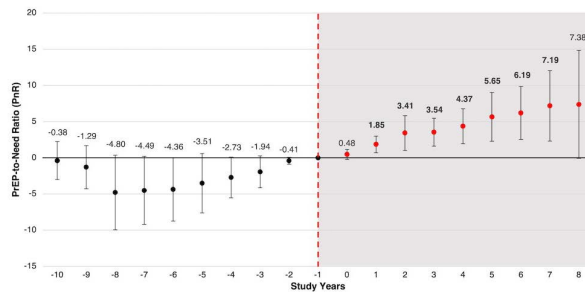


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ses, Medicaid expansion was associated with significant PnR increases across age strata and racial/ethnic groups (Black: ATT=1.54, CI: 0.24-2.85; Hispanic/Latinx: ATT=2.97, CI: 1.35-4.59; White: ATT=10.95, CI: 1.72-20.17), as well as among males (ATT=5.34, CI: 2.89-7.79).



Conclusions: Medicaid expansion was associated with a four-fold increase in state-level PnR, indicating public insurance expansion effectively increased PrEP access and initiations in populations with elevated risks of HIV acquisition. However, we observed differential impacts of Medicaid expansion by race/ethnicity, suggesting widening racial/ethnic PrEP disparities in the context of public insurance expansion.

Bringing out the Flora: Flora(I) impact on immune responses

OA2202

Linking host sensing of microbiota, inflammation and HIV acquisition in the female genital tract

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Background: Young women in sub-Saharan Africa bear a disproportionate burden of global HIV infection with 80% of HIV-infected women ages 15-24 years residing in this region. Previous studies have shown South African women with cervicovaginal microbial communities dominated by diverse anaerobes and low *Lactobacillus* abundance experience heightened genital inflammation and a four-fold increase in HIV acquisition rates. Certain species, such as *Prevotella bivia* (*P. bivia*) and *Sneathia sanguinegens* (*S. sanguinegens*), abundant in these diverse communities, correlate with upregulated inflammatory pathways in cervical antigen-presenting cells (APCs) and increased HIV acquisition risk in the female genital tract (FGT).

No animal models exist for studying bacteria-associated HIV infection in the FGT. Humanized mice, which reconstitute a human immune system, provide a platform for

this purpose. We hypothesized intravaginal inoculation of humanized mice with FGT bacteria could serve as a novel system to investigate genital inflammation and HIV risk.

Methods: Humanized mice were synchronized via sub-cutaneous progesterone injection, followed 5 and 7 days later by intravaginal inoculation with *Lactobacillus crispatus* (*L. crispatus*), *S. sanguinegens*, or *P. bivia*. Two days after the second bacterial inoculation, mice were intravaginally challenged with HIV. This cycle was repeated for 20 weeks, and HIV infection was analyzed via RT-PCR. Differences in infection rates were analyzed by Log-Rank test. Parallel experiments without HIV challenge analyzed local inflammatory cytokine concentrations in cervicovaginal lavages by Luminex and immune responses in the FGT using flow cytometry. Differences were analyzed using one-way ANOVA with Tukey's post-test.

Results: Intravaginal inoculation of humanized mice with *P. bivia* increased local concentrations of inflammatory cytokines and APC numbers compared to *L. crispatus*, while *S. sanguinegens* inoculation resulted in a non-significant increase in cytokine concentrations and APC numbers. Inflammatory cytokine concentrations positively correlated with cervicovaginal APC numbers. Inoculation with *P. bivia* significantly increased HIV infection rates in humanized mice ($p=0.039$) while *S. sanguinegens* drove a non-significant increase in HIV infection ($p=0.11$).

Conclusions: Intravaginal inoculation of humanized mice with genital bacteria induces inflammation and increased HIV infection. This system offers a novel *in vivo* model for modeling genital bacteria inflammation and evaluating potential interventions to prevent HIV infection in women.

OA2203

Inhibitory activity of lactic acid isomers against *L. iners* and BV-associated vaginal bacteria to prevent HIV transmission

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Background: In 2022, the global HIV burden remained high with women accounting for 46% of the 1.3 million new HIV infections (UNAIDS). Women with diverse, non-optimal vaginal microbiota, depletion of optimal lactobacilli and local inflammation, as exemplified by bacterial vaginosis (BV), are at increased risk of acquiring HIV. We have discovered that lactic acid (LA), a metabolite produced by Lactobacillus species, has potent immunobiological activities that may help protect women from acquiring HIV. The aim of this study was to investigate the bactericidal activity of LA isomers against vaginal bacteria.

Methods: To determine bactericidal activity, cultures of ~10⁶ colony forming units (CFU) of *L. iners* (ATCC 55195), *L. crispatus* (ATCC 33820) and *G.vaginalis* (ATCC 14018), and 4-5 different vaginal isolates from South African (SA) women (*L.crispatus*; and *L. iners* and *G.vaginalis* isolated from BV negative and BV positive women as determined by Nugent scoring), were treated with physiological levels of LA isomers 1% w/v (D-LA and L-LA) at different pH levels (3.8-7) at 37°C for 1h under anaerobic conditions. Cultures were then plated and viable bacteria quantified by determining CFU/ml. Bactericidal activity of LA isomers over time was investigated starting with cultures standard to 0.5 OD and propagated for 24 h with viable bacteria determined as above at different time points.

Results: Treatment with LA isomers for 1h showed similar selective bactericidal activity against *G. vaginalis* (50,000-fold reduction, n=3 p<0.0001) and *L. iners* (128-fold reduction, n=6, p=0.003) whereas *L. crispatus* (n=3, p>0.93) via-

bility was not affected compared to untreated bacteria. This activity was more potent than media at the same pH 3.8 indicating a LA-specific effect. A similar pattern was observed with primary SA isolates. LA isomers showed potent selective bactericidal activity over 24h against *G. vaginalis* and *L. iners* (>5,000 fold-reduction in CFU/ml) vs untreated controls while *L. crispatus* viability was not affected.

Conclusions: LA not only targets key BV-associated vaginal bacteria but also the less stable and suboptimal *L. iners*, which persists following metronidazole treatment of BV. These data reveal a potential antibiotic sparing strategy to promote colonisation with optimal lactobacilli as a potential intervention to prevent HIV acquisition.

OA2204

Reduced abundance of colonic CD4⁺ tissue resident memory T cells despite early initiation of ART is linked to systemic inflammation and changes in microbiota composition

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Background: HIV is primarily a disease of tissues, which are irreversibly damaged during acute HIV infection (AHI). CD4⁺ tissue resident memory T-cells (Trm) play an important role in mucosal homeostasis but may also be preferential targets of HIV infection.

Here we assess the impact of early initiated ART on mucosal CD4⁺ Trm in relation to systemic inflammation and the local microbiome.

Methods: A cross-sectional study was conducted in 16 people living without HIV (PWOH) and 35 people living with HIV (PWH), who initiated ART during early AHI (Fiebig (F) stage I to V) and were treated for ≥2 years. All participants underwent optional sigmoid colon biopsy. Mucosal immune phenotyping was carried out using flow-cytom-



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etry, with Trm defined as CD4⁺CD103⁺CD69⁺ and non-Trm as CD4⁺CD103⁻/CD69⁻. Soluble biomarkers were evaluated using ELISA and the mucosa-associated microbiome was assessed using 16s rRNA sequencing.

Results: Mucosal Trm had higher CCR5 expression compared to non-Trm (Trm: 81.7%, non-Trm: 38.4%; $p < 0.001$). In PWH, the frequency of total CD4⁺ T-cells was slightly reduced when ART was initiated during FI/II compared to PWOH (PWH: 44.8% vs PWOH: 48.9%; $p = 0.11$). However, if ART was initiated in FIII and later a significant decrease in CD4⁺ T-cells was observed (PWH: 40.4% vs PWOH: 48.9%; $p < 0.001$). Interestingly, the depletion was preferentially seen in Trm and was already observed when ART was initiated as early as FI/II (FI/II: 2.28% PWH vs 3.87% PWOH, $p = 0.03$; FIII-V: 2.39% PWH vs 3.87% PWOH, $p = 0.03$). No statistically significant difference was observed in the population of non-Trm. The frequency of Trm correlated inversely with plasma levels of Eotaxin-3 ($r = -0.46$, $p = 0.04$) and MDC ($r = -0.52$, $p = 0.02$).

Additionally, we observed a positive correlation between the frequency of Trm and the abundance of *Lachnospiraceae* ($r = 0.61$, $p = 0.01$), a taxa that plays a major role in mucosal barrier maintenance.

Conclusions: Overall, these data suggest that CD4⁺ Trm are preferentially depleted and/or not replenished, even if ART is initiated as early as FI/II. Trm depletion is associated with increased systemic inflammation and changes in the microbiota composition, which may be detrimental to mucosal barrier integrity. Future interventions to restore Trm may be warranted to limit systemic inflammation during ART.

OA2205

Impact of antimicrobials on foreskin HIV susceptibility, immunology and bacteria in uncircumcised men from Uganda: a randomized, open-label, phase I/II clinical trial

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Background: Bacteria Associated with Seroconversion, Immunology and Cells (BASIC species) may enhance penile HIV susceptibility in heterosexual uncircumcised men by inducing inflammatory cytokines that recruit HIV-sus-

ceptible CD4⁺ target cells to the inner foreskin. We performed a phase 1/2 clinical trial examining the impact of antimicrobials on *ex vivo* foreskin HIV susceptibility, penile immunology and BASIC species.

Methods: This randomized open label clinical trial allocated 125 HIV-uninfected Ugandan men seeking Voluntary Medical Male Circumcision (VMMC) to one of five arms (n=25): immediate VMMC (control group), oral tinidazole (TZ) for 2 days, or one of topical metronidazole (MTZ), topical clindamycin (CDM) or topical hydrogen peroxide (HP) twice daily for one week then biweekly until VMMC at 4 weeks.

The primary endpoint was *ex vivo* HIV pseudovirus entry into foreskin-derived CD4⁺ T cells.

Secondary endpoints were foreskin immune parameters, the preputial density of BASIC bacteria, and product tolerability.

Results: A total of 125 participants were enrolled and randomized; 116 (93%) completed the protocol. Demographics did not vary significantly between groups, and all antimicrobial treatments were well tolerated. Oral TZ and topical MTZ reduced the inner foreskin tissue density of HIV-susceptible CD4⁺ T cells. Oral TZ, topical MTZ and topical CDM also reduced the density of other key CD4⁺ T cell targets, including CCR5/CD4⁺ T cells and Th17 cells.

All topical antimicrobials reduced BASIC species and enhanced epithelial integrity; MTZ and CDM also reduced inflammatory cytokines in the prepuce. Changes in epithelial integrity and cytokines were strongly correlated with alterations in the abundance of BASIC bacteria.

Conclusions: This phase 1/2 randomized clinical trial provides the first proof-of-principle that antimicrobials can reduce *ex vivo* HIV entry into foreskin-derived T cells, reduce coronal sulcus inflammation, enhance foreskin epithelial integrity and reduce numerous T cell subsets in foreskin tissue. These effects were mediated via a reduction in BASIC species linked to HIV acquisition.

A more in-depth analysis of microbiome effects may guide specific agent selection for future clinical trials.

OA2206

Microbiota effects of a *Lactobacillus crispatus* live biotherapeutic to prevent recurrent bacterial vaginosis: findings from a randomized, placebo-controlled trial

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Background: Bacterial vaginosis (BV) affects $\geq 25\%$ of women globally and increases risk for HIV and other diseases. BV is characterized by pro-inflammatory, *Lactobacillus*-deficient vaginal microbiota and frequently recurs after standard treatment with metronidazole (MTZ).

A Phase 2b randomized, controlled trial found that Lactin-V, a live biotherapeutic product containing *Lactobacillus crispatus* strain CTV-05, significantly reduced recurrent BV (rBV) compared to placebo when administered after MTZ. However, efficacy was incomplete, with 39% of Lactin-V recipients developing rBV within 6 months.

We analyzed samples from the trial to assess microbiota and immune effects and correlates of treatment success.

Methods: The multi-center trial conducted in the USA enrolled premenopausal, non-pregnant women aged 18-45 years with BV (≥ 3 Amsel criteria and Nugent score ≥ 4). All received MTZ, then were randomized 2:1 to 11 weeks of intravaginal Lactin-V or placebo.

Vaginal swabs from 142 Lactin-V and 70 placebo recipients were collected pre-MTZ, post-MTZ (at randomization), and at 4, 8, 12, and 24 weeks post-randomization.

Microbiota composition, cytokines, and bacterial load were measured by sequencing, Luminex assay, and qPCR, respectively. CTV-05 strain percentage in metagenomes was estimated using StrainFacts, supported by bacterial isolations. Multi-block analyses of 'omic, clinical, behavioral, and demographic data provided weight-ranked correlates of treatment success.

Results: Lactin-V increased rates of high-level ($\geq 50\%$) *L. crispatus* colonization by 3.2-fold (95% CI: 1.3 - 7.7; Figure) at week 12 and by 4.4-fold (CI: 1.6 - 11.6) at week 24. CTV-05 colonization accounted for much of this effect, but $\sim 30\%$ of participants with high-level *L. crispatus* colonization at week 24 had a dominant strain other than CTV-05.

BV-associated cytokines including IL-1B, IL-1A, and TNFa decreased in both arms after MTZ, reverting to baseline by week 24 in the placebo but not the Lactin-V arm. *L. crispatus* colonization in Lactin-V recipients correlated pos-

itively with product adherence and inversely with post-MTZ total bacterial load, sexual activity, douching, lower education levels, and Black/African-American race.

Conclusions: An *L. crispatus* biotherapeutic improved BV treatment outcomes by enhancing high-level *L. crispatus* colonization. Identification of factors linked to treatment success suggests biological and behavioral targets to improve product efficacy.

PrEP in pregnancy and lactation

OA2302

Pregnancy and infant outcomes among individuals exposed to dapivirine ring during the first trimester of pregnancy in the MTN-025/HOPE open-label extension trial

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Background: Understanding the available safety data of the dapivirine vaginal ring (DVR) when used for HIV prevention during pregnancy is important to support expanded use of this PrEP method in this population.

Methods: Participants previously enrolled in MTN-020/ASPIRE were offered the DVR in the open-label extension study, MTN-025/HOPE. Participants were HIV negative, not pregnant or breastfeeding, and using an effective contraceptive with intention to continue use at enrollment. The DVR was provided monthly for the first three months, then quarterly thereafter. Participants could decline DVR and remain on study. Pregnancy testing was performed



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at all follow-up visits and DVR discontinued on awareness of pregnancy. We describe the incident pregnancies in MTN-025/HOPE and their outcomes.

Results: There were 70 participants with at least one pregnancy among 1,456 participants enrolled in MTN-025/HOPE over 1,402 person-years (5.0 pregnancies/100 person-years). One participant was excluded from the incidence calculation for being pregnant at enrollment and one became pregnant twice. The median gestational age at the time of positive pregnancy test was 45 days (IQR: 30, 64) based on estimated date of delivery (EDD). Of 72 total pregnancies, 59 (82%) had potential for exposure to DVR. Seventy pregnancy outcomes had data available, including one multiple gestation (twins). Adverse pregnancy outcomes were uncommon, did not differ based on potential DVR exposure, and were similar to those observed in MTN-020/ASPIRE (Table 1).

Four cases (6%) of gestational hypertension were observed; there were no other pregnancy complications reported. The median birthweight of infants was 3.3kg (IQR: 2.8, 3.7), with 5 babies weighting <2.5kg (11%), and no congenital anomalies.

Pregnancy outcomes*	MTN-020/ASPIRE [†]			MTN-025/HOPE		
	Placebo (N=94)	DVR (N=87)	All (N=181)	No DVR (N=12)	DVR (N=58)	All (N=70)
Full term birth (≥37 weeks)	53 (56%)	52 (60%)	105 (58%)	8 (67%)	36 (62%)	44 (63%)
Preterm birth (<37 weeks)	9 (10%)	0 (0%)	9 (5%)	0 (0%)	3 (5%)	3 (4%)
Stillbirth/intrauterine fetal demise (≥20 weeks)	2 (2%)	2 (2%)	4 (2%)	0 (0%)	3 (5%)	3 (4%)
Spontaneous abortion (<20 weeks)	21 (22%)	18 (21%)	39 (22%)	3 (25%)	11 (19%)	14 (20%)
Therapeutic/elective abortion	8 (9%)	14 (16%)	22 (12%)	1 (8%)	5 (9%)	6 (9%)
Ectopic pregnancy	1 (1%)	1 (1%)	2 (1%)	0 (0%)	0 (0%)	0 (0%)

*In ASPIRE, 175 pregnancies resulted in a single outcome, 3 pregnancies resulted in two outcomes (twins), and 1 pregnancy had no outcome available, resulting in a total of 181 pregnancy outcomes. In HOPE, 68 pregnancies resulted in a single outcome, 1 pregnancy resulted in two outcomes (twins), 3 pregnancies had no outcome available, resulting in a total of 70 pregnancy outcomes.

[1] Makanani B, Balkus JE, Jiao Y, et al. Pregnancy and Infant Outcomes Among Women Using the Dapivirine Vaginal Ring in Early Pregnancy. *J Acquir Immune Defic Syndr*. 2018;79(5):566-572.

Table 1: Pregnancy Outcomes in MTN-025/HOPE Compared to MTN-020/ASPIRE.

Conclusions: There were no notable adverse effects on pregnancy or infant outcomes observed when DVR was used during early pregnancy. These findings add to the growing evidence that the DVR is safe to use throughout pregnancy (Bunge 2024, Mhlanga 2024).

OA2303

Motivations of pregnant women initiating PrEP within antenatal care enrolled in a randomized trial to improve adherence: the mWACH-PrEP study

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Background: The mWACH-PrEP study (NCT04472884) is an RCT evaluating an interactive text messaging platform to improve adherence among women initiating PrEP during routine antenatal care at 5 clinics in Kenya. We analyzed baseline data from the mWACH-PrEP study to describe characteristics and motivations of pregnant women initiating PrEP.

Methods: Enrolled women were HIV-negative, ≥18 years, between 24-32 weeks gestation, had high HIV risk scores (corresponding to HIV incidence 7.3 per 100 person-years) and initiated daily oral PrEP that day. Participants were randomized 1:1 to receive the mWACH-PrEP adherence support intervention or standard of care (in-clinic adherence counseling only) and were followed through 9-months postpartum. The intervention platform sends PrEP-tailored, theory based, pre-programmed SMS to PrEP users on a weekly basis and allows users to communicate via text message with a remote nurse.

Results: Between January 2022 and July 2023, 600 cisgender women initiating PrEP enrolled during pregnancy at a median gestational age of 26 (IQR:24-29) weeks; 36% were primigravida. Median age was 25 years (22-29) and 71% of women were married, of which 11% were in a polygamous marriage. Only 5% of women had tested for HIV with their partners during this pregnancy and most (95%) women did not know their partners HIV status, while 3% had partners known to be living with HIV.

Over one-third (39%) of women believed their partner had other sexual partners and 1% tested positive for syphilis during pregnancy. All women had high HIV risk scores, yet only 36% perceived high HIV risk. Perceiving high HIV risk was more common among women who had symptoms of an STI (66% vs 35%, p<0.05).

Only 9% personally knew someone who was taking PrEP. The most frequent reasons for initiating PrEP were not knowing their partner HIV status (92%), wanting to protect their baby from HIV (51%), feeling at risk for HIV (40%), and believing their partner has other sexual partners (39%). Almost all (96%) reported high self-efficacy for taking PrEP pills.

Conclusions: Knowledge of partner HIV status was extremely low, yet PrEP self-efficacy was high among pregnant women initiating PrEP who enrolled in a mHealth trial aiming to improve PrEP adherence.

OA2304

Preferences for long-acting PrEP among pregnant and breastfeeding women in Southern Africa: a discrete choice experiment study

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Background: South Africa and Botswana have one of the highest HIV prevalence globally, particularly affecting women during pregnancy and postpartum, who face a two-fold increased HIV acquisition risk. Persistent structural and individual barriers hinder women's daily oral PrEP effective use. A discrete choice experiment (DCE) among pregnant and breastfeeding women (PBFW) not living with HIV explored preferences for long-acting PrEP, and multi-purpose prevention technologies, to inform delivery.

Methods: Between April and December 2023, we evaluated preferences for long-acting PrEP among PBFW accessing maternal services at primary healthcare facilities. The cohort included PBFW with PrEP use experience (Cape Town, South Africa), and those unfamiliar with PrEP (East London, South Africa, and Gaborone, Botswana). Data collection incorporated surveys and discrete choice experiments (DCE), with hypothetical scenarios describing various options.

This approach was informed by qualitative interviews and focus group discussions. Analysis included demographic characterization, site stratification, and latent class modelling.

Results: The study surveyed 450 PBFW (52% pregnant, 47% breastfeeding); median age was 26 (IQR 22-31). Women strongly favoured non-vaginally inserted (coefficient -1.57, 95% CI -1.89 to -1.29) and non-implanted (coefficient -0.79, 95% CI -1.00 to -0.59) PrEP compared to oral PrEP. HIV, STI, and pregnancy prevention combination prevention (coefficient 1.02, 95% CI 0.80-1.24) was preferred over HIV

prevention only. Site-specific differences were evident (Figure 1), with clinic PrEP pick-up preferred in East London and Gaborone compared to pharmacy or community delivery. PBFW in East London and Gaborone prioritized effectiveness over frequency of use. Three latent classes emerged: Class 1 (43%) prioritized combination prevention and less frequent dosing; Class 2 (25%) focused on physiological aspects; Class 3 (32%) avoided vaginal insertion, preferring specific pickup locations.

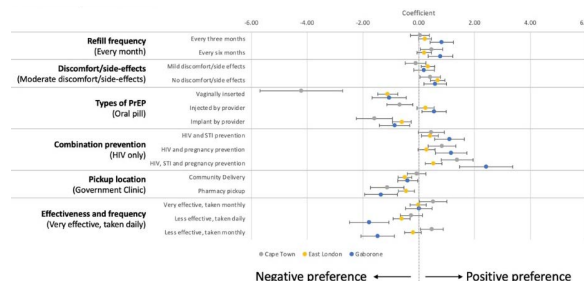


Figure 1. PrEP Choice - Main effects of a discrete choice experiment in pregnant and breastfeeding women in South Africa and Botswana, December 2023.

*All estimates are relative to the baseline characteristics for each PrEP attribute (in brackets).

Conclusions: PrEP modality, frequency, and pickup location are crucial in PrEP delivery choices. Future PrEP programs should prioritize user-centered approaches, ensuring alignment with PBFW's values and preferences to foster effective use.

OA2305

Discrete choice experiment on the preferences for long-acting pre-exposure prophylaxis (PrEP) among pregnant women without HIV in Kisumu and Siaya, Kenya

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Background: Suboptimal adherence to daily oral PrEP is common during pregnancy. New long-acting (LA-) PrEP methods may overcome barriers to taking daily oral PrEP, though research on long-acting PrEP among pregnant women lags behind other populations. Incorporating feedback from pregnant end-users could help understand preferences for PrEP attributes to support acceptability and effective use as long-acting methods are introduced.

Methods: We conducted a discrete choice experiment (DCE) among pregnant women without HIV who initiated daily oral PrEP during antenatal care and were enrolled in an ongoing RCT in Kisumu and Siaya Counties, Kenya (NCT04472884). In a series of 12 questions, pregnant participants were asked to choose between three hypo-





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thetical PrEP products composed of five attributes (form and dose, collection place, effectiveness, side effects, and availability of safety data). We used latent class modeling to identify patterns of PrEP preferences based on attributes.

Results: Between February 2023 and April 2024, 151 women completed the DCE. The median age was 24 years (IQR 21–29), median gestational age was 37 weeks (IQR 36.2–38.4), 84.8% had a partner of unknown HIV status, and 4.0% had a partner known to be living with HIV.

We identified four patterns of preferred PrEP attributes, characterized as “Primarily prefers injection form and high effectiveness driven” (29.2% of participants), “High safety and high effectiveness driven” (40.0%), “Oral PrEP or no PrEP” (6.6%), and “Injection form or No PrEP, high safety, and high effectiveness driven” (24.2%).

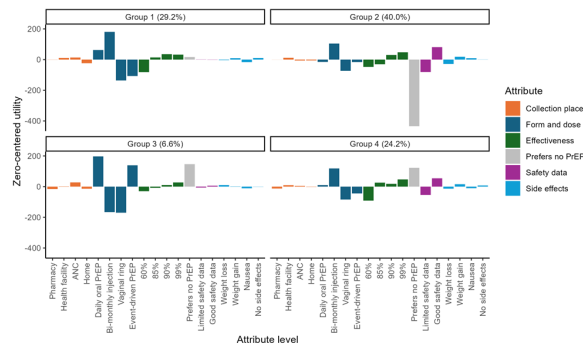


Figure 1. Zero-centered utility between four latent class groups.

Conclusions: Our results indicate that there is a large proportion of pregnant women with a high HIV risk who are interested in a long-acting injectable PrEP. PrEP attributes such as form/dosing, effectiveness, and safety drove PrEP preferences among pregnant women. Accruing safety data on the use of long-acting PrEP methods in pregnancy will support introduction into pregnant populations.

OA2306

Evaluation of potential pharmacologic interactions between CAB-LA or TDF/FTC and hormonal contraceptive agents: a tertiary analysis of HPTN 084

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Background: HPTN 084 found that long-acting cabotegravir (CAB-LA) was well-tolerated and significantly reduced the risk of HIV acquisition in women compared to tenofovir disoproxil fumarate/emtricitabine (TDF/FTC). During the blinded phase of the trial, participants were required to use long-acting reversible contraceptives. A nested hormonal contraceptive sub-study assessed potential pharmacologic interactions between PrEP agents (CAB-LA or TDF/FTC) and etonogestrel (ETO), medroxyprogesterone acetate (MPA), or norethindrone (NOR).

Methods: Participants were enrolled into the sub-study between 24 Feb 2020 and 26 Oct 2020. Based on the reported contraceptive regimen at baseline and subsequent study visits, plasma concentrations of ETO, MPA, and NOR were evaluated at enrollment and weeks 25, 49, and 73; plasma tenofovir (TFV) and CAB concentrations were determined at contemporaneous visits. Participants were allowed to switch contraceptives and pharmacokinetic (PK) assessments were adjusted accordingly. Geometric mean concentrations were calculated and compared using t tests or Fisher's exact tests.

Results: One hundred and ninety participants consented to the sub-study; 170 provided samples beyond the enrollment visit (CAB-LA: 80; TDF/FTC: 90). Changes in contraceptive regimens were common across both study arms (CAB-LA: 23.8%; TDF/FTC: 24.4%). Post-enrollment contraceptive concentrations were comparable between

study arms for all three contraceptive types (Figure). The percentage of participants with concentrations above thresholds associated with ovulation suppression (≥ 90 pg/mL ETO, ≥ 100 pg/mL MPA, and ≥ 1000 pg/mL NOR) was high and did not differ between arms (p -value range: 0.423-1.00). The time from last contraceptive dose until assessment (95% CI) ranged from 316-544 (ETO), 50-68 (MPA), and 41-54 (NOR) days. CAB concentrations were comparable across contraceptive types. TFV concentrations were unquantifiable for most participants, irrespective of contraceptive agent, rendering comparisons largely uninformative.

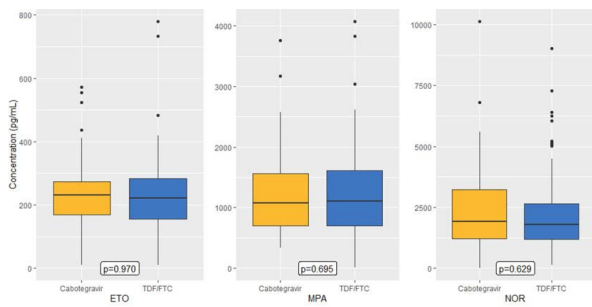


Figure 1. Plasma concentrations of hormonal contraceptives by randomized study arm.

Conclusions: Interactions between CAB-LA and ETO, MPA, and NOR were not observed. Associations between TDF/FTC and hormone concentrations could not be effectively evaluated due to low adherence to TDF/FTC.

Delivering on the promise of PrEP choice

OA2402

PrEP choice for women in Africa: uptake of oral PrEP and PrEP ring

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Background: Understanding uptake of oral PrEP and PrEP ring when women are offered choice is needed to guide expansion of PrEP programs in Africa.

Methods: The PEPFAR/USAID-supported CATALYST study aims to characterize an enhanced service delivery package for informed PrEP choice for women at public health sites in five African countries. Individuals aged ≥ 18 years,

including those pregnant and/or breastfeeding in permitting countries, are eligible to choose between PrEP ring and oral PrEP. We describe PrEP uptake among those offered PrEP choice between May-December 2023, explore factors associated with method choice among PrEP-naïve individuals using logistic regression, and describe reasons for choices made.

Results: Of 2,383 participants eligible for PrEP choice, 978 (41%) were ≤ 24 years, 709 (30%) reported sex work, 84 (4%) were pregnant, 243 (10%) were breastfeeding, and 1,526 (64%) were PrEP naïve. At enrollment, 1,464 (61%), 842 (35%), and 77 (3%) participants chose oral PrEP, PrEP ring, and no method, respectively. PrEP ring uptake among pregnant and breastfeeding women where allowed was 14 (17%) and 49 (20%), respectively.

Among PrEP naïve individuals eligible for PrEP choice, those reporting sex work, having condomless sex in the past month, and having multiple sex partners in the last 3 months were more likely to choose PrEP ring (Table 1). In a multivariable analysis that adjusted for country, no factors remained significantly associated with PrEP ring uptake. In permitting countries, pregnant and breastfeeding women were less likely to choose PrEP ring. Participants chose oral PrEP because it is easy to use (50%) and works well (29%), while PrEP ring was chosen because it is easy to use (56%) and does not require swallowing pills (53%).

Participant characteristics ^a	Oral PrEP (n=1019)	PrEP ring (n=436)	Crude OR (95% CI)	P value
Age 18-24 years	479 (47%)	190 (44%)	0.87 (0.69 - 1.09)	0.229
Sex worker	201 (20%)	110 (25%)	1.38 (1.05 - 1.79)	0.019
Multiple partners in last 3 months	246 (24%)	141 (32%)	1.50 (1.17 - 1.92)	0.001
Current contraceptive use	549 (54%)	263 (60%)	1.24 (0.98 - 1.58)	0.074
Any condomless vaginal sex in past month	317 (31%)	161 (37%)	1.29 (1.02 - 1.64)	0.034
Greater than primary education	762 (75%)	318 (73%)	0.91 (0.70 - 1.17)	0.462
Pregnant ^b	46 (12%)	8 (6%)	0.44 (0.20 - 0.95)	0.036
Breastfeeding ^c	113 (17%)	26 (10%)	0.57 (0.36 - 0.90)	0.016

^aThere are missing data for various variables, and these observations are excluded from the respective models.

^bCrude OR only includes data from Kenya and Lesotho where PrEP ring use is allowed among pregnant populations.

^cCrude OR only includes data from Kenya, Lesotho, and Zimbabwe where PrEP ring use is allowed among breastfeeding populations.

Table 1. Predictors of PrEP ring choice among PrEP-naïve individuals who chose a PrEP method (n=1455).

Conclusions: We demonstrate moderate uptake of PrEP ring when offered within existing real-world oral PrEP programs. Our findings inform implementation of PrEP choice in the region.



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OA2403

Provider and client perspectives on PrEP choice: quality of PrEP choice and factors influencing its provision in the CATALYST implementation study

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Background: Women in sub-Saharan Africa bear a disproportionate HIV burden, highlighting the need for new PrEP technologies. Limited evidence exists on the delivery of PrEP choice.

This mixed methods study describes early experience with PrEP choice implementation for women in the PEP-FAR/USAID-supported CATALYST study.

Methods: We analyzed enrollment cohort survey data (May–December 2023) across public health sites in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe. We adapted a PrEP method information index (PrEP MII) to ascertain the quality of provision of PrEP choice counseling using three indicators: informed about multiple methods (oral PrEP and PrEP ring), side effects, and possibility of switching methods. Logistic regression assessed variations in receipt of PrEP choice counseling across population subsets. We thematically analyzed 27 in-depth interviews with providers (October 2023–January 2024) across 10 sites to explore barriers, facilitators, and strategies to improve PrEP choice.

Results: Among cohort participants, 87% received quality PrEP choice counseling upon enrollment (N=2,548; PrEP MII scores=3/3). Rates varied by country, with Lesotho and Uganda scoring higher (96% and 95%), Zimbabwe (85%), and Kenya and South Africa scoring lower (80%). PrEP MII scores differed across populations. Pregnant and breastfeeding populations had lower odds of receiving PrEP choice (AOR=0.65, 95% CI [0.44,0.96], p=0.032; AOR=0.49, 95% CI [0.36,0.68], p<0.001, respectively) as did those with prior PrEP experience (use within 30 days of enrollment) (AOR=0.74, 95% CI [0.55,0.99], p=0.041) compared to PrEP-naïve individuals. Providers emphasized the comparative benefits of choice counseling to address clients' HIV prevention needs despite it being more time-consuming than counseling for oral PrEP alone.

Overall, providers were positive toward offering PrEP choice, overcoming initial implementation reluctance and challenges. Providers proposed strategies to boost motivation for offering PrEP choice, including more training, incentives, sufficient staffing, and tailored counseling. Additionally, they emphasized the importance of expanding community outreach and fostering opportunities for cross-learning.

Conclusions: Despite challenges, providers offered most participants key elements of PrEP choice counselling. However, providers require enhanced support to offer PrEP choice to pregnant and breastfeeding individuals and those with prior oral PrEP experience. PrEP implementation should address identified barriers and facilitators to enhance PrEP choice access.

OA2404

Contraceptive method mix and PrEP choice among young women seeking contraception at retail pharmacies in Kenya

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Background: Modern contraceptives choice and use among adolescent girls and young women (AGYW) remain a challenge. Understanding such preferences and HIV PrEP methods could inform co-delivery for this group. A differentiated approach where pharmacy delivery models are considered is key to improving access.

Methods: We analyzed baseline data on contraception method mix and PrEP choices among AGYW enrolled in an ongoing cluster randomized trial assessing pharmacy-based PrEP delivery models at 20 retail pharmacies in Kenya (NCT05467306). HIV-negative AGYW (15–24 years) purchasing contraception (emergency contraception [EC], oral contraceptive pills, injectables, implants, condoms) offered oral PrEP or dapivirine vaginal ring (DPV-VR) per national guidelines. AGYW who accepted PrEP received a one-month supply.

We obtained socio-demographic characteristics, contraception preference and sexual behavior data using structured questionnaires. We compared association between HIV PrEP option and contraceptive preference using adjusted Poisson regression model.

Results: Between May 2023 to March 2024, 1003 AGYW were enrolled: median age 21 years (IQR19–23); 19% (156/1003) were ≤18 years. Most AGYW (84%, 713/1003) were unmarried, condomless sex was common (88%, 765/1003), and 46% (461/1003) had a prior pregnancy.

About 21% (211/1003) of AGYW reported ≥1 sexual partner, 9% (90/1003) reported sex while intoxicated in the last 6 months, and 10% (100/1003) reported transactional sex. A quarter (23%, 231/1003) perceived themselves at moderate/high HIV risk.

Among AGYW dispensed PrEP (n=864), 664(77%) chose oral PrEP. EC was the most common contraceptive (55%, 475/864) purchased, followed by injectables (19%, 164/864), pills (13%, 112/864), condoms alone (11%, 95/864), and im-

plants (2%, 17/864); 71 % (613/864) of AGYW reported prior EC use. EC purchase was less frequent among AGYW who chose DPV-VR compared to those choosing oral PrEP (53% vs. 63%, $p=0.019$); no other differences in contraceptive method mix were detected (all $p>0.05$): injectables (20% vs. 16%), pills (12% vs. 14%), condoms alone (12% vs. 8%), and implants (2% vs. 0%). Self-selecting DPV-VR was not associated with purchase of long-acting (injectable or implant) contraception (aRR=0.95, CI: 0.91-1.01).

Conclusions: We found varying preferences for short and long-acting methods for contraception and PrEP among AGYW in Kenya, suggesting that providing multiple HIV and pregnancy prevention options at pharmacies may increase coverage.

OA2405

Switching between oral and injectable pre-exposure prophylaxis (PrEP) regimens in the United States: an investigation of reasons for switching in the real world

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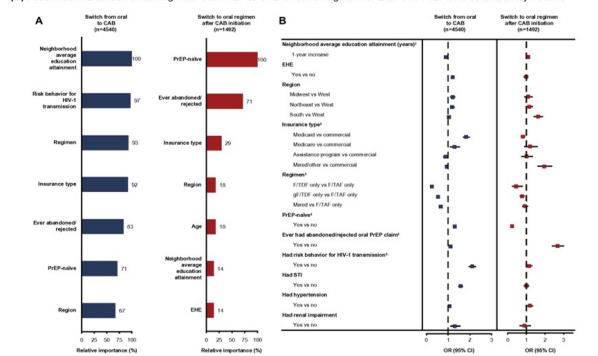
Background: Real world factors influencing individuals' switching patterns between daily oral and every-2-month injectable PrEP regimens for HIV-1 prevention are unclear. **Methods:** HIV-1-negative adults receiving ≥ 1 dispensed prescription of oral PrEP between January 1 and December 31, 2021, were identified from the IQVIA LAAD pharmacy claims database. Switching between injectable cabotegravir (CAB) and oral F/TAF or F/TDF was monitored after January 1, 2022. Key determinants driving PrEP switches were identified by a classification tree model and ordered by relative importance. Logistic regression was used to evaluate likelihood of switching PrEP modalities.

Results: Of 173,572 oral PrEP users, 2.6% switched to CAB; key switching determinants included education attainment, HIV-1 risk behaviors, and oral regimens used (Figure 1A). Individuals using Medicaid had increased odds of switching to CAB versus individuals with commercial insurance (1.84 [1.69-2.00]) (Figure 1B). Individuals with HIV-1 risk behaviors also had increased odds of switching to CAB (2.12 [1.96-2.30]); however, individuals using F/TDF only had decreased odds of switching versus F/TAF only users (0.25 [0.20-0.32]) (Figure 1B).

Of 5721 CAB users (new initiation and switched from oral), 26.1% switched or switched back to oral PrEP; key switching determinants included being PrEP-naïve prior to CAB initiation, having previous abandoned/rejected injectable claims, and insurance type (Figure 1A). People with increased odds of switching to oral PrEP had abandoned/rejected CAB claims (2.68 [2.37-3.03]) or lived in Southern versus Western states (1.62 [1.38-1.90]) (Figure 1B).

Approximately 67% of all CAB users missed ≥ 1 injection window; among these users, 5% subsequently filled new oral PrEP claims.

Figure 1. (A) Relative Variable Importance* for Predicting Probabilities of Switching from Daily Oral to Every-2-Month CAB among Individuals Who Had ≥ 1 Dispensed Oral PrEP Claim in 2021, and Switching to an Oral Regimen among CAB Users; **(B)** Associations Between Switching from Oral PrEP to CAB or Switching from CAB to Oral PrEP and Selected Key Factors



*Relative variable importance orders predictors based on their impact on model improvement, with the highest scoring variable considered the most important followed by others in descending order. This measure facilitates interpretation, expressing each variable's importance as a percentage relative to the most crucial predictor, which is assigned a value of 100%. †Education attainment data were derived from the 2020 Census, and American Community Survey 2016-2022 databases. ‡These variables refer to specific characteristics observed at the time of the first oral PrEP claim for those who had ≥ 1 dispensed oral PrEP claim in 2021, and at the time of the first injectable CAB use after January 2022. ††International Classification of Diseases 10th revision/Current Procedural Terminology codes-defined encounters that signify recommendation for PrEP use by providers. CAB, cabotegravir; CI, confidence interval; EHE, elective home education; FITAF, emtricitabine/tenofovir alafenamide; FITDF, emtricitabine/tenofovir disoproxil fumarate; gF/TDF, generic F/TDF; OR, odds ratio; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

Conclusions: PrEP switches were driven by identified individual characteristics and formulary coverage factors. Results underscore the need to develop interventions that can address the diverse requirements of individuals who would benefit from PrEP and provide oral bridging, to improve adherence and reduce HIV-1 acquisition.

OA2406

PrEP method (oral or ring) choice in a community based programme: findings from the DREAMS PrEP choice study in South Africa

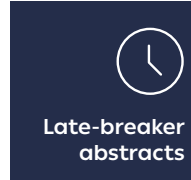
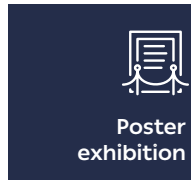
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¹Wits RHI, University of Witwatersrand, Johannesburg, South Africa, ²United States Agency for International Development (USAID), South Africa, Johannesburg, South Africa

Background: Dapivirine Vaginal Ring (PrEP Ring) was approved in 2022 as an additional PrEP method in South Africa. Understanding choice and uptake will be important parameters to guide countrywide introduction and scale up. This abstract presents uptake and factors associated with PrEP method choice in communities.

Methods: DREAMS PrEP Choice is an implementation science study offering oral PrEP and PrEP ring to women 18 years and older through a community-based programme utilising mobile clinics and pop-up gazebos in 36 sites across Johannesburg. Sociodemographic, behavioural and routine clinical data was extracted. Logistic regression using STATA version 18, was conducted to describe PrEP choice at enrolment and factors associated with uptake, adjusting for age a priori.

Results: Between October 2023 and March 2024, 709 clients were screened for study inclusion, with 87% meeting eligibility. Of 614 participants who consented, 589 (96%) chose a method. Seventy three percent (430/589) were between 18 and 24 years; and 84% completed secondary or tertiary education. Of those reporting a current sexual partner(s) (n=517), 66% did not know their partner's HIV status and 5% reported more than one sexual partner.





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Seventy-one percent chose oral PrEP, 28% PrEP ring and 1% selecting no method, noting that 21% were former oral PrEP users. Participants aged 25-34 years (aOR=1.68, 95%CI:1.07-2.63, p=0.0001); and reporting recent transactional sex (aOR=3.43, 95%CI: 1.09-10.74, p=0.0001) had higher odds of choosing PrEP ring at enrolment compared to oral PrEP. PrEP ring uptake differed by delivery site with higher learning institutions (aOR= 2.44, 95%CI: 1.18-5.05, p=0.001) and community safe spaces (aOR= 2.38, 95%CI: 1.14-4.99, p=0.001) having greater odds of choosing PrEP ring. PrEP naïve participants had lower odds of choosing PrEP ring (OR=0.50, 95%CI: 0.32-0.76, p=0.001). We found no association between method choice and past pregnancy, contraceptive use, or implementation model (mobile or gazebo).

Conclusions: Our findings demonstrate moderate PrEP ring uptake with participants 25-34 years, reporting transactional sex, tertiary education, and found at community safe spaces and tertiary institutions more likely to choose PrEP ring. Understanding who is likely to take up PrEP ring, and characteristics that drive choice can inform how programmes are designed and delivered at scale.

Driving PrEP implementation through community engaged science

OA2502

Appropriateness of a social influence campaign to de-stigmatize, de-medicalize, and generate demand for PrEP among young women and female sex workers in South Africa: a qualitative study

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Background: Despite growing PrEP availability, intersectional HIV and PrEP stigma has demotivated PrEP uptake and persistence among female sex workers (FSW) and adolescent girls and young women (AGYW) in South Africa. We examined the appropriateness of Le Kip Kip, a multi-component social influence campaign implemented to de-stigmatize and de-medicalize PrEP—among FSW, AGYW, and their communities in South Africa.

Methods: We conducted in-depth interviews with Le Kip Kip campaign implementers (venue-based peer PrEP champions and volunteer community mobilizers; n=30) and community members with potential campaign exposure (n=36) in uMgungundlovu, Zululand, and Ngaka Modiri Molema Districts.

We used deductive thematic analysis to evaluate campaign appropriateness across five domains: attractiveness, comprehension, relevance, acceptability, and credibility.

Results: PrEP de-medicalization via rebranding as Le Kip Kip was attractive to implementers and community members. Implementers noted that community members approached them with curiosity when wearing campaign-branded merchandise, availing opportunities to disseminate PrEP information.

Attention-grabbing marketing materials alongside social media pages enhanced campaign credibility, building community trust in the campaign and PrEP via informational content and consistent branding. Comprehension was high, with most community members demonstrating a correct understanding of PrEP; implementers noted that after clarifying the meaning of campaign materials, community members conceptualized PrEP and Le Kip Kip synonymously.

Community members emphasized the campaign's relevance in their community, noting that PrEP knowledge and acceptability were suboptimal before the campaign but improved with campaign exposure. Campaign implementers felt validated by their communities for their labor.



Figure 1. Images of promotional material and quotes illustrating perceptions of the campaign.

Conclusions: De-medicalization was perceived as appropriate and acceptable in this South African campaign, with attention-grabbing branding effectively disseminating destigmatizing, empowering PrEP messaging. Community members reported positive improvements in PrEP perceptions, reaffirming the promise of Le Kip Kip to cultivate a more enabling environment for PrEP uptake. Demand-generation for daily and long-acting PrEP formulations in South Africa may benefit from de-medicalization and messaging around empowerment.

OA2503

Science simplified – co-creating games with key communities to communicate HIV germline targeting vaccine design concepts in India and South Africa

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Background: The onset of experimental medicine vaccine design trials (EMVT) warrants an increasing need to enhance literacy towards the scientific rationale and purpose of new approaches like: germline targeting, mRNA vaccines, and complex boosting schedules.

Towards this, we co-created game-based tools for community engagement inspired by theories from behavioural sciences, social psychology and gamification in working with community stakeholders.

Methods: 10 consultations with over 30 scientists, community representatives and design experts across India and South Africa helped identify appropriate, accurate and relevant messages around EMVT including:

- Iterative process of germline targeting: step-by-step creation of immunogen in the lab (as recombinant protein or mRNA) and corresponding antibody response in the body
- B-cell maturation process in response to the sequential immunogens

Inspired by Kolb's experiential learning cycle, a puzzle-based competitive building-block game was created to understand the scientific rationale behind EMVT (Figure 1). The game was finetuned and finalized through iterative prototyping with community representatives.



Figure 1. Game design and flow to represent germline targeting, mRNA vaccines and b-cell maturation process.

A training-of-trainers was then conducted on the game implementation with 12 Community Liaison officers from India and South Africa.

Results: Interactive community feedback sessions, helped identify ways to enhance intuitiveness and simplicity of gameplay while maintaining scientific accuracy through relatable metaphors including:

- Lock-and-key mechanism for immunogen and antibody interaction,
- Incremental complexity of process to showcase b-cell maturation.

Participant feedback from the training indicated:

- A 'definite' and 'significant' enhancement of understanding and capabilities in implementing socio-behavioral research studies by 75% and 25% respectively.
- For scientific concepts of germline targeting and mRNA vaccine, exposure to training moved the average score on a 10-point familiarity scale to positive side by 50-55%.

Conclusions: Co-creating interactive gamified experiences with communities aided in enhancing a sense of collaboration and ownership in the research process.

Simplifying the science through games helped participants better engage and understand the scientific rationale for research, increasing their motivation for participation.

OA2504

Using local languages for accurate science reporting in Media Science Cafés in East and Southern Africa

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Background: The Media Science Café Program in Kenya, Malawi, Tanzania, Uganda, Zambia and Zimbabwe fosters an environment conducive to accurate reporting on HIV science by engaging journalists through interactive media science cafés. The program promotes accurate reporting on HIV science by engaging journalists in both English and the local languages in which many journalists report.

These sessions, hosted by national health journalism associations, facilitate knowledge exchange among scientists, civil society organizations and other experts, and journalists to unpack science and research and development.

Methods: All Media Science Café Programs promote accurate reporting on science and health by engaging journalists through interactive café sessions conducted in both English and local languages. Utilizing local languages at Media Science Cafés empowers journalists to convey stories with greater precision.

This approach benefits both scientists and journalists by facilitating clear communication and enhancing understanding of scientific concepts among diverse participants in a language they are most familiar with.

A translation database (<https://avac.org/translation-index/>) containing scientific and health terminology in local languages has been developed with input from café journalists and their communities, further aiding in the selection and packaging of content for wider dissemination.

This approach promotes consistency in comprehension and fosters trust among participants.



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Results: Key lessons learned include the simplification of scientific terminologies used during regular media science café discussions, enabling journalists to convey complex research outcomes more accurately to their audiences.

Furthermore, utilizing local languages helps cultivate confidence between experts, journalists, and the community by ensuring mutual understanding and reducing the risk of miscommunication or misrepresentation.

Conclusions: Insights gained from utilizing local languages at media science cafés in diverse countries have facilitated the creation of a comprehensive translation database covering scientific and health terms.

This resource pinpoints areas requiring further translation efforts, thereby enhancing the effectiveness and accuracy of science reporting for a diverse audience. The database is also a tool for research literacy, supporting dissemination of scientific and health information across various linguistic communities. The use of local languages during these engagements plays a pivotal role in enhancing comprehension of scientific concepts and assists journalists in articulating stories effectively for broader audiences.

OA2505

Lessons learned from engaging community stakeholders in product development for a proposed novel HIV intervention in early-phase clinical development

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Background: Good Participatory Practice (GPP) guidelines, among others, form the basis for community engagement when conducting HIV prevention trials, but engagement is generally initiated and focused on the trials including protocol and trial site preparation.

In early 2023 after a broad consultation on clinical trial design for HIV bnAbs identified earlier and more robust community engagement as a significant need, a community engagement working group (CEWG) was formed to promote and strengthen early involvement and to develop materials to increase community awareness of bnAbs for infant HIV prophylaxis (PNP) prior to trial site selection.

This abstract highlights key lessons from CEWG efforts to strengthen community-driven engagement in early-phase clinical development.

Methods: The CEWG formed in June 2023 to address this gap in early engagement by:

1. Convening different community groups from different countries with varying HIV contexts,
2. Mobilizing these community stakeholders to develop materials for future direct engagement,

3. Harmonizing community-level feedback on the product development (PD) pathway prior to development of trial protocols, and;

4. Creating a space for community voices on PNP. This strategy supported early awareness and education in communities, which can lead to products and trials better tailored to their target populations.

Results: Varying baseline levels of knowledge and participation were a challenge, highlighting a need for increased research literacy at a generalized community level and resources for capacity strengthening.

For meaningful engagement with community stakeholders, funding and support need to be mobilized for community stakeholder engagement outside of clinical trials and a strategy for engagement throughout product development needs to be communicated and integrated into GPP plans.

This model of early engagement demonstrates how the research community can rethink community engagement and the benefits to the end-to-end development for products.

Conclusions: These early activities bring attention to the importance of community-driven strategies for meaningful engagement across each step of the bnAb development process. Creating a strong foundation for collective dialogue across different areas of expertise requires significant preparation and ongoing engagement throughout the PD process to support informed trial participation, future introduction, and acceptability.

OA2506

Long-acting HIV technologies access in LMICs: stakeholder engagement to understand concerns of the community

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Background: HIV treatment and prevention therapies have predominantly been pursued through oral antiretroviral drugs for decades. Significantly, treatment has evolved from complex multi-pill regimens to more efficacious once-daily fixed-dose combinations. However, social stigma and high pill burden persist among other challenges. The novel technology in long-acting injectables like cabotegravir (CAB-LA) and lenacapavir (LEN) therefore herald a new era. Yet, little has been asked of the community to identify any concerns prior to their introduction. To address this, Afrocab Treatment Access Partnership organized two community forums in Kampala and Nairobi in June 2022 and May 2023.

Methods: The forums brought together advocates and representatives from Ministries of Health, the WHO, academia, implementers, and donors. CAB-LA and LEN's product profiles were introduced to prompt facilitated stakeholder dialogue.

Results: The crucial voice and role of community in product introduction (from development to policy discussions to introduction and scale-up) ensures a comprehensive and inclusive approach. Furthermore, key concerns below emerged:

1. Voluntary Licenses: The urgent need to issue voluntary licenses for both products, and for effective technology transfer to expedite generic development.
2. Affordable Pricing: Can sustained collaboration be ensured between donors and manufacturers towards an affordable CAB-LA/LEN price point, ensuring access for low- and middle-income countries (LMICs)?
3. Transparency in Regulatory Processes: Regulatory authorities and normative bodies (WHO PQ, US FDA, national regulatory authorities) and their commitment to increased transparency on review timelines for both products.
4. Treatment Literacy: Continuous education and sensitization efforts were emphasized to bridge knowledge gaps among stakeholders, disseminating information about product specifics, licensing, and regulatory timelines.
5. Community-Led Decision-Making: Value addition of community-led decision-making throughout the lifecycle of long-acting HIV products. Dialogue between communities and stakeholders empowers affected populations to timely shape policies, programs, and access strategies.

Conclusions: The forums laid a robust foundation for continued community engagement ahead of LMIC entry of long-acting HIV products. A collective commitment to collaboration, transparency, and community-centric approaches will foster a more effective and inclusive global response to HIV in this new era of long-acting injectables.

Insights on structure/function in vaccines design

OA2602

Cryo-EM characterization of diverse antibody interactions with HIV envelope to facilitate vaccine and therapeutic antibody development

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Background: In the last few years, advances in cryo-EM data collection and data processing technology have allowed for rapid structural annotation of antibody interactions with HIV-1 envelope. Such data informs the development of a wide array of interventions at various stages of progress.

Methods: HIV-1 envelope complexes with antigen-binding fragment of antibody or with nanobody were prepared at a concentration of 3-4 mg/ml, with 0.005% DDM, and vitrified on copper holey grids in liquid ethane using a Vitrobot Mark IV. Cryo-EM data were collected on a Titan Krios operating at 300 keV, equipped with a K3 detector (Gatan) operating in counting mode. Data were acquired using Leginon. For all structures, cryo-EM data was processed using CryoSPARC, and models were generated using Coot, Phenix, and UCSF Chimera.

Results: Here, we highlight single particle cryo-EM contributions through four HIV-focused vignettes.

First, we determined antibody-envelope trimer structures in a proof-of-concept study to induce high serum-neutralizing titers of over 50% breadth in macaques at the fusion peptide-site of vulnerability by a combination of fusion peptide vaccination and SHIV infection. Cryo-EM structure determinations revealed 15 of 16 isolated antibodies with cross-clade breadth to be directed towards the fusion peptide-site of vulnerability.

Second, we used cryo-EM to characterize antibodies elicited in humans by a phase I clinical trial of the "DS-SO-SIP"-stabilized envelope trimer from strain BG505. In specific, we showed how vaccine-elicited fusion peptide-directed antibodies may be highly strain specific.

Third, we determined cryo-EM structures of PGDM1400 (currently in clinical trials for the treatment of HIV-1) and an improved variant of the clonal relative PGT145 bound to BG505 envelope trimers; these structures revealed how different clades of a single antibody lineage can adopt different strategies for broad recognition at the V2 apex-site of vulnerability.



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Fourth, we determined the structure of vaccine-elicited nanobody R27 linked to the light chain of the V2 apex-targeting broadly neutralizing antibody, CAP256V2LS.

This bispecific chimera exhibited ultrapotent neutralization and breadth greater than other published HIV-1 broadly neutralizing antibodies.

Conclusions: Collectively, these vignettes demonstrate how structural biology will continue to accelerate the development of vaccines and therapeutics against HIV-1.

OA2603

Elicitation of HIV-1 cross-neutralizing serum IgG and monoclonal antibodies following sequential immunization of NFL Env trimers into non-human primates

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Background: The elicitation of cross-neutralizing antibodies toward broadly neutralizing determinants on the HIV-1 envelope glycoprotein (Env) remains a major vaccine challenge. Most cross-conserved sites on the trimeric HIV spike are occluded by host-encoded "self" N-glycans, limiting B cell recognition of the underlying protein surface. Exceptions are the Env primary receptor CD4 binding site (CD4bs) and the furin cleavage site.

We have pursued N-glycan deletion to better expose one or both Env regions for enhanced B cell priming in pre-clinical studies. Initially, we eliminated N-glycans proximal to the CD4bs while maintaining the native-like state of cleavage-independent (NFL) trimers.

Following glycan-deleted priming, we used heterologous boosting coupled with N-glycan restoration to preferentially drive B cells directed to conserved sites.

This strategy elicited two 'tier 2' broadly neutralizing antibodies (bNAbs); E70, a CD4bs-directed, N-glycan-dependent cross-neutralizing mAb and, 1C2, an 87% bNAb directed to the gp41-gp120 interface both structurally resolved by cryoEM.

Methods: In an ongoing experiment in non-human primates (NHPs), we immunized subjects with CD4bs glycan-deleted Env trimers in SMNP adjuvant followed by sequential heterologous trimer boosting coupled with glycan restoration to elicit cross-neutralizing antibodies.

Results: We elicited HIV-1 'tier 2' cross-neutralizing serum IgG activity in a subset of NHPs that maps proximal to the CD4bs and the Env furin cleavage site by EMPER (EM polyclonal epitope mapping).

To 'close the loop', we isolated over 200 monoclonal antibodies from memory B cells, several of which cross-neutralize multiple HIV clinical isolates in a 90-member global panel. The most potent/broad antibody lineage displays somatic hypermutation levels exceeding 20% from germline and maps proximal to the CD4bs as determined initially by cross-competition. By negative stain EM, these heavily somatically mutated antibodies interact with the gp120:gp120 interface spanning adjacent Env trimer protomers. High-resolution cryoEM structures of 2 representatives from this broadly neutralizing lineage reveal a new cross-neutralizing epitope bridging between the CD4bs and the gp120 interface of the adjacent protomer. We are performing similar monoclonal antibody analysis on other NHPs exhibiting cross-neutralization present in their serum IgG.

Conclusions: Glycan deletion and heterologous Env trimer prime:boosting elicits HIV-1 bNAbs in NHPs and we are beginning to test this concept in humans.

OA2604

Structure of a neutralizing VRC01-class antibody elicited after prime-boost germline-targeting immunization regimen

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Background: ~20% of people living with HIV-1 can develop broadly neutralizing antibodies (bnAbs) against the Envelope glycoprotein (Env) present at the surface of the virus. These bnAbs have been shown to be protective in animal models and the VRC01 bnAb prevented HIV-1 acquisition by susceptible viruses. VRC01-class antibodies have been isolated from multiple donors, target the conserved CD4 binding site and share common gene characteristics, including extensive somatic hypermutation from their germline precursors. VRC01-class antibodies are difficult to elicit by immunizations.

Methods: Here, we employed a germline targeting immunization approach that consisted of using a prime immunogen designed to engage germline VRC01-like B cells and subsequent boosts of more native Env immunogens to guide the maturation of VRC01-class B cell precursors. We isolated an antibody, G3-1, after immunizations in VRC01-class knock-in mice, that neutralizes the autologous virus and 25% of the heterologous tier 2 viruses panel (8 viruses) tested indicating it can bypass a major steric hindrance of VRC01-class precursors. We obtained cryoEM structures of G3-1 bound to WT 426c DS.SOSIP and of VRC01 bound to the same SOSIP.

Results: G3-1 and VRC01 approach the SOSIP with slightly different angles. G3-1, unlike VRC01, has no deletions in the CDRL1 and is still able to accommodate the N276 glycan and neutralize the virus. G3-1 also induces conformational

changes in Env upon binding, similar to CD4, in part due to a rare phenylalanine mutation that mimics Phe43 of CD4.

Conclusions: The structure of the G3-1 bound to WT 426c DS.SOSIP can be used to determine why different somatic hypermutations are necessary to become broadly neutralizing.

OA2605

Structural characterization of a vaccine-elicited NHP broadly neutralizing antibody lineage reveals a new quaternary neutralizing epitope on HIV Env

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Background: Immunization of non-human primates with stabilized single-chain NFL trimers in a heterologous prime-boosting soluble protein regimen resulted in the elicitation of broad serum antibody responses in NHPs. By single-cell sorting we isolated multiple antibodies that neutralized HIV-1 in a TZM-bl assay. Four antibodies belonging to the same lineage displayed broad neutralization of HIV-1 in an 80 pseudo-virus panel with neutralizing breadth exceeding 50% of the viruses tested (IC50).

Methods: Cross-competition mapping by Octet suggests that a lineage representative antibody competed with VRC01 for binding to Env. By cryo-EM we obtained a high-resolution structure of two antibodies (LJF-0034 and LJF-0085) in complex with a stabilized JR-FL NFL.664 trimer.

Results: The structure revealed a novel epitope with an extensive footprint on two adjacent protomeric Env units at the gp120 interface. The antibody light chain exclusively contacts the CD4 binding site of one protomer with most contacts being nearly 100% conserved. In contrast, the antibody heavy chain targets the V2V3 trimerization domain of the adjacent protomer where residues are less conserved.

Conclusions: Ongoing structural analysis of the antibody contacts in conjunction with sequence analysis of lineage-resistant viruses identifies specific residues in V3 that may explain escape from members of this broadly neutralizing lineage. These findings will help to redefine the immunization regimen to increase HIV neutralization coverage and more efficiently elicit these type of antibodies in future immunization studies.

OA2606

Recognition determinants of improved HIV-1 neutralization by a heavy chain matured pediatric antibody

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Background: HIV-1 bnAbs offer a promising template for structure-guided vaccine design, targeting highly potent therapeutic and preventive strategies against HIV-1. We observe rapid development of bnAbs in HIV-infected infants, contrasting with delayed response in adults, suggesting distinct maturation pathways in children. Despite extensive characterization in adults, pediatric bnAbs lack comprehensive study.

Our research focuses on a pediatric bnAb from antiretroviral-naive, chronically infected elite donors (EN), showing superior breadth and potency compared to the parental antibody.

Methods: We synthesized and extensively characterized a matured heavy chain lineage antibody known as 44m, originating from pediatric EN. 44m was isolated through longitudinal bulk BCR analysis of elite pediatric neutralizers, utilizing NGS. The heavy chain genes of 44m were codon-optimized for improved expression in mammalian systems. Antibody characteristics were assessed using IMGT/V-QUEST and ARMADiLLO. Binding reactivity and kinetics to BG505 gp140 trimer were confirmed through ELISA and Octet BLI. The neutralization potential against diverse HIV-1 viruses was evaluated at varying concentrations via TZM-bl assay. Structural insights, particularly in complex with BG505 gp40 trimer, were obtained through single-particle Cryo-EM.

Results: Our study addresses the knowledge gap in the evolving HIV-1 bnAb lineage in chronically infected children. The study revealed the functional importance of the 44m heavy chain for HIV-1 envelope binding and neutralization, with increased heterologous breadth when paired with the AIIMS-P01 light chain. Notably, the 44m antibody showed improved breadth (79%) and potency (geometric mean IC50 titer of 0.36 mg/mL) against heterologous viruses compared to AIIMS-P01. Testing against a global virus panel demonstrated a 58% breadth with an IC50 titer of 0.43 mg/mL. ARMADiLLO analysis identified four improbable amino acid mutations in 44m with less than a 2% frequency. Additionally, high-resolution structure analysis at 4.4 Å resolution highlighted the specificity of the pediatric HIV-1 bnAb 44m for the N332 supersite and the GDIR motif.



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Conclusions: In conclusion, our study highlights key factors boosting HIV-1 neutralization by the pediatric antibody 44m within the AIIIMS-P01 lineage. Factors such as recognition determinants heightened somatic hypermutation, and precise target sites enhanced 44m breadth and potency. These findings contribute to the potential of highly effective bnAb-based strategies for HIV-1 treatment and prevention.



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Cure, viral reservoirs and eradication/remission

TUPE003

Markers of immune memory/effector differentiation, exhaustion, activation and survival in people with HIV who start dual therapy: results from the ANDES trial

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Background: HIV viral reservoirs slowly decrease during antiretroviral treatment (ART), and the dynamic of this decay is shaped by T-cell differentiation and activation. We previously demonstrated no differences in viral reservoir levels among ART-naïve people with HIV (PWH) after one year of dual therapy (DT) compared to the standard-of-care triple drug therapy (TT).

Aim: To further investigate the relationship between phenotypic immune markers and HIV persistence in PWH who initiated ART with DT or TT during the ANDES clinical trial (ClinicalTrials.gov NCT02770508).

Methods: 32 PWH were enrolled (ANDES sub-study). 14 started DT (Darunavir/ritonavir800/100+Lamivudine300) and 18 TT (Darunavir/ritonavir800/100+Lamivudine300/Tenofovir300). Blood samples were obtained at weeks: 0 (W0, enrollment), 12, 24 and 48 (W48). T-cell differentiation (CD45RA, CCR7, CD95, CD27), exhaustion (PD-1), activation (HLA-DR, CD38) and survival (CD127) markers were quantified on CD8⁺ T-cells (CD8TCs), by flow cytometry. Cell-associated HIV-integrated DNA was quantitated by real-time PCR. Data was analyzed using non-parametric methods.

Results: All subjects achieved undetectable VL and increased CD4-counts (median CD4 DT:747cells/ μ L and TT:724cells/ μ L), at W48. In both groups, CD38 (DT: $p=0.022$; TT: $p=0.0009$), HLA-DR (DT: $p=0.0039$; TT: $p=0.0828$) and PD-1 (DT: $p=0.0013$; TT: $p=0.037$) expression significantly decreased at W48 compared to W0, with no differences on CD127 levels. Noteworthy, the expression of these markers at W48 was not different between both therapy regimens. The proportion of naïve-CD8TC (CCR7⁺/CD45RA⁺/CD27⁺/CD95⁺) was significantly increased at W48 compared to W0, for DT group ($p=0.018$), while lower levels of transitional-memory CD8TCs (CCR7⁺/CD45RA⁺/CD27⁺/CD95⁺) were observed at W48 in both groups (DT: $p=0.0004$; TT: $p=0.0237$).

Spearman analyses of grouped data showed direct correlations at W0 between HIV-integrated DNA levels and CD38⁺ ($r=0.4735$; $p=0.019$) and PD-1⁺ ($r=0.405$; $p=0.0496$) CD8TC percentages.

Moreover, HIV-integrated DNA at W0 directly correlated with PD-1⁺CD8TC ($r=0.6977$; $p=0.0002$) and CD38⁺/HLA-DR⁺/PD-1⁺ CD8TC ($r=0.607$; $p=0.0017$) percentages at W48.

Conclusions: One year of ART reverted the predominance of a transitional/effector CD8TCs to a less differentiated profile.

Significant reductions in activation markers were noted following ART, with no differences between DT and TT. A correlation between HIV persistence and immune activation markers was recorded, regardless of the ART regimen. Our results contribute with additional data that support the efficacy of dual therapy regimens.

TUPE004

A high proportion of HIV-1-infected elite controllers from Spain harbor viruses sharing a common ancestry, related to the earliest HIV-1 epidemic in the USA

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Background: The study of HIV-1-infected elite controllers (EC), exhibiting prolonged HIV-1 suppression and normal CD4⁺ T-cell counts without antiretroviral treatment, may provide insights into the mechanisms of HIV-1 pathogenesis and control.

Here we analyze HIV-1 near full-length genome (NFLG) and envelope sequences from a Spanish long-term elite controller (LTEC) cohort to examine viral genetic associations.

Methods: We studied 50 HIV-1 patients with EC status for ≥ 5 years, 11 of whom maintained EC status for ≥ 10 years, 11 for 5-10 years, and 28 had lost control after 5-18 years. In the last group, samples were collected before control loss in all but 1 patient. HIV-1 NFLG and full-length envelopes were amplified by PCR from PBMC-extracted DNA and sequenced.

Maximum likelihood phylogenetic trees were constructed with IQ-Tree and PhyML, using the best-fit evolutionary model and assessing node supports with ultrafast bootstrapping and SH-like approximate likelihood ratio test, respectively.



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Results: Eight NFLG sequences (≥ 8 kb) and 15 additional Env sequences were obtained. In phylogenetic trees, 4/8 NFLG and 16/23 Env sequences grouped in a well-supported cluster, that included 6 NFLG and 15 Env additional sequences from EC or long-term nonprogressors (LTNP), and 5 viruses from the earliest HIV-1 epidemic in USA, collected in 1978 or 1979 from men who have sex with men.

Most patients in the EC cluster were persons who inject drugs (PWID). In the NFLG tree, the EC cluster included a subcluster of 13 viruses (11 from Spain), most from PWID, not associated with EC or LTNP.

Conclusions: A high proportion of HIV-1 strains from LTEC from Spain share a common ancestry, grouping in a cluster deriving from a single introduction of a variant originated in the earliest USA epidemic. This cluster has been reported (Casado et al. 2013, Plos One, 8:e77663), but here we show that it is larger than previously known.

The results suggests either the existence of a viral genetic component contributing to the EC status or a cohort effect reflecting the early introduction of HIV-1 among PWID in Spain. The study of viral genetic features associated with the Spanish EC cluster could be useful for HIV-1 cure strategies.

WEPE002

HVTN 805/HPTN 093/A5393 Analytical Treatment Interruption (ATI) among African women with early ART initiation +/- VRC01 received within 8 weeks of HIV acquisition: safety, viral rebound and virologic control

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HVTN 805/HPTN 093/A5393 Study Team

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Background: Antiretroviral therapy (ART) prevents and treats HIV, but is associated with toxicity, stigma, and adherence challenges, and has been unable to cure HIV; viremia rebounds rapidly in most people with HIV upon ART cessation. Early ART initiation is associated with later ART-free virologic control—up to 20% among some cohorts of African women.

Also, broadly neutralizing anti-HIV-1 antibodies (bnAbs) may modulate immune responses to HIV. We evaluate whether early ART +/- anti-HIV bnAb VRC01, present at HIV acquisition, is associated with post-ATI control, and assess potential associations with observed control.

Methods: Thirteen women enrolled from South Africa, Malawi, Botswana and Zimbabwe after estimated HIV acquisition within 8 weeks of receiving VRC01 or placebo in the AMP HIV prevention efficacy study, followed by early

ART initiation and ≥ 1 year of viral suppression. Participants stopped ART and were monitored with frequent viral loads (VL) and CD4+ T-cell counts. ART re-initiation criteria include CD4<250, VL>1,000 copies/mL for 4 weeks without 0.5log₁₀ decline, or participant/clinician request.

Results: No serious adverse events, HIV transmissions, pregnancies or \geq Grade 2 AEs were observed. Eight STIs were diagnosed in 7 women during ATI. Two participants had tenofovir levels consistent with use during ATI; 2/11 (18%) who initiated ATI exhibited control (confirmed VL \leq 200) for ≥ 32 weeks off ART. Median time to confirmed VL>200 was 5.4 weeks (range 2.7-112 weeks). Most participants met virologic (n=7) or clinician/participant request (n=4) ART reinitiation criteria.

Controllers vs. non-controllers did not differ by VRC01 vs. placebo receipt, early post-acquisition viral load kinetics, time from estimated acquisition to closest placebo/VRC01 infusion or to ART initiation, or acquired viral isolate characteristics. See Figure 1.

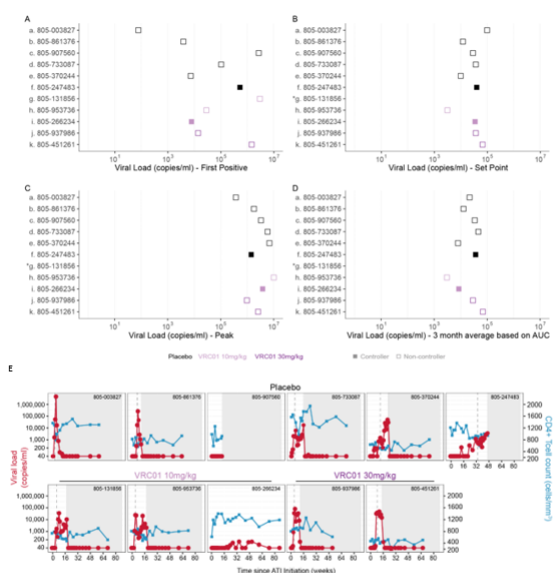


Figure 1. Viral load metrics in the parent AMP trial and individual participant viral load and CD4+ T-cell counts over time during ATI among African women. (A) First positive viral load observed in the parent AMP trial. Model estimated metrics (B) set point, (C) peak and (D) 3-month average, based on pre-ART viral load data from the parent AMP trial (Reeves DB, et al. *Nat Commun* 2023). Participant 805-131856 (indicated with *) did not have enough data to fit the models in B-D. Placebo (black), VRC01 30mg/kg (dark purple) and VRC01 10mg/kg (light purple). Filled squares indicate controller, open squares indicate non-controller. (E) Viral load shown in red circles, T cell counts in blue squares. The treatment each participant received in the parent AMP study is indicated above each panel. Time of first viremia (i.e., confirmed VL \geq 200 copies/mL) is indicated by the gray dashed line. Time of meeting ART re-initiation criteria is indicated by the beginning of the gray shaded areas. Two participants had Dried Blood Spot (DBS) antiretroviral (ARV) levels consistent with ongoing ARV use during ATI and are excluded from these analyses.

Conclusions: In a safe, well-tolerated ATI, most African women exhibited viral rebound; two (18%) showed post-intervention control. Analyses of their host and viral characteristics can inform HIV cure, prevention, and treatment strategies.

WEPE003

Highly networked CD8⁺ T cell epitopes have markedly few mutations in the latent HIV reservoir

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Background: The persistent HIV latent reservoir is a major impediment to the eradication of HIV infection for people living with HIV (PLWH). Efforts to utilize CD8⁺ T cell-based approaches have largely been unsuccessful due to the emergence of escape mutations at targeted epitope sites. Recent data from our laboratory identified a subset of epitopes, known as highly networked CD8⁺ T cell epitopes, that are constrained from mutation and preferentially targeted by individuals who naturally control HIV. In this study, we assessed whether highly networked epitopes represent a set of mutationally constrained targets for CD8⁺ T cells within the latent HIV reservoir to guide future T cell vaccine efforts.

Methods: To determine mutational frequencies of highly networked and non-networked epitopes in the latent reservoir, we performed proviral and near full-length individual proviral (FLIP) sequencing on genomic DNA from latently infected CD4⁺ T cells in 22 HIV⁺ individuals. All participants were fully suppressed with ART for >1 year and maintained undetectable viral loads at the time of sample collection. Sequence analysis of viral epitopes was performed using an established computational pipeline. *Ex vivo* and expanded IFN- γ ELISpot mapping assays were performed to determine the specificity of T cell responses and enable comparisons of T cell targeted epitopes.

Results: Sequences analyses revealed that highly networked epitopes overall had a markedly reduced frequency of mutations than non-networked epitopes in integrated proviruses (P<0.0001). A sub-analysis of epitopes restricted by individual participant HLA class I alleles also yielded significant differences between highly networked and non-networked epitopes (P<0.001). Furthermore, when analyzed epitope sequences were restricted to those targeted by CTLs, highly networked epitopes continued to demonstrate reduced mutational frequencies, indicating differences in viral evolution at highly networked epitope sites in comparison to non-networked epitopes even in response to immune pressure.

Conclusions: This study reveals that highly networked epitopes have markedly few mutations in the latent reservoir from ART-suppressed HIV⁺ individuals. These findings therefore suggest that highly networked epitopes represent a set of mutationally constrained targets for therapeutic T cell vaccine approaches that may enable durable viral suppression following ART cessation.



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TUPE005

Use of biomedical prevention technologies and HIV transmission risk among men engaged in transactional sex in Lima, Peru

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Background: Male sex workers (MSWs) play an important but understudied role in HIV transmission networks in Lima, Peru. We explored use of biomedical prevention tools (PrEP and ART) and risk factors for HIV transmission in a sample of men engaged in transactional sex from Lima, Peru.

Methods: Between May 2022–April 2023, we screened 2,282 MSM for an STI control study in Lima, Peru. Participants were tested for HIV and STIs and completed surveys detailing demographics, sexual practices including transactional sex, HIV testing history, and use of ART or PrEP. Descriptive statistics characterize risks for HIV transmission among men reporting transactional sex in the previous 6 months.

Results: 491 participants (21.5%) reported transactional sex in the previous 6-month period of whom 27.5% identified as sex workers. Men identifying as sex workers reported a median 4 days per week (IQR: 2, 5) engaged in transactional sex, during which they exchanged sex with a median of 4 clients per day (IQR: 1, 5).

Receptive and/or insertive anal intercourse (RAI/IAI) was requested by 52.1% and 53.7% of clients, respectively, with 57.8% and 53.8% reporting that most or all clients requested condomless RAI or IAI.

Prior HIV testing was reported by 88.8% participants with 42.4% (84/198) of HIV-uninfected men tested at least once every 6 months. 14.1% of HIV-uninfected MSW described any history of PrEP use, with only 4 (2.0%) were currently taking PrEP. 24.8% of MSW living with HIV reported their last HIV test was negative, indeterminate or unknown.

Most MSW known to be living with HIV were on ART (94.4%) and 65.9% (118/179) reported an undetectable viral load. 23.3% (58/249) of all participants living with HIV, 10.9% of men previously diagnosed, and 7.9% on ART had a viral load >200.

Urethral gonococcal (GC) and/or chlamydial (CT) infection was diagnosed in 4.9%, rectal GC/CT in 21.0%, and untreated syphilis (RPR >1:16) in 14.5% of participants.

Conclusions: Primary risks for HIV acquisition and transmission among MSW in Peru include undiagnosed infection, uncontrolled viremia, and scarce use of PrEP.

Promotion of HIV testing and linkage to prevention and treatment should be a focus of prevention efforts for this population.

TUPE006

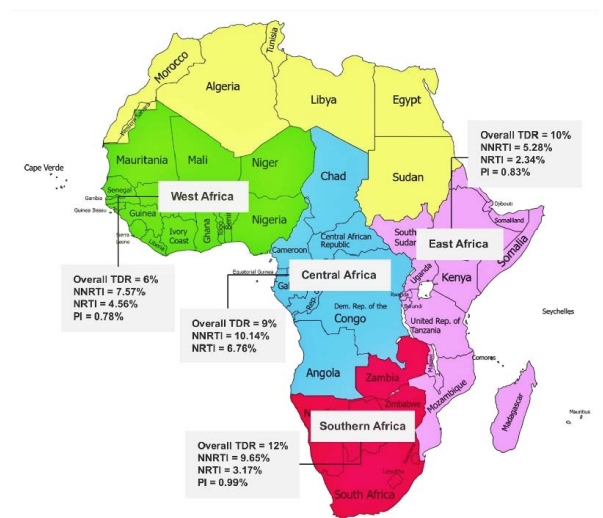
Prevalence and regional variations of primary antiretroviral resistance among treatment-naïve persons living with HIV-1 in sub-Saharan Africa: a systematic review and meta-analysis

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Background: Pretreatment drug resistance (PDR) among antiretroviral therapy (ART) naïve persons is concerning, as it increases the risk of ART inefficacy and virological failure.

This systematic review aimed to provide updated knowledge on the prevalence and regional variations of PDR among ART-naïve persons in sub-Saharan Africa (SSA).

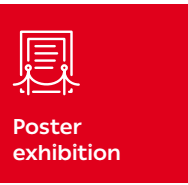
Methods: Adhering to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, a systematic literature search was conducted through PubMed, EMBASE, Web of Science, and EBSCOhost. Studies published between 2010 and 2023 that met the inclusion criteria were screened and selected. A meta-analysis of the PDR prevalence estimates was implemented using R-4.3.2 software.



Results: A total of 41 cross-sectional and cohort studies were included. The total number of ART-naïve people living with HIV was 10,567, of which 1,083 had PDR mutations. The overall pooled prevalence of PDR was 9.3% (95% CI: 7.1%–11.8%, I=93.3%) across 20 countries in SSA. In terms of regional pooled prevalence estimates, the highest



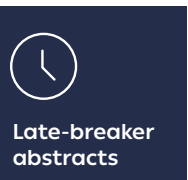
Oral abstracts



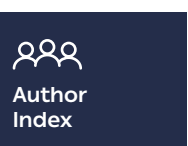
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PDR prevalence was in Southern Africa with 12% (95% CI: 7.0%–19.0%, I =96%), and the lowest was in West Africa with 6% (95% CI: 3.0%–9.0%, I =74%), while Central Africa was 9% (95% CI: 2.0%–19.0%, I =93%) and East Africa 10% (95% CI: 7.0%–19.0%, I =96%). The pooled PDR prevalence based on drug class was 7.0% (5.5–8.6) for Non-Nucleoside Reverse-Transcriptase Inhibitors (NNRTIs), 3.7% (2.7–4.8) for Nucleoside Reverse Transcriptase Inhibitors (NRTIs), and 1.1% (0.5–1.7) for Protease Inhibitors (PIs).

Conclusions: The overall prevalence of PDR mutations among ART-naïve persons in SSA was moderate, but is still above the 5% threshold recommended by the World Health Organization (WHO). Understanding the regional differences in PDR prevalence is crucial for tailoring treatment strategies based on local epidemiological patterns. The higher prevalence of NNRTI resistance emphasizes the need for incorporating integrase strand transfer inhibitors (INSTIs) in ART regimens.

WEPE004

Sexual partnership heterogeneity and HIV burdens among adolescent girls and young women in Cameroon and Côte d'Ivoire: a partner-level latent class analysis

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Background: Much of the evidence related to heightened HIV vulnerability among adolescent girls and young women (AGYW) has been generated in high-prevalence settings throughout East and Southern Africa. Given West and Central Africa's distinct HIV epidemic profile, identifying contextually specific drivers of AGYW's HIV risk is needed to adequately tailor HIV prevention programming to AGYW and their partners in the region.

Methods: We pooled data from two population-based HIV-seroprevalence surveys conducted in Cameroon (N=27,085) and Côte d'Ivoire (N=18,327). Among sexually active AGYW aged 15-24 years, we used latent class analysis (LCA) to partition past-year sexual partnerships into discrete typologies based on six relationship characteristics: cohabitation, known partner HIV status, condom use at last sex, age mixing (≥ 5 -year age disparity), transactional sex, and likelihood of having sex again. We then used Bayesian mixture modeling with cluster-robust standard errors to assess differences in AGYW's HIV status, confirmed using the Geenius™ HIV-1/2 Supplemental Assay, by partnership type.

Results: Overall, 5,482 AGYW reported 6,389 past-year sexual partners. Four distinct partnership types emerged from LCA (Figure):

Type 1 (*Cohabiting, Age-Disparate Partners*: ~46%); Type 2 (*Non-Cohabiting, Similar-Aged Partners*: ~15%); Type 3 (*One-Off, Age-Disparate Partners*: ~30%); and Type 4 (*Non-Cohabiting, Permanent, Age-Disparate Partners*: ~9%). In multivariable analysis, AGYW reporting *One-Off, Age-Disparate Partners* exhibited significantly elevated odds of HIV seropositivity relative to AGYW reporting *Cohabiting, Age-Disparate Partners* (Adjusted Odds Ratio [adjOR] 2.28, 95% confidence interval [95% CI]: 1.96-2.61, $p=0.001$) and *Non-Cohabiting, Similar-Aged Partners* (adjOR 7.46, 95% CI: 6.86-8.06, $p=0.005$), respectively.

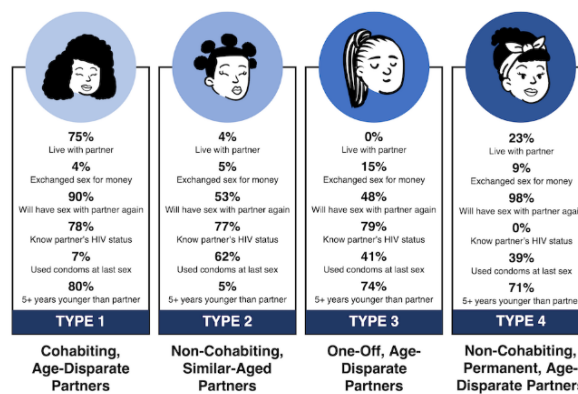


Figure.

Conclusions: LCA uncovered heterogeneous sexual partnership types—and the clustering of HIV burdens among them—reported by AGYW in Cameroon and Côte d'Ivoire. An expanding menu of HIV prevention (i.e., long-acting injectable pre-exposure prophylaxis) and diagnostic (i.e., HIV self-testing) technologies should be availed to AGYW with older, non-permanent partners, where HIV burdens appear most pronounced.

WEPE005

HIV situation among prisoners case study conducted in 30 prisons of Masaka and south western regions in Uganda (October-December 2022)

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Background: Purpose: To assess the prevalence rate of HIV/AIDS in prisons.

Objective: To reverse the trend of HIV/AIDS to less than 1% **Hypothesis;** zero new HIV, zero discrimination and zero HIV/AIDS related deaths

problem being analyzed

- High HIV prevalence rate among prisoners due to Homosexuality, un awareness, limited programs for HIV prevention and control
- Uganda Prison Service FY2021/2022 annual performance report shows that HIV prevalence rate among male prisoners were 14.4% and 24.2 % among females which is above the national prevalence rate of 5.8%.



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Methods: Study period; October – December 2022
Setting and location; Prisons of Masaka and Southwestern regions in Uganda
Study population; 1478 inmates in 30 prisons
Study design; Research and experimental observations
Data collection and methods of analysis;

- Group/Individual therapy
- Statistical analysis
- Questionnaires
- Interviews
- Case studies

Results:

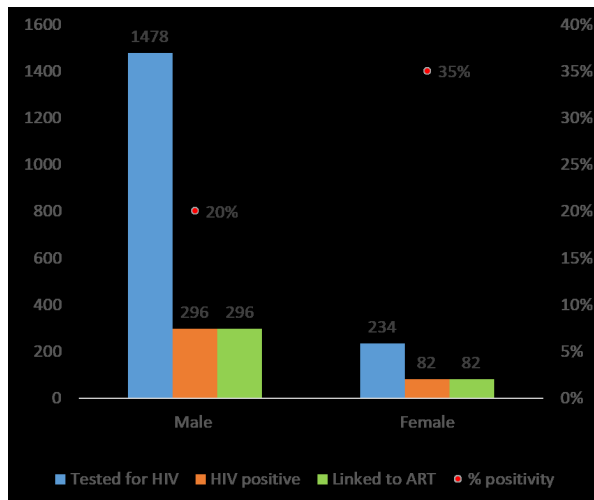


Figure 1. HIV positivity among new prisoners

- HIV positivity was 22% both male and female,
- All 30 prisons were not ART accredited, although ART Linkage was to nearby ART accredited public health facilities
- ART refills and viral load monitoring depended on availability of transport to and from ART sites

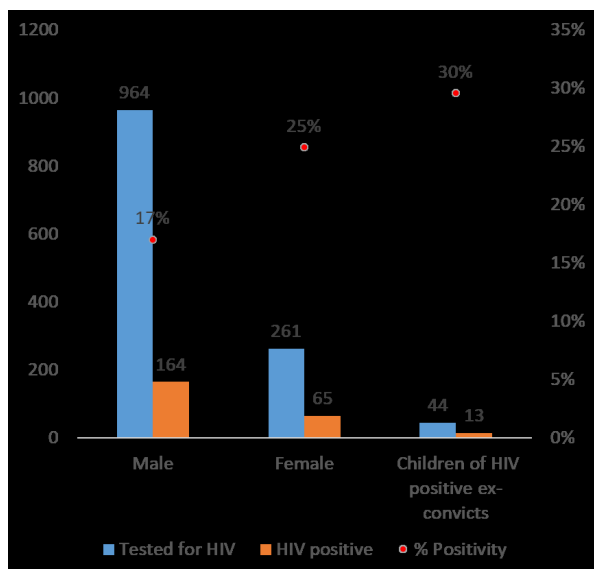


Figure 2. HIV positivity among ex-convicts one month after release

- HIV positivity among ex-convicts 19%;

It was difficult to ascertain whether these clients acquired HIV while in prisons since HIV testing at entry was conducted but it wasn't done during and on exit, although those tested HIV positive didn't reach the referral facility due to social economic factors.

Conclusions: Significance
 For policy, linkage and continuum of care
 For research and study purpose

WEPE006

Mapping the geographic differences of HIV prevalence and examining the spatial link between urbanicity and HIV among adolescent mothers and non-parenting adolescent girls in sub-Saharan Africa

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Background: Across sub-Saharan Africa (SSA), majority of new HIV diagnoses occur within micro-epidemics (areas with high HIV prevalence) and 80% of adolescent HIV diagnoses are among adolescent girls (AGs), with adolescent mothers (AMs)—an overlooked population—at increased risk. Urbanicity is a structural determinant of HIV risk. Yet, no studies have examined by maternity: geographic differences in micro-epidemics and HIV prevalence or the spatial link between urbanicity and HIV prevalence. Understanding geographic differences and spatial determinants of HIV prevalence by maternity is important for designing tailored prevention strategies for AMs. Therefore, the study's purpose is to: (1) map HIV prevalence among all AGs, AMs, and non-parenting AGs; (2) examine geographic differences in HIV prevalence and micro-epidemics by maternity; (3) examine the association between travel time to an urban center and HIV prevalence.

Methods: Data are drawn from the Demographic Health Surveys (DHS) of 5 countries in SSA. Using a sample of 8,500 AGs (15-19 years old) across 1,944 DHS clusters, we interpolated and mapped cluster-level HIV prevalence using empirical Bayesian kriging for all AGs and by maternity. To examine geographic differences, we mapped micro-epidemics (2 standard deviations above the mean) by maternity and the difference in HIV prevalence estimates between AMs and non-parenting AGs. We examine the association between travel time to urban centers and HIV prevalence amongst all AGs, AMs, and non-parenting AGs, separately, using OLS linear regression.

Results: There was geospatial heterogeneity in HIV prevalence across all three groups. When mapping micro-epidemics (2 standard deviations above the mean), there were locations with high HIV among AMs that were not present among non-parenting AGs. Mapping differences

showed that AMs tend to have higher prevalence than their non-parenting peers. Among all AGs, travel time was associated with HIV prevalence ($\beta=-1.60$; $SE=0.002$). Estimates were smaller for non-parenting AGs ($\beta=-1.13$; $SE=0.002$) and AMs, and ($\beta=-0.43$; $SE=0.005$).

Conclusions: Results show that AMs are a particularly vulnerable population, with micro-epidemics that are not consistently present in non-parenting AGs. This heterogeneity coupled with the differing associations between traveling time and HIV prevalence by maternity emphasizes the need to further understand the micro-epidemics for AMs by identifying structural drivers.

WEPE007

Characterizing multimorbidity and the risk for hospitalization among people living with HIV from the African Cohort Study

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Background: Multimorbidity, or the co-occurrence of two or more long-term health conditions, is not well-understood among people living with HIV (PLWH) and may impact outcomes such as hospitalization. In a cohort of PLWH, we explored the presence of multimorbidity clusters and factors associated with hospitalization.

Methods: We analyzed African Cohort Study participant multimorbidity diagnoses, and demographic data at enrollment between 2013-2024. We calculated the incidence rate of hospitalization and performed hierarchical clustering to explore multimorbidity clusters. We modeled the association of first hospitalization with an individual's

multimorbidity condition count, presence of commonly identified condition clusters, and demographics (age, sex, and country).

Results: Among 3231 adult participants, 510 were hospitalized, and 208 had two or more multimorbid conditions. Together, chronic diarrhea ($n=43$), neuropathy ($n=119$), and heart conditions ($n=10$) was the first group of conditions identified through cluster analysis (Figure 1).

There were 3.28 hospitalizations per 100 person-years, or 793 total hospital visits and 17276.7 person-years followed. Report of neuropathy, diarrhea, or heart condition at enrollment was not associated with hospitalization. Men were less likely ($OR=0.56$; $95\%CI: 0.45-0.69$) to be hospitalized than women. PLWH from Nigeria, Tanzania, and Uganda were more likely to be hospitalized than PLWH from Kenya.

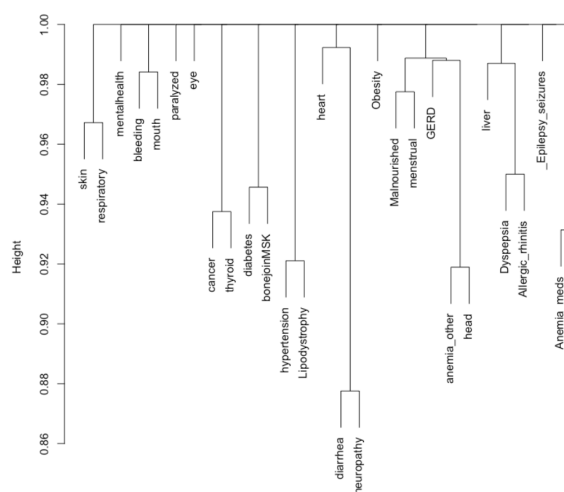
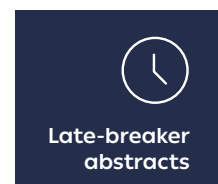
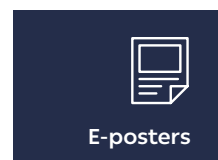
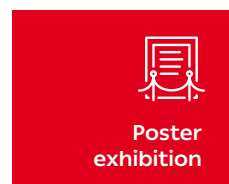
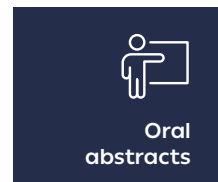


Figure 1. Hierarchical cluster analysis of multimorbidity among adult African Cohort Study participants at enrollment.

Conclusions: Integrating cluster analysis with traditional epidemiologic methods can identify groups of multimorbid health conditions among PLWH and estimate the risk of hospitalization, taking into account differences by sex and country. This information may be used to target screening and intervention for PLWH with multimorbid conditions to prevent hospitalizations or other severe outcomes and inform decisions about resource allocation in funding-constrained environments as the PLWH population ages.





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WEPE008

Burden of tuberculosis (TB) in transgender women (TGW) from the cohort TransCITAR in Buenos Aires, Argentina

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Background: Tuberculosis presents a significant public health challenge, especially in vulnerable populations with constrained healthcare access. Identifying high-risk groups for preventive treatment is crucial. This study examines active TB cases, their incidence, and associated morbidity and mortality in transgender women (TGW).

Methods: A retrospective analysis of active TB was done among TGW from Buenos Aires enrolled in the TransCITAR cohort (Sep 2019-2022). Occurrence is defined as all active cases during the study period. Incidence is defined as new confirmed cases on bacilloscopy, culture, or PCR after enrollment. Hospitalization data was used to measure morbidity. We conducted descriptive analysis, and used Pearson's Chi-squared and Fisher's exact tests, along with logistic regression, to identify factors associated with TB occurrence.

Results: Study enrolled 436 TGW, median age 30 (IQR 26-37). Active TB occurred in 3.4% (n=15), with higher rates in people with HIV (PWH) (5.8%; n=12) than HIV- individuals (1.3%; n=3) (p=0.010). Annual active TB incidence was 133.3/100,000 (CI: 60.2-206.4), 40% had multidrug resistance (6/15), 80% (12/15) were pulmonary, and 67% (10/15) were bacilliferous; 40% required hospitalization (n=6/15), all PWH, with one active TB-related death. PWH have 364% more probability of having active TB (45% - 1056%), p=0.02. All PWH active TB cases (100%; n=12) were on antiretroviral therapy (ART); median viral load was <40 copies/mL (IQR: 40 - 16,383), and median CD4 count was 531 (IQR: 326 - 667). When modelling with other factors, only HIV status remained statistically significant (p=0.02) for active TB.

Variable	n	Odds ratio	95% CI	p
Age	417			
HIV	219			0.89 (0.92, 1.00)
	198			0.81
	219			Reference
Highest educational level	219			5.04 (1.47, 23.45)
	204			0.02
	219			Reference
Actual sexual work	198			1.58 (0.91, 5.40)
	219			0.44
	198			Reference
Unstable housing	219			1.42 (0.45, 4.90)
	244			0.56
	173			Reference
Drug use	299			0.44 (0.13, 1.35)
	118			0.16
	338			Reference
Problematic alcohol use	79			0.62 (0.14, 2.10)
	285			0.48
	122			Reference
Migrant	122			0.50 (0.07, 2.13)
	330			0.40
	87			Reference
Residency	330			0.40 (0.10, 1.86)
	87			0.29
	243			Reference
Tobacco use	174			0.24 (0.01, 1.43)
	174			0.20
	174			Reference
	174			0.84 (0.26, 2.63)
	174			0.78

Figure 1: Factors associated with the occurrence of active tuberculosis.

Conclusions: The high incidence and morbidity, including drug-resistant forms, of active TB in TGW living with HIV emphasizes the need for tailored public health strategies in line with the WHO End Tuberculosis Strategy. This underscores the importance of improving TB detection and prevention treatment within this high-risk group.

HIV sequencing insights, including viral diversity and antiretroviral resistance

TUPE007

Performance of plasma separation card to determine HIV Drugs Resistance (HIVDR) in patients experiencing virologic failure

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Background: The emergence of HIVDR is a worldwide concern which threat long-term effectiveness of Antiretroviral Therapy (ART). The Plasma is the preferred specimen for HIVDR detection, however, has limited use in low-resource settings due to logistical requirements. Plasma Separation Card (PSC) allow obtain and use dried plasma for HIV VL test and other molecular analysis without complex logistical requirements. This study evaluated the performance of PSC for HIVDR detection in patients with virologic failure.

Methods: Adults with at least six months on ART, two consecutive VL≥1000 copies/mL and three adherence counseling appointments were enrolled in two Health Facilities (HF) in Mozambique between January - June 2023. Venous blood was collected from each patient to fill three delineated areas of the PSC and the remnant specimen was centrifuged to separate plasma for VL testing. Plasma with VL≥1000copies/mL and corresponding PSC were selected for New Generation Sequencing. The agreement between results was accessed based on Stanford database and plasma results were considered as reference.

Results: From 8261 patients on ART in two HF, 66 patients were enrolled and 51.5% (34/66) of these had the third VL≥1000 copies/mL. Virus isolated in plasma and PSC specimens from 27/28 patients was classified as subtype C and in 1/28 patient as subtype A. The similarity DRM detected in both specimens was 25% (1/4) for protease, 75% (21/28) for Reverse Transcriptase and 69% (9/13) for Integrase genes. High level resistance was detected for PI (71%), NRTI (50%), NNRTI (39.2%) and INSTI (32.1%). The INSTI was recently (2019) introduced for ART schemes in Mozambique. Hence, this finding constituting a potential concern and need of further monitoring.

Conclusions: The high-level similarity on the mutational profile and subtypes reported for plasma and PSC suggest the use of PSC as alternative for HIVDR detection. This would improve the access for HIVDR monitoring in low-resource settings.

TUPE008

Dapivirine is protective against HIV-1 containing NNRTI drug resistance mutations from Individuals on failing ART regimens in an *ex-vivo* ectocervical tissue challenge model

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Background: Dapivirine (DPV) vaginal ring is a safe and effective HIV prevention method for cisgender women and is currently used in multiple countries in sub-Saharan Africa. In trials, non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance frequency in participants who seroconverted did not differ between active and placebo ring arms, indicating NNRTI resistance was transmitted from a partner. The protective efficacy of DPV ring against transmitted NNRTI strains is not known. We used an *ex-vivo* ectocervical tissue challenge model to evaluate the susceptibility of donor-derived HIV-1 containing NNRTI drug resistance mutations (DRMs) to varying concentrations of DPV.

Methods: Seven donor-derived HIV-1 with at least one NNRTI DRM were isolated from ART-experienced individuals; two donor-derived viruses from ART-naïve individuals with no DRMs were included as controls. Ten-fold dilutions of DPV (500 µM to 0.5 µM) formulated as gel were applied to the apical surface of ectocervical explants from healthy donors. Explants were challenged with 5x10⁴ TCID₅₀ HIV-1 and supernatants were collected over 21 days. Viral replication was quantified by p24 and percent inhibition was calculated for each virus.

Results: The highest concentration of DPV (500 µM) achieved 52-100% inhibition for all viruses tested and >90% inhibition was achieved for four of seven viruses at 500 µM DPV. All three viruses unable to achieve >90% inhibition at 500 µM DPV contained HIV-1 NNRTI DRM K103N in combination with one to four additional NNRTI DRMs. Two of seven viruses had >90% inhibition at 50 µM DPV, and one of seven at 5 µM DPV.

Donor-derived virus	NNRTI DRMS	% Inhibition in DPV			
		500 µM	50 µM	5 µM	0.5 µM
1	L100I, K103N, V108I, E138K, P225HP	52	11	0	0
2	V90I, K103N, V108I, Y181C, K238T	83	0	0	31
3	L100M, K101E, V106M, E138K, F227L	94	0	0	0
4	K103N, Y181C	87	0	0	0
5	V106M, Y188C, G190A	100	96	73	0
6	K103KN	100	90	70	0
7	V106M, F227L	100	92	90	81

Table 1. Percent inhibition at day 11 of ectocervical explant culture.

Conclusions: The ectocervical explant model demonstrated viral inhibition against commonly transmitted NNRTI-resistant strains containing 1-3 NNRTI DRM, but DPV was only partially protective against highly resis-

tant strains with accumulated NNRTI mutations. Monitoring for HIV acquisition and drug resistance with DPV ring rollout will be important in settings with high rates of pre-treatment NNRTI resistance.

TUPE009

Genetic characterization of viral blips in people living with HIV following suppressive ART

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Background: Antiretroviral therapy (ART) has seen HIV-related mortality decline worldwide. On initiating treatment, most people can suppress plasma viral RNA to undetectable levels (<50 copies/mL). People on ART frequently experience intermittent viremia (viral blips), however the genetic nature and source of these rebounding viruses while on suppressive ART remains unclear.

Methods: Four women living with HIV-1 subtype C were identified from the Females Rising through Education, Support and Health (FRESH) acute infection cohort who experienced viral blips >2000 copies/mL following suppressive ART (median 584 days). Two participants initiated treatment during the chronic infection phase (~625 days post-detection) while the other two initiated treatment immediately upon detection of infection. RNA was extracted from stored plasma samples of participants' transmitter/founder (T/F) (~3 days post-detection), pre-treatment initiation, and during viral blips. Gag and Env genes were amplified by single genome amplification followed by sequencing. The protease and reverse transcriptase region of the *pol* gene were amplified, and bulk sequenced. Liquid chromatography and ddPCR were used to quantify ART levels and proviral reservoirs in plasma and PBMCs, respectively.

Results: Phylogenetic relatedness and genetic differences were visualized using Maximum-likelihood trees and Highlighter plots respectively (Los Alamos). Gag and env blip sequences of the acute-treated participants were similar to those of the T/F, while those of the chronic-treated participants were genetically distinct from the T/F but similar to the Pre-ART. In the acute-treated participants, all the transmitted HLA-associated gag CTL escape was retained at the blip, however the chronic-treated participants experienced an increase of ~0.8% at the blip. The development of a reduced replication capacity mutation (HLA-B*5701/5801 T242N), and the reversion of a transmitted K97E bnAb mutation in a chronic-treated participant indicated immune pressure before ART. Mutations associated with bnAb escape in the cD4 binding and gp120/gp41



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were identified in the PreART and blip sequences of the chronic-treated participants, whereas the acute-treated retained the same amino acid residues at T/F and blip. Viral blips were associated with an increase in proviral DNA and ART non-adherence. Only one chronic-treated participant developed resistance to efavirenz (K103N).

Conclusions: This data suggests that immune response-inducing / bnAb therapies may benefit early ART initiators.

WEPE009

High level of pre-treatment drug resistance in persons re-initiating antiretroviral therapy in Haiti: results from a national representative survey

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Background: We conducted a nationwide cross-sectional study to estimate pre-treatment drug resistance (PDR) prevalence in adults re-initiating antiretroviral treatment in Haiti between December 2018 to July 2019 following WHO's recommendations.

Methods: HIV drug resistance was determined on plasma using population-based sequencing of the protease, reverse transcriptase and integrase genes and interpretation done based on Stanford HIVdb v9.6. Analyses were weighted to adjust for multistage sampling and genotypic failure rate.

Results: We included 237 clients who were re-initiating treatment after previous disengagement from care. The mean age was 37.9 years (95%CI 34.6-41.3) and 51.5% were female. The median time of disengagement from care based on 62 observations where data were available was 12.7 months (IQR: 6.7-24.0). Twenty-nine percent of participants had advanced HIV disease with CD4 counts of < 200 cells/mm³ or WHO stage III/IV disease. The prevalence of resistance to non-nucleoside reverse transcriptase inhibitors (NNRTI) drugs efavirenz /nevirapine was 27.7% (95%CI 23.8-32.1) but was slightly higher among women (30.8, 95%CI 23.2-39.5) than men (24.5%, 95%CI 17.0-34.0). The prevalence of NNRTI PDR was also higher among those with advanced HIV disease compared to those with no advanced HIV disease (33.4%, 95%CI 26.6-41.0 vs 21.1, 95%CI 16.6-26.5). NRTI PDR prevalence was 6.8% (95%CI 3.9-

11.5) while that for protease inhibitors was 2.2% (95%CI 0.6-7.8). Dual resistance to NRTI and EFV/NVP was 6.8% (95%CI 3.9-11.5) but was higher among clients with advanced HIV disease (14.0%, 95%CI 9.4-20.3) compared to those without advanced HIV disease (2.8%, 95%CI, 0.8-9.8).

Conclusions: A high prevalence of efavirenz /nevirapine PDR was reported in this population of clients re-initiating treatment after previous disengagement from care and was especially high in women and those with advanced HIV disease. These findings highlight the need to fast-track the transition to the WHO-recommended dolutegravir based first-line ART as well as implement strategies to maximize retention in care.

WEPE010

Linkage of amino acid variants in HIV RT, IN, and gag to protective alleles near the *CHD1L* locus in an African population

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Background: HIV viral load (VL) is variable among individuals and is a predictor of disease progression and transmission. Genome-wide association studies have estimated that host genetics contribute to ~25% of the variability in VL; with ~30% contributed by viral genetics. A recent genome-wide association study identified a novel association between a locus on chromosome 1, near *CHD1L*, with reduced VL. However, not all individuals with protective alleles at this locus maintain low VL and this regions' impact on viral evolution has not been fully investigated.

Methods: Here, we conducted a viral escape mutation scan in 148 people living with HIV (PLWH) from South Africa, primarily infected with HIV subtype C, with available viral sequences for *reverse transcriptase (RT)*, *protease (PR)*, *gag*, and *nef* and host sequence data for 4 protective variants near *CHD1L*. Our analysis was later extended to 33 PLWH from Kenya, primarily infected with HIV subtypes A and D, with available plasma. For the Kenyan cohort, HIV sequences for *RT*, *PR*, and *integrase (IN)* were acquired via Sanger sequencing and genotypes for 4 host variants

near *CHD1L* were acquired by qPCR. Of 33 individuals, we were able to acquire *RT*, *PR*, and *IN* sequences for 27 (82%), and 5 (15%) individuals were heterozygous for the minor allele of the 4 *CHD1L* variants. Logistic regression was used to test the association between HIV amino acid variants in *RT*, *PR*, *IN*, *gag*, and *nef* with host alleles near *CHD1L*.

Results: In the South African cohort, we observed associations between the *CHD1L* variants rs77029719, rs7519713, rs59784663 and rs73004025 with codon 248 of *RT* and variant rs7519713 with codons 18 ($p=3.2 \times 10^{-2}$) and 147 ($p=3.9 \times 10^{-2}$) of *gag*. In the Kenyan cohort, we observed significant associations between the variant rs7519713 and codons 60 ($p=1.3 \times 10^{-2}$) and 216 ($p=3.3 \times 10^{-2}$) of *IN*, suggesting a mechanism of HIV restriction by *CHD1L* during integration and replication.

Conclusions: Here, we show evidence of selective pressure by variants near *CHD1L* on *RT*, *IN*, and *gag*. Our findings provide further insight into how genetic variability, near the *CHD1L* locus, contributes to viral evolution and host control in a population highly affected by HIV.

Innate and trained immunity

TUPE010

Immune activation by Tenascin-C impacts HIV-1 replication

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Background: The extracellular matrix molecule Tenascin-C (TNC) is naturally induced upon tissue injury, playing a role as danger associated molecular pattern (DAMP) molecule and in subsequent tissue repair. Interestingly, TNC was described to be highly expressed upon viral infection and to interfere with virus infection including infection by HIV.

Our project aims to characterize the effects of TNC on HIV-1 replication using novel TNC targeting tools.

Methods: Here, the impact of TNC on HIV-1 replication has been investigated *in vitro* in cell culture experiments assessing T cell activation and cytokine release. The impact of TNC on cellular HIV reservoirs was studied using the latently infected U1 cell line. We have also determined TNC serum levels during the course of HIV disease using a newly in-house developed ELISA covering the short and long TNC isoforms.

The TNC concentrations were measured in sera from non-HIV infected individuals in comparison to different cohorts of people living with HIV including sera during primary infection (PRIMO cohort), during chronic infection (EP14 cohort), and in HIV controllers (CODEX cohort).

Moreover, using the non-human primate (NHP) model, the level of TNC was recorded in lymph node tissues for SIV-infected macaques.

Results: Our results indicate that TNC-modulated T cell activation promotes HIV replication that is associated with an upregulation of the CCR5 co-receptor by TNC and, modifications of cytokine release. Moreover, TNC prolonged HIV persistence in the latently infected U1 cell line suggesting a TGF- β effect. In sera, the total TNC concentration was decreased following HIV infection, whereas TNC levels were increased in tissue lymph nodes for SIV-infected NHP. These results indicate a potential local redistribution of TNC in infected tissues.

Conclusions: These results suggest that upon infection abundant TNC induced locally interferes with HIV replication by reprogramming the tissue microenvironment in particular by activating immunity on one side and inflammation on the other side, thus opening novel opportunities for HIV disease management by targeting the immune-modulating properties of TNC.

Mathematical modelling: Impact and effectiveness

TUPE011

Novel use of predictive modeling to assess if the Uganda DREAMS program is enrolling the target population of adolescent girls and young women at risk of HIV

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Background: In sub-Saharan Africa (SSA), adolescent girls and young women (AGYW) aged 15-24 years are three times more likely to acquire HIV than their male counterparts. The Determined, Resilient, Empowered, AIDS-Free, Mentored and Safe (DREAMS) program aims to reach SSA AGYW at high HIV risk to address their HIV vulnerability. We applied a predictive model for HIV acquisition developed from the 2020 Uganda Population-based HIV Impact Assessment (UPHIA) to the Uganda DREAMS enrollment database to assess whether the CDC-supported DREAMS program is reaching its target population.

Methods: With UPHIA, we created a deidentified database of AGYW using variables aligned with the DREAMS eligibility criteria (e.g., HIV risk behaviors such as irregular condom use, transactional sex), district-level population HIV viral load (PVL), and HIV positivity. We appended



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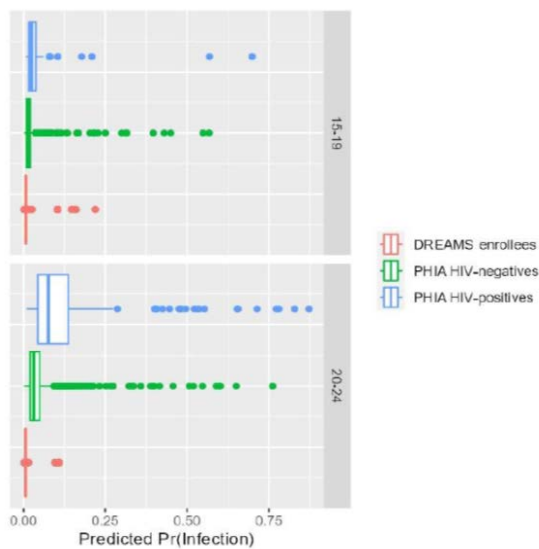


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deidentified Uganda DREAMS enrollee data on the same variables (except HIV positivity was unavailable) for participants aged 15-19 years (n=18,528) and aged 20-24 years (n=38,935) enrolled 10/1/22-4/30/23. For the UPHIA sample, we generated HIV probabilities using a Bayesian joint geospatial model for HIV positivity and the DREAMS eligibility criteria and PVL as covariates. We used the same model to impute HIV probabilities as missing outcome data for Uganda DREAMS enrollees and compared HIV probability distributions across UPHIA HIV positive (+) AGYW, UPHIA HIV negative (-) AGYW, and DREAMS enrollees for both age bands.

Results: District-level PVL was the strongest predictor for HIV status. The median HIV probabilities differed across comparison groups for both age bands (15-19: UPHIA HIV+ AGYW=0.025, UPHIA HIV- AGYW=0.013, DREAMS enrollees=0.007; 20-24: UPHIA HIV+ AGYW=0.076, UPHIA HIV- AGYW=0.031, DREAMS enrollees=0.0076) (Figure 1). HIV risk behaviors were highly reported among DREAMS enrollees, yet sites were not located in high PVL districts.

Figure 1: Probabilities for HIV Acquisition Among Adolescent Girls Young Women (AGYW) Enrolled in Uganda CDC DREAMS Program Compared to Similar Aged HIV- and HIV+ AGYW in Uganda's Population-based HIV Impact Assessment Based on the Same Risk Factors



Conclusions: Alignment of DREAMS sites to ensure coverage within PVL could address the under-representation of high-risk AGYW into DREAMS programming.

TUPE012

Scaling a non-human primate physiologically-based pharmacokinetic model of extended-release MK-2048 and combination MK-2048/vicriviroc (MK-2048A) intravaginal rings into humans using phase 1 MTN-027 and MTN-028 studies

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Background: Physiologically-based pharmacokinetic (PBPK) modeling provides a valuable tool for predicting drug distribution and concentration-time profiles in biophases of interest. This work scaled a previously developed non-human primate (NHP) PBPK model to humans to describe the disposition of the drug in the vaginal luminal fluid and plasma after intravaginal rings (IVR) administration. IVRs loaded with MK-2048 or a combination of MK-2048/vicriviroc (MK-2048A) were investigated for their potential as a pre-exposure prophylaxis (PrEP) strategy. We hypothesized that the human PBPK model would predict human vaginal fluid and plasma drug concentrations within a 90% prediction interval of those observed in human MTN-027 and MTN-028 clinical studies that investigated IVR administration in healthy women.

Methods: We scaled a mechanistic NHP PBPK model into humans using physiological parameters such as body weight, organ size, blood flow, pH, etc. The model also integrated physicochemical properties and IVR release kinetics from NHP and human MTN-027 and MTN-028 studies. The mrgsolve package in R was used to simulate the pharmacokinetic profiles after IVR administration. The digitized MTN MK-2048 IVR (30mg) and MK-2048A IVR (10 and 30mg) data were used to calibrate and validate the model, respectively.

Results: The human PBPK model successfully described the distribution of the drug in the vaginal tissues and plasma following MK-2048 or MK-2048A IVR administration. Simulation results demonstrated accurate prediction of drug concentrations in both compartments, with most predictions falling within the 90% prediction interval.

Model validation with the MK-2048A ring data confirmed the robustness and reliability of the PBPK model in predicting MK-2048 pharmacokinetics in the luminal fluid and plasma, providing valuable insights into drug distribution after vaginal administration.

Conclusions: This work showcases the adaptation of a mechanistic NHP PBPK model for humans to predict vaginal fluid and plasma concentrations after IVR administration, leveraging data from the Phase 1 studies MTN-027 and MTN-028. The model's ability to predict most drug concentrations within a 90% prediction interval highlights

its utility in guiding IVR design and dosing optimization for PrEP. Future work includes continued refinement of the PBPK model and extending the model to evaluate other vaginal formulations for PrEP interventions.

WEPE011

Contrasting deterministic and traditional volume-averaged computational PBPK modeling for topical PREP analysis

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Background: Computational PBPK modeling informs topical PREP device design and performance evaluation. Common methodology (first-order volume-averaged [VA] drug transport between compartments) has fundamentally limited accuracy, especially for localized vs. systemic drug delivery; implementation requires large multi-parameter fits to PK data with limited accuracy/precision. Deterministic modeling (causal principles of drug transport - diffusion, convection) is fundamentally more accurate, inputs key parameters measurable directly, and outputs spatiotemporal compartment drug concentrations, enabling more comprehensive PK and PD analyses.

Methods: Analysis here compared predictions of the modeling approaches. An archetypal two-compartment model contained either an intravaginal ring (IVR) or gel donor compartment, and vaginal luminal fluid or mucosal tissue as receptor. Parameters for the deterministic model were from direct measurements for Tenofovir. Key VA model parameters were obtained by fitting predictions to simulated measurements in PK studies (from deterministic results).

Results:

	t _{max} (hours)		C _{max}		C(t ₁)		C(t ₂)		C(t ₃)	
	Det	VA	Det	VA	Det	VA	Det	VA	Det	VA
IVR-Fluid	.0186	.180	.00709	.00273	2.02e-4	.00273	7.6e-5	.00269	3.8e-5	2.56e-3
IVR-Tissue	1.75	.605	.0176	.00156	.00499	.00156	.00182	.0015	9.05e-4	1.33e-3
Gel-Tissue	.761	.109	.166	.191	.0237	.0462	.00201	.0111	1.4e-5	6.39e-4

Concentration C units – concentration/vehicle-loaded concentration; Gel volume 4 mL, thickness 0.8 mm; tissue thickness 1 mm; IVR dimensions: outer diameter 5.3 cm, X-section diameter 0.76 cm; Times t₁, t₂, t₃ for IVR - 1, 7, 28 days; for Gel - 6, 12, 24 hours; fluid layer thickness 0.2 mm

Conclusions: In coital-linked gel use, kinetics of onset/loss of protective API concentrations over 24h are paramount. For sustained IVR drug delivery over ≥ 1 cycle (28d), time scales for onset/maintenance/loss of protection are longer. Our VA gel-tissue model gave 6X faster t_{max} than deterministic prediction, and much slower loss of tissue con-

centration over the final 18 hours. Computations here did not introduce measures of protection per se, but these results suggest VA modeling would tend to over-predict both rapidity and duration of protection. VA-IVR results (tissue, fluid) had shorter t_{max}'s than deterministic ones, and substantially under-predicted tissue concentrations during the first week; for the remaining 3 weeks, VA vs. deterministic predictions were similar. These results suggest VA modeling is better suited for sustained release by IVRs vs. transients during the first week of use.

These computations are a simplified but representative scenario to contrast predictions of the two modeling types for vaginal API delivery. They caution against reliance on traditional VA modeling for topical vaginal delivery of microbicides. (NIH AI150358).

WEPE012

Using deterministic computational PBPK modeling in IVR design and performance evaluation

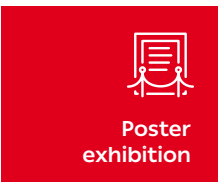
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Background: Design and performance evaluation of IVRs combine *in vitro* and *in vivo* experimentation. Current methodology is fundamentally limited in linking *in vitro* to *in vivo* PK outcomes, and measuring those outcomes comprehensively. Deterministic PK modeling using fundamental principles of mass transfer (e.g. diffusion and convection mechanisms) can help overcome these limitations, improving interpretation of *in vitro* studies, informing IVR design before *in vivo* studies, guiding their design, and improving characterization of kinetics of onset, maintenance, loss of protection.

Methods: Our deterministic PBPK model is a system of coupled partial differential equations expressing diffusion-convection conservation of mass across IVR, vaginal luminal fluid, vaginal mucosal epithelium, mucosal tissue and blood. It connects *in vitro* measurements (drug release into sink-RIS) to spatiotemporal *in vivo* drug concentrations (thus generating an *in-vitro-in-vivo*-correlation, IVIVC).

Outputs delineate kinetics of post-insertion concentration rise, sustained plateau, and post-removal concentration drop across compartments, as related to IVR design and host environment factors. Computations here are for Islatravir loaded into silicone-resin CLIP™-printed rings at 15, 30, 60 mg.





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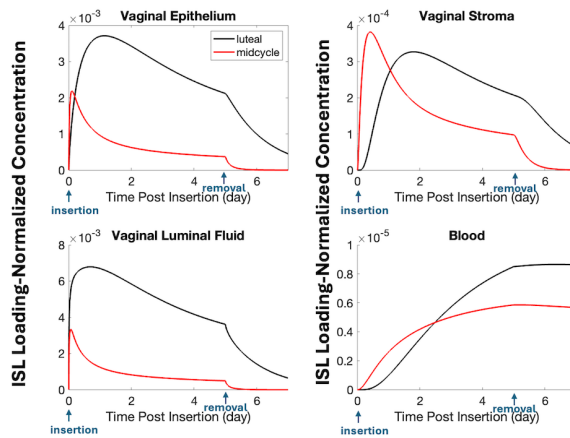


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Results:



Conclusions: RIS data yielded both the ISL diffusion coefficient and solubility in the ring, central to creating an IVVC. Dose proportionality in *in vivo* PK is lost if loading exceeds C_s . Concentration rise post-insertion was faster at midcycle, but concentrations during sustained release were multifold higher for luteal phase insertion, implying greater protection.

This guides sampling timing in PK studies, accounting for cycle phase at insertion. Kinetics of ISL-trisphosphate production in stromal host cells can be computed from these results, but results do here imply that a ≥ 5 day wait post-insertion is needed to achieve sustained protection. Loss of concentration was rapid after removal, except for blood.

This model can incorporate *in vivo* residual drug measurements in IVRs in multiple ways, to improve concordance with *in vivo* data. (Supported by NIH AI150358).

WEPE013

Hyper-local mathematical modeling of HIV transmission in Indonesia: integrating mobility patterns and intervention strategies for optimized prevention

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Background: Indonesia's archipelagic nature and diverse mobility patterns pose a unique challenge in understanding and preventing HIV transmission.

This study uses hyper-local mathematical modeling to analyze the influence of internal migration and local travel on HIV spread among key populations within Indonesia. By focusing on the interplay between mobility patterns and HIV transmission dynamics, we aim to offer novel perspectives into designing highly effective, region-specific HIV prevention strategies.

Methods: Utilizing detailed mobility data (including seasonal migration, daily commutes, and regional travel) and HIV prevalence rates from various Indonesian provinces, we constructed a compartmental model segmented by key populations (MSM, IDUs, and sex workers). This model integrates mobility networks with HIV transmission rates, accounting for local social and behavioral factors, to simulate the spread of HIV across geographic and demographic areas over a decade. The effectiveness of targeted interventions (customized PrEP deployment, mobility-aware education campaigns, and community-based testing) in mitigating HIV spread was assessed through rigorous scenario analysis. A stochastic model component was included to account for uncertainties in travel patterns and interaction frequencies, providing a comprehensive view of potential intervention impacts.

Results: Preliminary simulations indicate that integrating mobility-aware interventions could decrease new HIV infections by 54% (95% CI: 50%-58%) in high-mobility areas, significantly outperforming the baseline strategy by 26%. Specifically, dynamic PrEP allocation models, which adjust distribution based on real-time mobility data, were found to be the most cost-effective strategy, with an Incremental Cost-Effectiveness Ratio (ICER) of \$7,300 per QALY gained. Furthermore, localized education campaigns tailored to the mobility patterns of the population achieved a 33% increase in intervention uptake compared to generic campaigns.

Conclusions: Our research presents an innovative approach to HIV prevention in Indonesia by leveraging detailed mobility data to inform and optimize intervention strategies. The findings emphasize the importance of considering mobility patterns in the design and implementation of HIV prevention strategies, showing that mobility-aware approaches can significantly improve the effectiveness and efficiency of interventions in reducing HIV transmission.

TUPE014

Gardnerella induces microbe-binding IgA response in the urethra of sexually experienced males

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Background: The urethra is a critical site of HIV acquisition in both circumcised and uncircumcised men. Although correlates of urethral HIV acquisition are unknown, in the coronal sulcus and vaginal, high abundances of anaerobic bacteria are associated with elevated levels of the chemokine IL-8 and an increased risk of HIV acquisition. The impact of host genital-microbiome binding antibodies on bacterial abundance and inflammation is not clear; however, in the gut microbiome-binding IgA plays a role in the clearance of bacteria and the development of immune tolerance to inflammatory bacteria.

Methods: Here, we employed a flow cytometry-based assay to quantify urethral IgA and IgG that bind *Gardnerella vaginalis* and *Streptococcus mitis* in a cross-sectional cohort of 45 uncircumcised men from Uganda and evaluated the associations of urethral IgA and IgG with the urethral microbiome and local soluble immune factors.

Results: Urethral IgA, but not IgG, frequently bound *G. vaginalis*. *G. vaginalis*-binding IgA was elevated in participants with detectable urethral *Gardnerella*, which was only present among participants with a prior history of penile-vaginal sex. However, the presence of the common urethral bacteria *S. mitis* was not associated with differences in *S. mitis*-binding IgA.

Furthermore, recent penile-vaginal sex was strongly associated with higher urethral concentrations of total IgA, *G. vaginalis*-binding IgA, and the chemokines IL-8 and MIP-1B; the latter were independently associated with higher total IgA concentration, but not *G. vaginalis*-binding IgA.

Conclusions: Our findings suggest that sexual debut leads to the colonization of *Gardnerella* in the male urethra and induces a *G. vaginalis*-binding IgA response. These findings hold potential implications for HIV prevention including the development of microbiome-targeting vaccines.

TUPE015

Plasma biomarkers for non-invasive assessment of gut mucosal dysfunction in PLWH undergoing cART

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Background: Despite receiving effective combined antiretroviral therapy (cART), people living with HIV (PLWH) still encounter elevated rates of morbidity and mortality. HIV-induced mucosal CD4 T cell depletion is accompanied by epithelial barrier dysfunction and increased levels of microbial translocation which are key drivers of HIV disease progression. The invasiveness of anorectal biopsies emphasizes the need for validated non-invasive plasma biomarkers to evaluate gastrointestinal (GI) damage. This study aimed to unveil the link between the altered expression of structural and immunological genes at the GI level and plasma biomarkers indicating gut damage and microbial translocation in PLWH receiving cART.

Methods: Anorectal biopsy and plasma from 40 PLWH were analyzed for:

- 1) Mucosal gene expression of 14 structure- and 14 immune-related genes (via RT-PCR);
- 2) Plasma biomarkers of intestinal damage (I-FABP, zonulin, OCLN, E-cadherin, REG3 α , and TFF3), microbial translocation and systemic inflammation (LPS, LBP, sCD14 and IL-6) (via ELISA).

Group comparison based on clinical stage or cART regimen were assessed.

Correlation analyses and multiple linear regression models were applied to evaluate potential correlations between patterns of gene expression in the mucosa and plasma markers.

Results: Severe clinical stage results in *CLDN3*, *CLDN7*, *CLDN15*, and *TJP3* downregulation and *IL-22* upregulation (Figure 1A).

CLDN3, *MMP3* and *SPLI* were found to be differentially expressed within different cART regimens (Figure 1B).

Among the evaluated plasma biomarkers, OCLN, E-cadherin and IL-6 showed the highest number of statistically significant correlations with mucosal gene expression and other plasma biomarkers of GI dysfunction (Figure 1C and 1D).

A strong linear association between OCLN and E-cadherin in plasma levels was observed.



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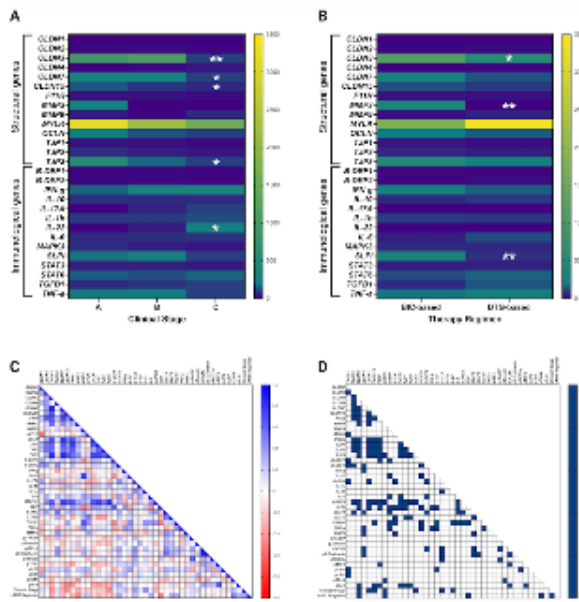


Figure 1. Gene expression profiling of structure- and immune-related genes and correlation analysis between mucosal gene expression and plasma biomarkers. Mucosal gene expression analysis of different groups of subjects stratified using clinical stage (A) or CD4⁺ regimen (B) as criteria. *p<0.05. **p<0.01. A: log₂ vs. log₂. B: log₂ vs. log₂. Correlation analysis between mucosal gene expression and plasma markers concentration. Spearman correlation r values (C) and p-values (D). Dark blue squares identify correlation with p-values lower than 0.05. Created with BioRender.com

Conclusions: Measuring OCLN, E-cadherin and IL-6 concentration in plasma offers an indirect evaluation of gut barrier function.

These results could help in developing non-invasive diagnostic strategies to assess GI integrity in PLWH and might be useful to identify risk biomarkers for non-AIDS comorbidities.

TUPE016

Changes in penile microbiome of South African cis-gender men and transwomen following surgical circumcision

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Background: Penile circumcision has been shown in multiple studies to reduce HIV acquisition via the penis, with hypothesized mechanisms including reduction in target cells, reducing time of exposure to the virus, and lowering local inflammation by changes to the microbiome through exposure to oxygen.

Methods: Participants aged 18 to 45 seeking elective surgical penile circumcision at community health centers around Cape Town, South Africa provided swabs of the coronal sulcus (CS) prior to the procedure and at follow up

visits 2 and 4 weeks later. The V3-V4 segment of the bacterial 16S rRNA gene was sequenced using DNA extracted from the swabs to characterize changes in the surface bacterial communities of the glans penis.

Results: Twenty-nine participants had sequencing data available before and after circumcision. They had median age of 26 years and reported a median of 5 lifetime sexual partners. HIV testing at baseline confirmed no participants were living with HIV infection. We observed a decrease in alpha diversity between the baseline (pre-circumcision) and follow up visits (mean Shannon diversity decrease of 0.67 from visit 1 to visit 3, paired t-test p=1.8x10⁻³). *Corynebacterium* species were prevalent, identified in 99.4% of swabs.

Bacterial species that changed significantly in relative abundance following circumcision included *Corynebacterium tuberculostearicum* (2.54-fold more abundant at visit 3 than visit 1, adjusted p<0.001) and two anaerobes with declining relative abundance: *Finexgoldia magna* (decreased by 2.6-fold at visit 3 from visit 1, adjusted p<0.001) and *Peptoniphilus grossensis* (decreased by 1.5-fold at visit 3 from visit 1, adjusted p<0.001).

Conclusions: Bacterial diversity at the CS of the penis decreased following circumcision. The relative abundance of two anaerobes previously associated with higher risk of HIV acquisition decreased, and the skin commensal *Corynebacterium* increased. This supports the proposed mechanism of circumcision's protective effect for HIV acquisition through reduced inflammation from anaerobic bacterial dysbiosis.

TUPE017

Phase 2 randomized placebo-controlled trial of the vaginal live biotherapeutic LACTIN-V among women at high risk of HIV acquisition in South Africa

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Background: Absence of vaginal lactobacilli and accompanying genital inflammation is associated with HIV acquisition. Vaginal live biotherapeutics containing *Lactobacillus crispatus* may improve health and prevent HIV.



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Methods: This phase 2 randomized, placebo-controlled trial evaluated LACTIN-V (*L. crispatus* CTV-05), a vaginal live biotherapeutic vs placebo in 45 cis-women 18-23 years old with Nugent score 4-10 who completed 7-days of oral metronidazole (MTZ). Participants were randomized (2:1) to LACTIN-V (2×10^9 CFU/dose) or placebo over 4-weeks. Vaginal microbiota were assessed by qPCR and 16S rRNA gene sequencing, endocervical immune cells by flow cytometry, and vaginal fluid inflammatory markers by Luminox in samples collected before MTZ, after MTZ (Week 0), after study product (Week-4) and in follow-up (Week-8).

Results: Forty-five black South African women were randomized to LACTIN-V (n=32) or placebo (n=13). The CTV-05 strain was detected in 69% of participants at Week 4; *L. crispatus* dominant microbiomes were identified in 40.6% (Week-4) and 25.8% (Week-8) of participants in the LACTIN-V arm vs. 0% and 9% in the placebo arm (Week-4 p=0.009; Week-8 p=0.40). The proportion of activated endocervical HIV target cells/total T cells increased post-MTZ to Week-4 in the placebo but not LACTIN-V arm: 0.916 (IQR 0.791, 2.004) vs. 0.086 (IQR -1.155, 0.51) median log₂ fold change; p=0.02. Change in 13 immune markers between pre-MTZ and Week-4 was not statistically different by arm. Three-quarters of participants "strongly agreed" or "agreed" they would use the product again. Adverse events (AEs), mostly mild, occurred in 77.8% of all participants. Local solicited AEs, most commonly vaginal discharge, were mild with no significant difference by arm.

Conclusions: The use of LACTIN-V after MTZ significantly increased vaginal *L. crispatus* colonization. Women in the placebo arm had an increase in endocervical CD4+ HIV target cells during recovery compared to the LACTIN-V arm. The product was safe and highly acceptable.

WEPE015

Lactic acid, a key *Lactobacillus* metabolite, reduces HIV internalisation and migration through the cervicovaginal epithelial barrier

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Background: Young women in sub-Saharan Africa are disproportionately affected by HIV. A *Lactobacillus*-dominated cervicovaginal microbiome reduces the risk of HIV acquisition by decreasing genital inflammation, which disrupts the female reproductive tract (FRT) epithelial barrier and enables the virus to infect target cells in the submucosa. We have discovered that lactic acid (LA), a key metabolite of optimal *Lactobacillus* spp. strengthens

the cervicovaginal epithelial barrier. However, LA's ability to inhibit passage of cell-free virus in between epithelial cells (transmigration) or HIV uptake (internalisation) and transcellular migration through epithelial cells (transcytosis) via LFA/ICAM-1 interactions are unknown.

Methods: Immortalised ectocervical (Ect1) and vaginal (VK2) cell lines were cultured in a transwell system, treated apically for 1h with 0.3% LA (pH 3.9), lactate (pH 7.0), or acidified media (pH 3.9, HCl adjusted). At 24h post-treatment, cells were thoroughly washed, and HIV (HIV_{Bo-L}, 10ng p24) or infected peripheral blood mononuclear cells (PBMCs) were added apically for 24h, after which p24 was quantified in basolateral supernatant and cell lysates. Antibodies against ICAM-1 and LFA-1 were added prior to HIV addition to block binding.

Results: LA treatment (pH 3.9), but not HCl or lactate (neutral pH) reduced HIV migration to the basolateral supernatant by 72±5.8% in Ect1 (mean ± SEM) and 89±6.8% in VK2 cells relative to untreated cells and reduced internalised virus in cell lysates by 49±7.3% in Ect1 and 67±10% in VK2 cells (p<0.05, n=5-11). LA additionally reduced HIV internalisation from infected PBMCs. LA treatment reduced ICAM-1 expression in the presence of inflammatory mediators, indicating a potential protective mechanism for LA against HIV. Furthermore, blocking ICAM-1 and LFA-1 on FRT epithelial cells with antibodies abrogated the protective effects of LA against HIV internalisation (p<0.05).

Conclusions: This study is the first to demonstrate a direct effect of LA on HIV migration through epithelial cells and provides novel insights into its potential mechanism of action.

These findings have implications for developing novel strategies to prevent HIV transmission in women utilising the protective properties of optimal FRT microbial metabolites. LA-containing intravaginal gels will be administered to women and analysed in an imminent clinical study.

WEPE016

Associations between rectal mucosal inflammation and the microbiome among HIV-negative MSM

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Background: Men who have sex with men who engage in receptive anal intercourse (MSM-RAI) demonstrate a unique rectal mucosal (RM) immune environment typified by elevated inflammatory cytokine levels and a distinct microbiome composition.

Here, we evaluated associations between RM inflammation and the microbiome among MSM-RAI and men who did not engage in RAI (controls).





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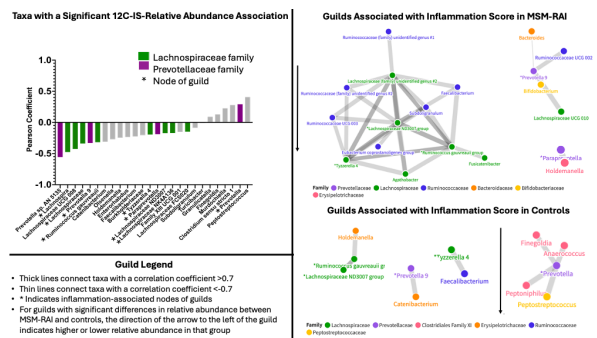
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Methods: MSM-RAI (n=19) and controls (n=6), all without HIV, aged 18-59 years underwent RM secretion collection via anoscopy. Cytokine concentrations were measured by LegendPlex, and a composite inflammation score (12C-IS) was calculated. Microbiome composition was characterized by 16S rRNA sequencing. Linear decomposition modeling (LDM) examined associations between 12C-IS and the global microbiome.

BOUTH analysis identified the phylogenetic level and taxa contributing to the LDM global enrichment signal. SparCC analysis identified inflammation-associated microbiome guilds, or groups of bacteria that thrive and decline together, measured by positively or negatively correlated relative abundance.

Results: The global microbiome composition and 26 individual taxa were significantly associated with 12C-IS (LDM global p=0.007). Twelve taxa were within the Lachnospiraceae and Prevotellaceae families, which were the most significant contributors to the global LDM association in BOUTH analysis (p<0.0001 for both). Nine of these 12 were identified as nodes of distinct inflammation-associated guilds in MSM-RAI and controls.

After assigning a strict correlation coefficient cutoff (+/-0.7), three guilds associated with high- or low-inflammation states in MSM-RAI and four in controls were identified (Fig1).



Conclusions: Microbial guilds, particularly those belonging to the Lachnospiraceae and Prevotellaceae families, were associated with RM inflammation among MSM-RAI and controls without HIV. These findings are particularly relevant given the known production of immunomodulating short chain fatty acids by Lachnospiraceae family members and the previously demonstrated Prevotellaceae family enrichment among MSM-RAI. Microbial guild analyses can provide a more nuanced understanding of RM inflammation and should be incorporated into future HIV research.

Preclinical studies for HIV prevention

TUPE020

Weekly oral prophylaxis with MK-8527 protects rhesus macaques from rectal challenge with simian-human immunodeficiency virus

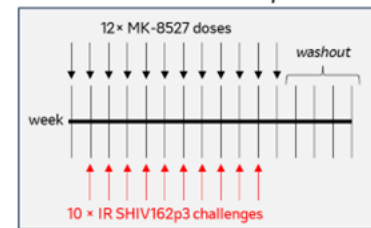
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Background: MK-8527 is a novel reverse transcriptase translocation inhibitor (NRTTI) in development for HIV prophylaxis. MK-8527 is phosphorylated intracellularly to MK-8527 triphosphate (MK-8527-TP), which is a potent inhibitor of HIV replication. MK-8527 efficacy was evaluated in a rhesus macaque preexposure prophylaxis (PrEP) model with simian-human immunodeficiency virus (SHIV) intrarectal challenge.

Methods: Two groups of male rhesus macaques (n=8/group) were administered MK-8527 weekly for 12 consecutive weeks and challenged intrarectally with SHIV162p3 weekly starting 1 week after initiation of dosing, for 10 total intrarectal challenges (Figure-1A).

A. Schematic for each dose panel



B. Infection curve

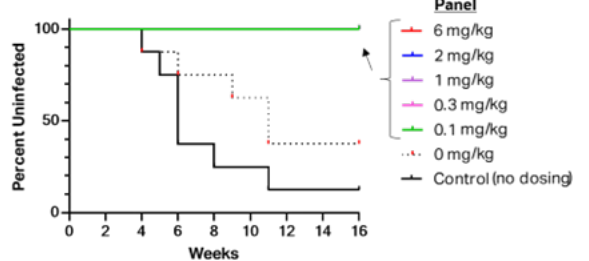


Figure 1. MK-8527 doses ≥ 0.1 mg/kg provided protection from intrarectal (IR) challenge.

A separate group (n=8, control) was challenged in the absence of any dosing. Plasma viral load was monitored weekly, and infection confirmed by 2 consecutive viral loads >100-copies/mL. In groups A and B, a washout period of ≥ 4 weeks followed each dose level after which uninfected animals were dosed and rechallenged in a subsequent panel.

There were 3 panels in Group A (6-mg/kg, 1-mg/kg, 0-mg/kg) and Group B (2-mg/kg, 0.3-mg/kg, 0.1-mg/kg); dosing proceeded from highest to lowest dose, alternating between groups. Concentrations of MK-8527 (plasma) and MK-8527-TP (PBMCs and rectal biopsies) were measured using LC-MS/MS. The IC₅₀ for MK-8527-TP against SHIV162p3

in vitro (IC_{50} = 0.0063 pmol/10⁶ cells) was used to calculate the inhibitory quotients ($IQ = MK-8527-TP C_{trough} / in\ vitro\ IC_{50}$) at each dose level.

Results: Doses of MK-8527 ≥ 0.1 -mg/kg were fully protective while 7 of 8 animals in the control group and 5 of 8 animals in the 0-mg/kg panel became infected (Figure-1B). These data indicate an 11.11-fold ($p=0.009$, by log-rank test) or 18.00-fold ($p=0.0004$, by log-rank test) lower risk of infection for the MK-8527 dose levels ≥ 0.1 -mg/kg compared to 0-mg/kg or control group, respectively. MK-8527-TP trough concentrations at the 0.1-mg/kg dose corresponded to a mean IQ of 2.2.

Conclusions: MK-8527 provides complete protection in the rhesus macaque intrarectal challenge model supporting its continued clinical development as an HIV prophylactic agent.

WEPE018

Safety/pharmacokinetics/pharmacodynamics and immunogenicity studies of griffithsin fast dissolving insert in rhesus macaques

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Background: Griffithsin (GRFT) is a potent non-antiretroviral HIV entry inhibitor. When combined with carrageenan (CG), GRFT has strong activity against HSV-2 and HPV. We reported that first-in-human Phase 1 study of 4 mg GRFT in a CG-based vaginal gel demonstrated no systemic absorption, and no safety signals in healthy, HIV-negative women. Our GRFT freeze-dried fast dissolving insert (GRFT FDI) containing CG for on-demand use equivalent of 1x clinical gel dose (4 mg) protected rhesus macaques from a high dose vaginal SHIV SF162P3 challenge 4 hours after FDI insertion.

Our goal was to evaluate GRFT FDI dose equivalent of 3x of clinical gel dose compared with the equivalent of 1x dose.

Methods: We evaluated 1 mg and 3 mg GRFT FDIs in adult female Indian rhesus macaques (*Macaca mulatta*). GRFT concentrations in CVL and plasma, anti-GRFT antibodies in plasma (anti-drug antibodies assay (ADA)), and cytokines in CVL were measured using MSD-ECL platform. Anti-HIV-1BaL, -HSV-2 and -HPV16 pseudovirus activity was evaluated in TZMbl, Vero, and HeLa cells, respectively.

Results: GRFT FDIs did not induce an increase in CVL proinflammatory cytokine concentrations. CVL GRFT concentrations above those associated with in vivo efficacy were detected at least 12 hours following 3 mg GRFT FDI administration. We detected potent anti-HIV-1BaL activity of CVL collected at 24 and 12 hours following 3 mg and

1 mg GRFT FDI administration, respectively. CVL strongly inhibited HSV-2 at 4 hours and HPV at 12 hours after FDI administration. ADAs were detected in several animals in both GRFT FDI groups.

Conclusions: CVL GRFT concentrations and anti-HIV activity of CVL collected from animals treated with 3 mg GRFT FDIs suggest a longer (up to at least 12 hours) window of protection against HIV-1 in vivo. Similarly, we demonstrated anti-HPV and HSV-2 activity, however with a shorter duration of protection. Since no GRFT was detected in plasma, ADAs would not alter pharmacokinetic profiles. In addition, preclinical ADA studies have limited predictive value for the development of ADA responses in humans, and, therefore, these data are unlikely to have clinical implications. Overall, our data raise no safety concerns and support further GRFT FDI clinical testing.

Transmission of HIV

TUPE021

Macrophage- and CD4⁺ T cells produce SIV with distinct glycosylation, infectivity and neutralization sensitivity

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Background: The human immunodeficiency virus (HIV) requires its envelope protein (Env) to infect the target cells. For the immune system, Env is the sole available target on the viral surface but the dense N-glycosylation of Env hinders effective recognition by neutralizing antibodies. Previous studies showed that CD4⁺ T cells and macrophages, key target cells of HIV, glycosylate Env differently. Further, earlier works hint towards an influence of host cell origin on HIV functionality.

In this study, utilizing the simian immunodeficiency virus (SIV) as a model for HIV, our objectives were twofold: (i) to elucidate, for the first time, the distinct N-glycosyla-



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tion patterns of Env produced by CD4⁺ T cells and macrophages, and (ii) to characterize the potential impact of virus production in these cell types on viral infectivity and neutralization sensitivity.

Methods: SIVmac239/316 Env was produced in rhesus macaque CD4⁺ T cells (T-SIV) or monocyte-derived macrophages (M-SIV). The *N*-glycome of the Env subunit gp120 of both viruses was determined via xCGE-LIF following integral glycan release. *In vivo* infectivity was assessed in rhesus macaques, while *in vitro* infection, transmission, and neutralization experiments were conducted to evaluate functional differences between T-SIV and M-SIV.

Results: We found quantitative but not qualitative differences between the *N*-glycomes of gp120 of T-SIV and M-SIV. T-SIV incorporated higher amounts of oligomannose-type *N*-glycans and the complex-type glycan profiles of both viruses varied considerably. Although both viruses were transmittable in an exploratory *in vivo* study, M-SIV displayed features indicative of higher efficiency of viral spread *in vitro* in comparison to T-SIV. These included higher Env incorporation, infectivity, and transmissibility by cellular lectins. Furthermore, host cell origin modulated the sensitivity of SIV to neutralizing agents: Mannose-specific carbohydrate binding agents blocked T-SIV more efficiently, while M-SIV infection was more strongly inhibited by SIVmac239-specific sera.

Conclusions: In this study, we provide the first detailed comparison between the *N*-glycomes of SIV Env as produced by the CD4⁺ T cells and macrophages. Further, we demonstrate an influence of host cell origin on SIV infectivity and neutralization sensitivity *in vitro*, with potentially important implications for the development of biomedical interventions against HIV.

WEPE019

Influence of HIV-1 replicative capacity on T-cell metabolism, cytokine induction and viral cell-to-cell spread

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Background: HIV-1 viruses with high replicative capacity (RC) are associated with elevated viral loads and faster disease progression in the absence of antiretroviral therapy. However, lower-RC viruses may also play a role in transmission dynamics. Understanding the mechanisms

underlying the spread of viruses with variable RCs is crucial for developing novel anti-HIV interventions. Metabolic reprogramming of CD4⁺ T cells, particularly glucose metabolism, is known to favour HIV-1 pathogenesis. We hypothesised that viruses with varying RCs differentially modulate T cellular metabolism, influencing viral transmission.

Methods: Chimeric viruses incorporating patient-derived gag-proteases from HIV-1 subtypes B and C were generated in the NL4-3 backbone (n = 27). RC was assessed using a GFP-reporter T cell-line assay, and cell-to-cell spread capacity was evaluated via flow cytometry-based detection of Gag p24. Glucose and fatty acid uptake were quantified using flow cytometry-based 2-NBDG and bodipy uptake assays, with glutamine levels measured using a luminescence-based assay.

Results: Subtype B viruses exhibited higher RCs compared to subtype C viruses (p = 0.003). Notably, virus RC correlated with T-cellular glucose uptake (p = 0.02, r = 0.5), but not with fatty acid uptake. Interestingly, fatty acid uptake was higher in cells expressing HIV Gag, regardless of virus RC, compared to bystander cells within the same culture (p = 0.02). Moreover, cell-to-cell spread correlated with virus RC (p = 0.008, r = 0.5), accompanied by increased glutamine consumption in T-cell cultures. Low RC subtype C viruses showed heightened induction of TNF- α and IL-8, along with reduced induction of PDGF-bb and IL-7 (all p < 0.05). Additionally, mitochondrial depolarization was higher in subtype B infections compared to subtype C infections (p = 0.008).

Conclusions: Our findings indicate that high RC strains and subtypes, when compared with low RC strains, exhibit enhanced cell-to-cell spread, promote increased glucose uptake and glutamine consumption, and are associated with mitochondrial dysfunction and the induction of IL-7 and PDGF-bb. These features may contribute to enhanced HIV pathogenesis associated with high RC strains and have implications for understanding the differential clinical outcomes by viruses with variable replicative capacities.

Contraception, pregnancy and HIV prevention (including vertical transmission)

TUPE022

Clinical and *in vitro* data suggests differential regulation of select growth factors and epithelial barrier function in the female genital tract between progestin-only injectable contraceptives depo-medroxyprogesterone acetate and norethisterone enanthate

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Background: Sub-Saharan Africa has high HIV incidence in females of reproductive age. Observational studies suggest that the use of injectable contraceptive depo medroxyprogesterone acetate (DMPA-IM), unlike norethisterone acetate (NET-EN), increases the risk of HIV-1 acquisition in women. DMPA-IM and NET-EN use have been shown to have different effects on growth factor levels in the female genital tract (FGT); however, results are inconsistent and there is limited information for NET-EN. Growth factors regulate cell growth, differentiation, migration and signalling which are necessary to maintain FGT epithelial cell barrier integrity. Differential growth factor regulation by MPA and NET could differentially affect FGT barrier function and the risk of HIV acquisition.

Methods: The Women's Health Injectable Contraceptive and HIV (WHICH 2018-2019) study collected samples from 521 South African women, randomized equally to DMPA-IM or NET-EN. This secondary study used Luminex to measure secreted growth factors in randomly selected vaginal swab supernatant samples from 93 women at baseline and peak serum progestin levels, one week after the 6-month injection. RT-qPCR and ELISAs were used to measure mRNA and protein secretion of fibroblast growth factor (FGF2), vascular endothelial growth factor (VEGF) and desmoglein-1 (mRNA only) in the Vk2/E6E7 vaginal cell line after treatment with MPA, NET or the glucocorticoid dexamethasone (DEX). Wound healing was investigated using scratch assays.

Results: Clinical data for FGF2 and VEGF showed a decreasing trend in the DMPA-IM arm and an increasing trend in the NET-EN arm, with a significant difference in the change in VEGF levels between contraceptive groups. In Vk2/E6E7 cells, MPA and DEX decreased mRNA levels of epithelial cell adhesion protein desmoglein-1, FGF2 and

VEGF, and VEGF protein levels, whilst no changes were detected with NET. MPA and DEX impaired wound healing, while NET had no effect.

Conclusions: Clinical and *in vitro* data showed differential expression of growth factors between DMPA-IM/MPA and NET-EN/NET users. The Vk2/E6E7 cells further showed MPA-induced decreases in growth factor expression, consistent with impaired wound healing data. Similar results were obtained with DEX, suggesting glucocorticoid receptor involvement in the MPA-induced response. Results suggest that NET-EN use may be more protective in the genital tract than DMPA-IM.

TUPE023

Its possible to involve pregnant and breastfeeding women in HIV prevention clinical trials

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Background: Women spend a significant part of their lifetime pregnant or breastfeeding, wherein they are at heightened risk of HIV acquisition, yet they remain widely excluded from clinical trials due to safety and fertility concerns. Moreover, intensive ethical oversight and additional regulatory review processes potentially delay marketing for them. Its critical to study drugs in these populations to provide safe HIV prevention options and prevent mother-to-child transmission. There is limited data on their involvement in research of new HIV prevention agents.

Methods: MU-JHU has participated in HIV prevention studies involving pregnant and breastfeeding women i.e. MTN-042 (Safety Trial of Dapivirine Vaginal Ring and Oral Truvada Use in Pregnancy), IMPAACT 2009 (Cohort study of HIV-uninfected pregnant adolescents and young women) and HPTN-084 (Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Oral Truvada in HIV-Uninfected Women). Before study start; stakeholders including civil society, policy makers, regulators, religious leaders, community healthcare providers and political leaders were involved from protocol development; community representatives were engaged to ease community education and recruitment; hospital-based staff were hired to ensure delivery of quality health care to participants while in hospital; study staff were trained on handling and counseling mothers on risk perception; male partner involvement and disclosure counseling were done to promote openness and mitigate social harm.

Results: Joint ethical regulatory review improved concordance between all parties involved, shortened approval timelines e.g. 2 months for the MTN-042 study and led to its adoption by the Uganda National Council for Science and Technology; Male involvement improved retention to study product and visits; Holistic care given to mothers



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and their families improved wellbeing and retention in the studies i.e. 98%, 96% and 95% respectively; Risk perception education enhanced women's understanding of the need to protect themselves and their infants from HIV with the help of tools such as the Enrollment Decision Tool on which reasons for study participation were documented during pre-screening.

Conclusions: Participation of pregnant and breastfeeding women in clinical trials is achievable through implementation of collaborative and inclusive practices aimed at advocating for their involvement. Key stakeholder involvement can mitigate the ethical approval dilemma.

TUPE024

Empowering adolescent health: impact of VPL program on HIV prevention, contraception access, and community engagement

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Background: In Bangladesh, adolescent sexual and reproductive health (SRH) is a critical concern due to high rates of early marriage and childbearing. The research aims to assess the impact of the Volunteer Peer Leadership (VPL) program on adolescent SRH outcomes, including HIV prevention and contraception access. It hypothesizes that the VPL program reduces pregnancy rates and STIs by empowering adolescents through peer-led advocacy. The study addresses socio-economic and gender-based determinants, aiming to improve overall adolescent health in Bangladesh.

Methods: Between September 2021 and November 2023, a mixed-methods study was conducted in urban and rural areas across Dhaka, Narayanganj, Mymensingh, and Netrakona districts of Bangladesh. Adolescents aged 10-19 were surveyed, alongside the analysis of data from Adolescent Friendly Health Centers (AFHCs). Qualitative data was gathered through focus groups and interviews with stakeholders. Descriptive statistics and thematic analysis were employed to evaluate the impact of the Volunteer Peer Leadership (VPL) program on adolescent sexual and reproductive health outcomes, such as HIV prevention and contraception access. Triangulation ensured the reliability of the findings.

Results: The study demonstrates significant improvements in adolescent sexual and reproductive health (SRH) outcomes following the implementation of the Volunteer Peer Leadership (VPL) program in Bangladesh. Quantitative analysis indicates a nearly three-fold increase in Adolescent Friendly Health Centers (AFHCs) utilization, rising from 1,254 to 4,121 visits annually among 10 to 19-year-olds in the four districts studied. Gender disparities are evident, with girls showing higher engagement. Qualitative findings confirm the positive impact of the VPL program on SRH awareness and satisfaction with services. Participants praise peer-led advocacy, highlighting enhancements in HIV prevention, contraception access, and STI

awareness. The results also underscore evolving community attitudes toward adolescent SRH, emphasizing the importance of ongoing support and peer-led interventions to promote adolescent well-being in Bangladesh.

Conclusions: The study showcases significant improvements in adolescent SRH outcomes post-VPL program implementation in Bangladesh. Quantitative analysis reveals a three-fold increase in AFHC utilization among adolescents aged 10-19 across four districts. Qualitative data supports VPL's positive impact on SRH knowledge and community attitudes. The findings advocate for peer-led interventions in advancing adolescent SRH.

TUPE025

Empowering futures: a comprehensive sex-education initiative for HIV/AIDS and teenage pregnancy prevention in Mityana District, Uganda

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Background: The "Comprehensive Sex-Education Initiative for HIV/AIDS and Teenage Pregnancy Prevention" addresses the heightened risks of HIV/AIDS, early marriages, and teenage pregnancies in Uganda, particularly exacerbated by the COVID-19 pandemic. Targeting adolescents and youth aged 14-24, the program aims to enhance sexual and reproductive health outcomes by providing accurate information, life skills, and a supportive environment for informed decision-making. The overarching goal is to reduce HIV/AIDS transmission and instances of teenage pregnancies within this vulnerable demographic.

Methods: Implemented for a period of one year starting in January 2023, the initiative focused on Mityana District, Uganda. Collaborating with 10 schools, including Buzibazi, St. Hennery, Bujubi, Avima, St. Kizzito, Maanyi Community P/S, Maanyi Parents P/S, Bujubi P/S, Sserinya P/S, and Misigi P/S, the program engaged young men and women aged 14-24. The initiative involved recruiting and training 100 young people as peer educators and 10 teachers as mentors. Activities included comprehensive training sessions for both peer educators and mentors, workshops on sex education, parental education sessions, HIV counseling and testing campaigns, and the provision of referral services.

Results: The project has yielded significant successes, with outcomes indicating increased awareness and knowledge among participants regarding HIV/AIDS transmission, prevention, and related topics. The peer education model has proven effective in mobilizing students for HIV counseling and testing campaigns. Notable results include improved understanding of HIV/AIDS transmission and prevention, as well as increased engagement in sexual and reproductive health services.

Conclusions: This initiative holds significant potential in reducing HIV/AIDS prevalence and teenage pregnancies through targeted sex education interventions. The

peer education approach, complemented by parental involvement, has emerged as a successful strategy. The outcomes of the project underscore the critical importance of comprehensive sex education in mitigating reproductive health risks. Future steps involve sustaining partnerships, expanding initiatives to other districts, and advocating for continued support for similar programs. Ultimately, this project serves as a foundation for fostering positive behavior among adolescents and contributing to broader HIV prevention efforts in Uganda.

TUPE026

Contraceptive use and pregnancy incidence in the HVTN 705/HPX2008 HIV vaccine trial in southern Africa

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Background: Clinical trials evaluating HIV prevention strategies often recruit women of childbearing potential and may require contraceptive use.

Methods: Secondary data analysis was performed from HVTN 705/HPX2008, a phase 2b HIV vaccine trial conducted in five southern African countries between 2017-2021. Baseline characteristics and contraceptive use were described among participants during the protocol-mandated contraceptive use period of months 0-15. Incidence rates for first study pregnancy were calculated for months 0-15 and months 0-36 including time when contraceptive

use was not required. Cox regression analysis assessed factors associated with incident pregnancy, accounting for changes in contraceptive use and method.

Results:

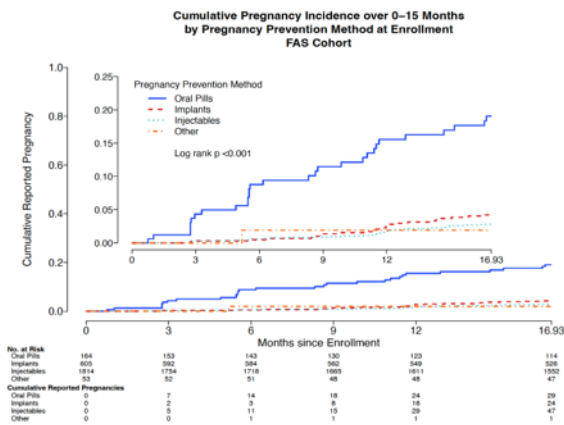


Figure 1. Cumulative reported pregnancy incidence, months 0-15, among all women who received at least one investigational product, stratified by pregnancy prevention method. Pregnancy prevention method was modelled as a time-varying covariate. Data was censored at 16.93 months which includes follow up time for participants who came late for the Month 15 visit.

Among 2636 cisgender female participants who received at least 1 dose of study product or placebo, the median age was 23 years (range 18-35) and 81.8% lived in urban settings. At entry, contraceptives used included injectables (62.9%), implants (22.1%), oral contraceptives (5.7%), and intrauterine devices (1.5%).

The pregnancy rate during months 0-15 was 2.95 per 100 person-years (py) (95% CI: 2.40, 3.58), ranging from 2.27 (1.39, 3.50) /100 py for ages 18-20 years, 3.33 (2.63, 4.16)/100 py for ages 21-30 years and 1.75 (0.48, 4.48)/100 py for ages 31-35 years.

Pregnancy incidence increased after month 15; rates during all 36 months were 6.10/100 py (placebo) and 6.89/100 py (product).

Oral contraceptive users had the least reduction in incident pregnancy over 36 months, while implant users had the most reduction, compared to no contraception (p < 0.001). Each additional year of age was associated with 8% decrease in pregnancy (p=0.014).

Conclusions: During this vaccine trial, most women delayed fertility for 15 months, and oral contraceptives were associated with more incident pregnancy than other methods.

When protocols require extended periods of contraceptive use, it is critical to support participants to access and use effective contraceptive methods of their choice.

Keywords: HIV-1 vaccine trials, HIV prevention, contraception, pregnancy

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TUPE027

Integrating group interpersonal psychotherapy in HIV prevention programs as a treatment strategy of depression among adolescents and young women in Homa Bay County, Kenya

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Background: Whereas group interpersonal psychotherapy (IPT-G) has proved to be effective in treating depression among adolescent girls and young women (AGYW), its integration in HIV prevention programs remains sub-optimal. LVCT Health; Vukisha95 Project integrated IPT-G into the Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe (DREAMS), the program that aims to reduce new HIV infections among AGYW aged 15-24 years implemented in 7 wards in Homa Bay County. We assessed the treatment outcome of IPT-G integrated into the DREAMS program for the management of depression among AGYW.

Methods: IPT-G integration targeted AGYW attending DREAMS safe spaces between October and December 2023. Thirty facilitators were identified among DREAMS mentors and social workers and trained to provide IPT-G. Education and pre-assessment for depressed mood and anhedonia were done using Patient Health Questionnaire (PHQ)-2; those AGYW who scored ≥ 3 were pre-grouped and screened for depression using PHQ-9; those who scored 10 and above were enrolled into IPT-G therapy for six sessions and met once per week for 2 hours in six weeks.

Those who completed the six sessions were rescreened before termination. Safety plans that included follow-ups and referrals for specialized treatment were administered to those with suicidal ideation and those who still experienced depression. A standardized form was used to abstract data from screening forms into an Excel sheet, and descriptive statistics were generated.

Results: As of December 2023, 4,449 AGYW attended safe space, 23.9% (n=1,064) received IPT-G education, while 61.6% (n=655) were pre-assessed using PHQ-2, and 94.5% (n=619) were eligible for pre-grouping. The majority 92.1% (n=603) had depressed symptoms after being screened for depression using PHQ-9 and were assigned to sixty-one groups of 8-12 people, where 96% (n= 579) completed therapy sessions.

Overall, 89% (n=518) of all who completed the six sessions had no symptoms of depression. Safety plans were administered to 4% (n=23) who had recorded suicidal ideation and 10.5% (n=61) who were still depressed after the sessions.

Conclusions: The majority of AGYW receiving IPT-G as a treatment for depression reported favorable outcomes. Integration of IPT-G into HIV prevention programs may result in similar outcomes in the treatment of depression among vulnerable populations.

TUPE028

Low pregnancy incidence and high PrEP uptake among HIV-exposed women in urban KwaZulu-Natal, South Africa

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Background: Women need prevention strategies to mitigate HIV acquisition during pregnancy.

Methods: We conducted a single-arm longitudinal study offering safer conception counselling including TDF/FTC as PrEP with quarterly adherence support (Healthy Families-PrEP) for periconception use in South Africa. We enrolled HIV-uninfected women with a partner with HIV or unknown serostatus, and plans for pregnancy. Women were followed for one year or until end of pregnancy. We used modified Poisson regression to estimate adjusted relative risk (aRR) for factors associated with incident pregnancy.

We evaluated PrEP adherence by proportion of days with electronic pillcap opened (summarized quarterly) and quarterly detectable ($>=10\text{ng/mL}$) plasma tenofovir concentrations (reflecting 4 or more doses in the past week).

Results: From November 2017 to January 2020, we enrolled 326 women with median age 24 (IQR: 22-27) years. Partner HIV-serostatus was unknown by 316 (97%). Over 3,204 person-months of follow up, 56 women became pregnant (incidence rate 1.7 per 100 person-months). Factors associated with pregnancy included younger age (aRR 0.89 [95% CI: 0.82-0.97] per year increase) and ≥ 2 vs. 0 prior pregnancies (aRR 2.73 [1.27-5.84]).

Among pregnant women, 35 (63%) used PrEP. Mean (95% CI) adherence by pillcap during pregnancy was 53.1% (46.9-59.3%), with adherence of 53.8% (34.8-72.7%) at month 3, 61.9% (42.0-81.8%) at month 6, and 23.3% (11.6-58.3%) at month 9. Plasma tenofovir concentrations were detected among 25.0% of women with samples at months 0-3,

15.4% at months 4-6, and 12.5% at months 7-9. No HIV seroconversions were observed. Pregnancy and infant outcomes were reassuring with no observed differences between pregnancies exposed vs. unexposed to PrEP.

Conclusions: We observed low pregnancy incidence among a cohort planning for pregnancy in South Africa. Safer conception counselling may have supported delayed pregnancy plans.

Most (63%) women used PrEP in pregnancy, taking over half of doses, with reassuring safety data. Up to a quarter had plasma tenofovir concentrations consistent with taking at least four doses per week –reflecting pharmacokinetics of pregnancy and adherence challenges.

These data reflect high interest and promise for PrEP use in pregnancy and ongoing need to optimize adherence support and prevention choices in pregnancy.

TUPE029

Microenvironmental factors associated with HIV-1 activity of cervicovaginal secretions at baseline in a contraceptive initiation study in African and US women

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Background: HIV-1 transmission in the female reproductive tract is affected by mucosal factors and conditions such as vaginal infections, hygienic practices, and contraceptive use. The UMPALA trial evaluated the impact of four widely-used contraceptives on the cervicovaginal (CV) mucosa of HIV-negative women from Kenya and USA. While post-treatment analysis is ongoing, here we present data on CV factors associated with HIV-1 activity of baseline CV secretions (CVS).

Methods: The effect of CVS, collected with swabs, on HIV-1_{Bal} infection of TZM-bl cells was monitored by luciferase production and expressed as percentage (%) of control HIV-1 infection (virus + cells and no CVS). Vaginal Nugent score, pH, glycogen, L/D-lactic acid, SLPI, RANTES and β -defensin-2 levels were also measured. Univariate and multivariate analyses were performed to determine statistical significance.

Results: HIV-1 infectivity levels in the presence of CVS were broadly distributed among both Kenyan and US women, and their medians were not statistically different between these two cohorts.

We then categorized all CVS as "enhancers," "inhibitors" and "neutrals" based on infection rates $\geq 125\%$, $<125\text{--}75\%$, and $\leq 75\%$ compared to controls, respectively.

Higher prevalence of enhancers (43% vs 31%) and lower of inhibitors (13% vs 27%) were observed in Kenyan participants, suggesting differences in microenvironmental factors modulating CVS HIV-1 activity. Overall, CV glycogen ($p<0.0001$) and L- ($p<0.0001$)/D-lactic acid ($p=0.0022$) content were negatively correlated, and Nugent score ($p=0.0005$) and pH ($p<0.0001$) positively associated with infection levels. RANTES tended to be positively associated, and β -defensin-2 negatively associated with infection in both cohorts without reaching statistical significance. Enhancers showed the lowest levels of glycogen, L-lactic acid and β -defensin-2 and the highest values for Nugent scores, pH and RANTES.

Conclusions: Innate baseline CV secretions of Kenyan and US women enrolled in a contraceptive study demonstrated significantly different effects on ex vivo HIV-1 infection of target cells, from enhancement to inhibition. Enhancing effects were more prevalent in Kenyan women and overall correlated with decreased glycogen, lactic acid, and β -defensin levels, and with higher Nugent score and pH, suggesting an association with CV dysbiotic states. Ongoing analysis will determine the potential impact of initiation of hormonal and non-hormonal contraception.

TUPE030

Enhancing capacity for contraceptive counselling through counselling for choice (C4C) among healthcare providers in Migori, Narok, Homabay and Kilifi Counties, Kenya

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Background: The Kenya Demographic Health Survey (KDHS) 2022 highlights a 14% unmet need for Family Planning (FP), with a goal to reach a 64% modern contraceptive prevalence rate by 2030. Limited counselling and service delivery skills contribute to early FP discontinuation. The C4C training platform, developed by Population Services International (PSI) and USAID, prioritizes client-centered care, informed choice, and collaborative dialogue to improve client satisfaction, contraceptive uptake and continuation.

C4C utilizes evidence-based strategies, emphasizing rigorous training and digital delivery methods like WhatsApp, accelerated by the COVID-19 pandemic.

Methods: To address contraceptive counseling knowledge and skills gaps among HCPs, PSI through PS Kenya with County government buy-in, adopted the C4C training and implemented it through digital platforms in 2022. Leveraging its popularity, C4C content was delivered through the WhatsApp platform (+254203893451) allowing convenience, accessible and cost-effectiveness.

In February 2023, the course content was adopted by Medical Learning Hub, a web-based platform to further expand the reach of training initiatives. After the training,



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the HCPs skills are assessed through simulated and real clients' interactions during support supervision by Ministry of Health trained ToTs.

Results: In the A360, an adolescent led AYSRH project implementing in MoH facilities in Migori, Homabay, Kilifi and Narok; (685)76% of HCPS working MCH/FP have completing the course, of this a sample of 100(15%) were assessed. Notable outcomes included: increased utilization of job aids by HCPs during counselling sessions. There was improved articulation of contraceptive-related menstrual changes and enhanced communication of key information with clients. By placing clients at the center of counseling, avoid medical jargon in counselling and emphasizing informed choice has contributed to reduction of unmet Family planning needs among adolescent girls and a notable reduction in contraceptive discontinuation due to menstrual changes in the project. To support replication and sustainability of the C4C course, efforts are underway to integrate the training at MOH's digital training platforms.

Conclusions: C4C exemplifies effective utilization of digital platforms to address healthcare challenges in contraceptive counselings .C4C has demonstrated significant improvements in the quality of care and client satisfaction. C4C has contributed towards reduction of unmet family planning needs among adolescent girls.

WEPE020

Experiences with and recommendations for a dual prevention pill (DPP) for HIV and pregnancy prevention: in-depth interviews with women participating in a crossover acceptability study in Johannesburg, South Africa

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Background: A dual prevention pill (DPP) combining oral pre-exposure prophylaxis (PrEP) with oral contraception (OC) for simultaneous HIV/pregnancy prevention could potentially increase oral PrEP uptake among women. In parallel with product development, we evaluated an over-encapsulated DPP containing PrEP and an OC (DPP capsule) as a proxy for the co-formulated tablet.

Methods: We enrolled 96 16-40-year-old OC-using women in Johannesburg, SA who used the DPP capsule and 2 separate pills (PrEP, OC) for 3m each, followed by a 6m Choice period August 2022-December 2023).

We interviewed a purposively selected subset of participants at study exit based on Choice regimen (DPP, 2 pills) or early withdrawal. We investigated motivations for par-

ticipation, experiences with DPP capsule/2 pills, and recommendations for DPP introduction. We analyzed interviews using a rapid analysis framework.

Results: We conducted 21 interviews: (n=10, DPP; n=10, 2 pills; n=1 early exit for relocation). Most cited access to convenient HIV/pregnancy prevention and sexual health services as key motivators for joining study. Reasons the DPP was preferred (versus 2 pills) included convenience/ simplicity of taking 1 pill, reliability compared to condoms that can "burst" during sex, and potentially providing protection if raped. Barriers to DPP use were pill size, bulky packaging, and side effects. Many participants found it easier to swallow 2 separate pills, however citing more difficulty with adherence, often forgetting to take one of the two. Even participants selecting 2 separate pills during Choice said that a co-formulated tablet like the DPP would be their preferred choice "in the real world" if it was smaller than the study's DPP capsule. Most participants recommended that the DPP should be free at local clinics, although several women preferred pharmacies with shorter waiting times.

Conclusions: The DPP is likely to be an acceptable dual prevention option for many South African women, however, it is unlikely to work for everyone. Pill size and packaging will be important for developers to consider as they plan for introduction of the actual co-formulated DPP. Studies in larger, more diverse populations will be important for increasing the number of women with access to methods that meet their HIV and pregnancy prevention needs.

WEPE021

Comparison of self-reported, pill count and biomarker measures of adherence to oral PrEP or a dual prevention pill in crossover clinical trial in Harare, Zimbabwe

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Background: Oral PrEP use is low among women globally. A dual prevention pill (DPP) combining oral contraception (OC) with PrEP may increase effective PrEP use. We compared different adherence measures of the DPP versus PrEP (and OCs) taken separately.

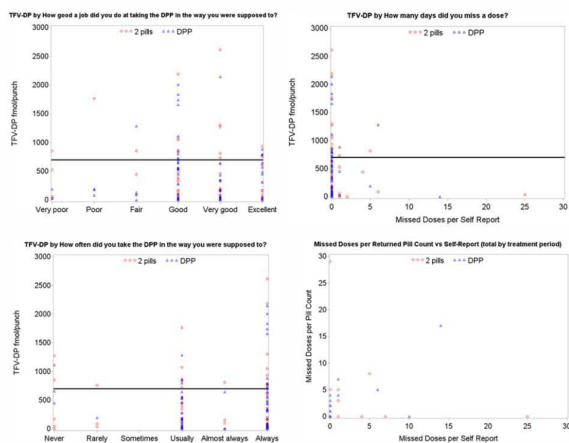
Methods: We enrolled and randomized (1:1) 30 16-24-year-old cisgender females at risk of HIV and pregnancy (Harare; November 2022-September 2023) to the sequence an over-encapsulated DPP and 2 separate pills (Truvada for PrEP, OC) used for 3 months each.

We measured adherence monthly by tenofovir diphosphate (TFV-DP) levels in dried blood spots (DBS), pill count and self-report via computer-assisted self-interview. We defined "adherent" per DBS if drug levels indicated ≥ 4

doses/week (≥ 500 fmol/punch, Month 1; ≥ 700 fmol/punch, thereafter). We compared adherence by DBS, self-report and pill count using mixed-effects regression models.

Results: 26 participants completed the study. Adherence was similarly low between regimens by DBS (mean TFV-DP levels, 392 fmol/punch, DPP; 385 fmol/punch, PrEP). Overall, 25% of DBS samples indicated adherence. 10% of participants were consistently adherent per DBS, 31% had some DBS samples indicating adherence and for 59% of participants none of their DBS samples were indicative of adherence.

Adherence per self-report/pill count was high (Figure 1); participants reported doing a good/excellent job and usually/almost always taking medication as instructed and missing no doses at 88%, 92% and 89% of timepoints, respectively. Pill counts indicated 97% of doses taken. Adherence by DBS was not associated with self-report or pill count; pill count and self-reported missed pills were correlated ($p < 0.0001$).



Conclusions: For both the DPP and PrEP taken separately, adherence was low per drug levels in blood though high per self-report and pill count. Our findings echo results of prior studies, highlighting the limitations of self-report and pill count versus biomarkers. It is critical that future HIV prevention research include objective adherence measures.

WEPE022

Pregnant women in an acceptability trial for oral HIV pre-exposure prophylaxis in Africa

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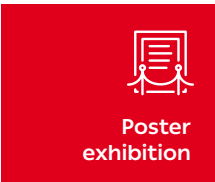
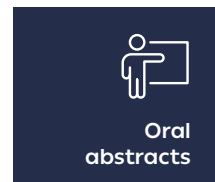
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Background: There is a need to include pregnant women in clinical trials where ethically justifiable to help close the gaps in knowledge regarding this important population. We conducted a 6-month randomized two-arm open label study to examine acceptability of, and adherence to, standard oral PrEP daily dosing regimen of Truvada (F/TDF) and an investigational regimen of Descovy (F/TAF) in adolescent girls and young women (AGYW) in South Africa and Zimbabwe, allowing pregnant women to enroll or remain in the study.

Methods: Eligibility criteria included: 15 to 24 years old, healthy, singleton low-risk pregnancy ≥ 33 weeks gestation with antenatal care or those who became pregnant during the trial. Randomization was 1:1 to F/TAF or F/TDF. Women who became pregnant during the trial were given the choice to stop product or were re-consented to stay on current assignment or switch to the approved product. Surveys were administered at screening, baseline, month 1, month 3 and month 6. A subsample of pregnant participants ($n=8$) were also selected for qualitative in-depth interviews.

Results: From a total of 330 participants enrolled 17 became pregnant in the trial; 9 found out their status at the exit visit, 1 stopped taking the study product, and 7 continued in the trial (of whom only 1 switched to the approved product, F/TDF, and the rest remained on their assigned product). At baseline, average age was 20 years, 3 were in school, 17 had a regular partner or husband, and 10 had a previous pregnancy. Pregnancy outcomes include 6 full-term deliveries, 1 voluntary termination, 2 spontaneous abortions < 20 weeks, and 8 pending. 9 planned on continuing to take PrEP after the trial. Qualitative data themes included a desire to protect their baby with little to no concerns of negative effects.

Conclusions: By including pregnant participants, we were able to gather acceptability data in this often excluded population. This preliminary analysis of blinded data shows that pregnant women were interested in joining the trial and those who became pregnant during the trial chose to continue taking PrEP for the health of their baby and themselves. Further analysis will include product specific acceptability and adherence data.





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WEPE023

PrEP use among partners of pregnant women living HIV: insights from a peer-led intervention trial

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Background: PrEP use among heterosexual men remains low. Here, we evaluate whether HIV disclosure, discussions around using PrEP in sero-different couples are associated with PrEP use among male partners of pregnant women with HIV.

Methods: We performed a secondary analysis of data from a randomized controlled trial assessing a peer-led intervention aimed at improving postpartum retention in HIV care for pregnant women living with HIV. Inclusion criterion involved being in a relationship for over six months, while exclusion criterion encompassed women with partners known to be living with HIV.

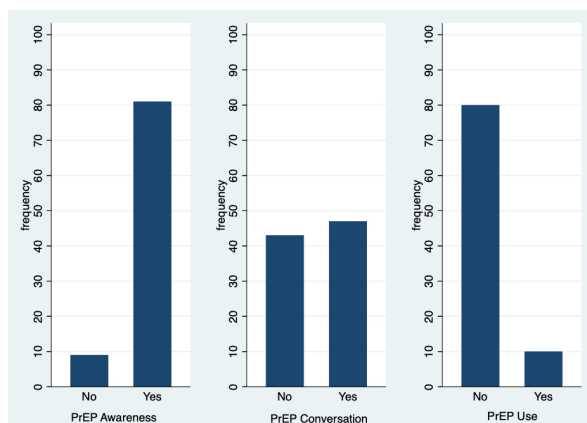
We evaluated the association between HIV disclosure, PrEP discussions, and social support regarding HIV medication adherence, and the male partners' use of PrEP, using chi-squared analysis.

Results: Between March 2020 and March 2024, out of 137 pregnant women enrolled in the trial, 90 had male partners with HIV-negative or unknown status. Women exhibited high PrEP awareness (90%), with 52% discussing PrEP with their partners.

However, only 11% reported that their partners were using PrEP. 78% disclosed their HIV status to their partners, and they were more likely to discuss PrEP with their partners ($p = 0.0$), but this didn't significantly impact their partners' PrEP usage.

Notably, all partners taking PrEP had engaged in conversations with the women about its use, underscoring communication's importance in prevention.

In addition, HIV medication adherence and desire for conception showed no significant links to PrEP discussions or usage, but partner reminders about HIV medication were associated with PrEP discussions ($p = 0.005$).



Conclusions: Despite high rates of PrEP awareness, HIV disclosure and conversations about PrEP, PrEP use remained low among partners of pregnant people with HIV. However, the fact that all the male partners using PrEP engaged in PrEP discussions with the women, demonstrate that PrEP discussions among serodifferent couples could serve as one of many facilitators for PrEP uptake.

WEPE024

History of injectable contraception was associated with women's willingness to use long-acting injectable PrEP: findings from US women across nine cities

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Background: Despite available and effective HIV prevention via oral PrEP, only 15% of US women who could benefit receive a PrEP prescription. Long-acting injectable (LAI) PrEP, a novel formulation, was approved in the US in 2021. While nascent research suggests LAI PrEP hesitancy

among women, data are lacking on whether prior experience with injectable medication use may increase uptake. Thus, we examined whether women's history of injectable contraception use (e.g., Depo-Provera) was associated with willingness to use LAI PrEP.

Methods: From October 2020–November 2021, we administered a cross-sectional survey among women without HIV across nine MACS/WIHS Combined Cohort Study sites in Atlanta, GA; Birmingham, AL/Jackson, MS; Bronx, NY; Brooklyn, NY; Chapel Hill, NC; Chicago, IL; Miami, FL; San Francisco, CA; and Washington, DC. The survey used a 5-point Likert scale to assess willingness to use LAI PrEP; we collapsed this scale into two categories: "definitely" or "probably" would try LAI PrEP versus "not sure", "definitely would not", and "probably would not."

We used Poisson regression with robust standard errors to assess the association of self-reported prior use of injectable contraception with interest in LAI PrEP, controlling for age, race/ethnicity, education, sexuality, income, insurance, self-perceived HIV risk, unprotected sex, depression, drug use, and marital status.

Results: Among 475 participants, median age was 52 years, 74% self-identified as Black, 38% reported an annual income <\$12,000, and 18% had previously used injectable contraception.

Overall, 21% were probably/definitely willing to try LAI PrEP, including 25% of women with prior injectable contraception use vs 19% of those without (Prevalence Ratio (PR)=1.85; 1.29–2.66). In the adjusted model, prior injectable contraception use was associated with willingness to try LAI PrEP (α PR)=1.68; 1.08–2.61), as was a high/some self-perceived HIV risk (α PR)=2.35; 1.45–3.80).

Conclusions: Overall interest in LAI PrEP was low among a geographically diverse cohort of U.S. women, though key interested subgroups included women with prior injectable contraception use and with self-perceived risk of HIV. These findings support efforts to advance dual and injectable formulation prevention technologies (contraception-PrEP) among women to innovate client-centered intervention strategies supporting women's choice that could be deployed in family practice and reproductive health clinics.

WEPE025

Lessons learned from the Forum for Collaborative Research working group on long-acting pre-exposure prophylaxis use during pregnancy and lactation: strengthening African regulatory and surveillance systems

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Background: In many countries, pregnant and lactating people are at high risk of HIV acquisition and could benefit from pre-exposure prophylaxis (PrEP). An increasing number of PrEP options are becoming available, with the World Health Organization (WHO) recommending oral PrEP, the dapivirine vaginal ring, and long-acting injectable cabotegravir.

Further PrEP products are undergoing clinical studies. However, data on the safety of PrEP during pregnancy and lactation is often scarce, and rollout of PrEP for these populations has been slow. Post-approval surveillance to generate safety data is needed but, in the African region, pharmacovigilance systems are often limited.

Methods: The Forum for Collaborative Research, a public-private partnership based at the University of California, Berkeley, formed a working group consisting of experts and representatives from regulatory agencies, industry, community, and normative bodies.

The objective was to facilitate discussions between US, European, and African regulatory authorities and other stakeholders on critical issues around the use of long-acting PrEP during pregnancy and lactation, with a focus on safety surveillance, to ensure the safe introduction of current and future products.

Results: The working group noted improvements in the inclusion of pregnant and lactating people in clinical trials on PrEP but highlighted the need for post-approval surveillance. This is due to large sample sizes required to evaluate associations between products and rare outcomes. The need to strengthen pharmacovigilance systems and regulatory agencies in Africa was emphasized. Weak regulation and limited technical and financial resources were identified as barriers. Innovative approaches, e.g., digital systems for reporting adverse events, use of sentinel surveillance sites, regulatory harmonization across Africa, and pooling of resources were discussed as possible solutions. The importance of learning exchange between African countries and with high-income countries was underscored.



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Conclusions: Consensus-building among diverse stakeholders is necessary to address pressing issues in HIV prevention. The working group concluded with the aim of convening an expanded group of representatives from African regulatory authorities to facilitate exchanges with regulators in the US and EU. The overarching objective of this meeting is to strengthen surveillance systems in Africa. The Forum for Collaborative Research is organizing this meeting for the second half of 2024.

WEPE026

Preference for and adherence to a Dual Prevention Pill (DPP) versus two separate pills for PrEP and contraception among women in Johannesburg, South Africa

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Background: Women in South Africa face dual risks of HIV and unintended pregnancy, yet few self-controlled options for protection exist and uptake remains low. We hypothesized that a dual prevention pill (DPP) combining PrEP with an oral contraceptive (OC) may be preferable over two separate pills.

Methods: We enrolled 96 HIV-uninfected, non-pregnant, sexually active cisgender women and randomized (1:1) their order of using a single over-encapsulated DPP and oral PrEP and OCs taken separately (2 pills) for 3m each, followed by a 6m choice period using a selected regimen. The primary outcome of preference was evaluated by testing whether the proportion preferring the DPP capsule vs 2 pills (after crossover) was >0.5 (exact binomial test). We measured adherence by tenofovir diphosphate (TFV-DP) levels monthly in dried blood spots (DBS). We defined "adherent" as DBS drug levels corresponding to ≥4 doses/week (≥500 fmol/punch, Month 1; ≥700 fmol/punch, thereafter) and compared adherence during the crossover period between regimens using mixed-effects regression models.

Results: 85 participants completed the crossover period (August 2022–December 2023). Mean age was 27.4 years (range: 18–40); 98% had finished secondary school. 74% had ≥1 child; Half had ≥2 partners (range 1–30) At enrollment: 56% were worried about HIV and 90% said it was very important to avoid pregnancy. At the end of the crossover, preference for the 2-pill regimen was 61% and 39% for the DPP (p=0.037). Overall adherence was low and not different by regimen; only 18% of DBS specimens (during the crossover) indicated adherence. Nine women became pregnant, and three women seroconverted (Table 1); none had DBS indicative of adherence when they tested positive.

	# of pregnancies, Pearl Index (95% CI)	# of HIV infections, Incidence per 100 woman years (95% CI)
DPP Regimen	4, 13.2 [3.6-33.9]	2, 6.6 [0.8-23.9]
2 pills regimen	5, 13.5 [4.4-31.6]	1, 2.7 [0.07-15.1]

Table 1. Pregnancy and HIV incidence, by regimen

Conclusions: While a majority of women preferred the two pill regimen, nearly 40% preferred the DPP, indicating a potential market for the DPP. Overall adherence was low, and incidence of pregnancies and seroconversions were similar between regimens.

Further analyses in future studies of the smaller, co-formulated tablet will be essential to understand the interactions between product acceptability, adherence and clinical outcomes.

WEPE027

Utility of PrEP in averting seroconversion among infants of breastfeeding mothers with postpartum HIV incidence, initially testing HIV negative at delivery in Eastern Province of Zambia

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¹Eastern Provincial Health Office, Ministry of Health in Zambia, Chipata, Zambia

Background: In Zambia, HIV negative pregnant and breastfeeding women require routine HIV retesting as part of elimination of mother-to-child transmission (EMTCT). Pregnant women attending antenatal are retested during these visits. After delivery, however, postnatal mothers often elude HIV retesting. In such settings, maternal postpartum HIV acquisition contributes to a significant proportion of infants with HIV. Pre-exposure prophylaxis (PrEP) is a safe and effective prevention strategy to reduce women's risk of HIV in pregnancy and postpartum.

We will describe and assess the utility of PrEP in averting seroconversion among infants born from breastfeeding mothers testing HIV negative at delivery in Eastern Province of Zambia.

Methods: This retrospective review utilized 2021 program data from DHIS2. The data included counts of HIV negative breastfeeding women (BFW) which we categorized into two subgroups: those receiving PrEP and those not receiving PrEP. Descriptive statistics were used to summarize the demographic characteristics of the BFW and the mother-infant HIV status outcomes at 24 months postnatal. Chi-square test was employed to assess differences in the mother-infant HIV status outcomes between the two subgroups. Statistical significance was set at p<0.05.

Results: In December 2021, 2,261 (23%) BFW were receiving PrEP, while 7,704 (77%) were not. Among the PrEP cohort, 95% had status outcomes, of which 99.8% were negative. All children (100%) from the 3 BFW who seroconverted remained HIV negative. From the no PrEP cohort, 86% had documented outcomes. 4% had a seropositive outcome, of whom 20% had a concordant maternal-infant se-

rostatus. Maternal seroconversion was significantly lower among the PrEP cohort at 0.2%, compared to those not on PrEP (4%) ($p < 0.001$).

Similarly, infant seroconversion was not observed in the infants of seroconverted mothers from the PrEP cohort, but was significant (20%) among infants from mothers who seroconverted and not receiving PrEP ($p < 0.001$).

Conclusions: Though only 23% of PBW during the review period were receiving PrEP, this analysis shows low post-natal maternal incident HIV and vertical transmission outcomes.

In contrast, unfavourable HIV serostatus outcomes persisted among BFW not receiving PrEP and their infants. These findings underscore the critical role of PrEP services in complementing other interventions to optimize EMTCT efforts.

Drug development and pharmacology (PK and PD studies)

TUPE031

Efforts to enhance capacity in early HIV and pregnancy prevention product development research in East and Southern Africa

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Background: An urgent need to build a critical mass of mid-level and early-career African scientists to lead HIV and pregnancy prevention (HPP) research and development (R&D) exists. The USAID-funded MATRIX Project intends to strengthen local capacity for early-stage product development research through the Capacity Strengthening, Engagement and Mentorship (CaSE) program.

We describe findings from landscape analyses and how these were used to create a sustainable training pro-

gram that advances theoretical and practical skills development in early-stage product development in Kenya, South Africa, and Zimbabwe.

Methods: Scientists at all career levels from Kenya, South Africa and Zimbabwe were interviewed and/or completed an online survey to understand the gaps/challenges, and potential solutions to build a sustainable environment for African-led R&D, including product development in HPP. We employed random sampling to survey scientists and targeted key leaders in the R&D and adjacent fields, and referral sampling techniques to identify other relevant interviewees for in-depth interviews (IDIs).

Results: 82 surveys and 20 IDIs were conducted. Emerging themes included that African scientists need advanced skills in topical and vaginal product formulations, long-acting/sustained release products, and clinical trial design. Lack of technical expertise, poor infrastructure, and a limited number of formulation scientists were challenges faced in Kenya and Zimbabwe. In South Africa, challenges were funding access, inadequate numbers of local collaborators, and relocation of trained African scientists to higher-income countries.

Although academic programmes in product development exist, these were not focused on HPP and lacked the absorptive capacity to encourage African scientists to pursue HPP R&D locally.

Conclusions: To address these gaps/challenges, the CaSE fellowship aims to establish a critical mass of African scientists through Global North and South collaborations where fellows will gain hands-on skills and mentorship in HPP product development over 24 months.

To induce absorptive capacity, financial support to facilitate sustainability for the fellows upon their return to their primary institution will be implemented. Region-specific approaches for developing sustainable research capacity in HPP product development are required as part of capacity-strengthening initiatives.

The CaSE fellowship provides a multicomponent comprehensive training program to support the development of African scientists to lead HPP product development to advance these objectives.



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WEPE028

Development of a multipurpose intravaginal ring for controlled release of Q-Griffithsin combined with contraceptive hormones: *in vitro* and *in vivo* evaluation

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Background: Multipurpose prevention products for women that combine contraceptive and anti-HIV activity are limited. Our goal is to develop a multipurpose intravaginal ring (IVR) delivering the potent non-antiretroviral (non-ARV) HIV entry inhibitor Q-Griffithsin (QGRFT) and contraceptive hormones Etonorgestrel and Ethinyl Estradiol. The EEQ IVR could reduce both the emergence of ARV-resistant HIV and concern of potential increased risk of HIV transmission associated with use of progestin-only contraceptive products. QGRFT is an oxidation-resistant variant of GRFT, which retains its chemical, anti-viral and safety properties.

We reported that first-in-human Phase 1 study of 4 mg GRFT in a carrageenan-based vaginal gel demonstrated no systemic absorption, and no safety signals in healthy, HIV-negative women. Our GRFT freeze-dried fast dissolving insert (FDI) for on-demand use equivalent of 1x clinical gel dose protected rhesus macaques from a high dose vaginal SHIV SF162P3 challenge 4 hours after FDI insertion. Herein we report progress on development of EEQ pod-IVR focusing on QGRFT release optimization.

Methods: Our iterative QGRFT formulation optimization focused on IVR pods containing QGRFT (QGRFT loading, excipients controlling release, pod thickness/hardness, pod coating procedure) and silicone elastomer ring bodies (total delivery channel cross-sectional area). The formulations were evaluated *in vitro*, *in vivo* in adult female Indian rhesus macaques (*Macaca mulatta*), and *ex vivo*. *In vitro* and *ex vivo* analysis of pod-IVRs/segment release was done using UV-Vis absorption spectroscopy and HPLC. QGRFT concentrations in cervico-vaginal lavage (CVL) and blood plasma were measured using MSD-ECL platform.

Results: QGRFT processing (lyophilization, pod formulation) did not affect its activity *in vitro*. *In vitro* release studies demonstrated that silk fibroin, microcrystalline cellulose and sodium chloride had minor impact on the release. Testing of pod QGRFT IVRs (~32 mg QGRFT per IVR) without excipients resulted in CVL concentrations within

a range of concentrations associated with efficacy (~ 57 mg/mL MEAN) at days 3 and 7 post IVR insertion. QGRFT in plasma was undetectable.

Conclusions: Our proof-of-concept data indicate that continuous *in vivo* target release of QGRFT from pod-IVR is achievable. These data support further development of EEQ IVR.

Perinatal prevention

TUPE032

The contribution of maternal retesting strategy in intensifying early HIV case identification among pregnant and breastfeeding women in southern highlands

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Background: Maternal HIV testing during pregnancy, labor and breastfeeding identifies women with incident infections, those living with HIV who are not aware of their status, and infants at risk of vertical transmission of HIV. Based on World Health Organization recommendations for maternal retesting, Tanzania adopted and scaled up the 5-tests algorithm in 2022.

We present retesting data for women receiving maternity and child health services at healthcare facilities in four southern highlands (SHL) regions in Tanzania.

Methods: We reviewed routinely collected program data on maternal HIV retesting from 394 facilities supported by the HJFMRI/US MHRP_PEPFAR program in Katavi, Mbeya, Songwe and Rukwa regions in the SHL. From January to December 2023, a sit-in-mentorship approach was utilized to support the scale-up of five rounds of HIV testing at different reproductive and child health (RCH) service delivery points.

We report numbers and proportions of women eligible for retesting following their first ANC visit; those returning for care; those retested and newly diagnosed with HIV following retesting at designated service delivery points namely, ANC and child welfare clinics.

Results: A total of 200,926 pregnant women tested for HIV during their first ANC visit; 2,203(1.1%) were newly diagnosed and linked to ART services. A total of 160,444(79.9%) women were subsequently retested in designated service delivery points, and 244(0.15%) were newly diagnosed HIV individuals and linked to ART services.

In the last quarter of 2023, we started desegregating data for maternal retesting data whether it was done during labor and delivery or postnatal, 52,248 women were retested during this period. 27,355(52%) women were retested during labor and delivery and 24,893(48%) women during postnatal; 27 women were found to be HIV infected during labor and delivery and 56 during postnatal.

Conclusions: Maternal retesting has shown promising results in identifying incident HIV infection enabling timely intervention for the mother-baby pair. This success story serves as a compelling call for sustained collaboration between IPs, R/CHMT and healthcare providers for the success of this initiative. We suggest continued efforts in tracking women who miss retesting to enable every eligible woman to be HIV retested as per the national HIV testing guideline.

WEPE030

Exploring one-month PrEP continuation via real-time urine tenofovir immunoassay among pregnant people using daily oral PrEP in South Africa

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Background: Pregnant and lactating people in South Africa experience barriers to PrEP continuation. We explored characteristics and predictors of PrEP continuation among pregnant individuals in South Africa, measured by real-time urine tenofovir (TFV) immunoassay.

Methods: From September 2022 to March 2024, we enrolled pregnant individuals without HIV initiating or continuing PrEP (in standard clinical care) in a randomized control trial evaluating PrEP continuation through 12-months postpartum. The trial is evaluating the impact of biofeedback counseling on PrEP adherence using TFV measures from real-time urine immunoassays versus standard of care. Intervention-arm participants reporting PrEP use provided urine samples and received biofeedback counselling at baseline and 1-month follow-up. We compared intervention-arm participant characteristics by TFV result and used age-adjusted logistic regression to assess predictors of positive urine TFV result at 1-month study visit.

Results: Of 224 pregnant individuals (median age 26y; IQR=21-32), 132 (59%) reported PrEP use at study enrollment, and 92 (41%) initiated PrEP at enrollment. At 1-month follow-up, 98 (44%) reported using PrEP in the last week and 130 (58%) had a positive urine TFV result, indicative of PrEP use within 72 hours of testing.

Positive urine TFV result was positively associated with age (aOR=1.05, 95%CI=1.01, 1.10, p=0.011), multigravidity (aOR=1.85, 95%CI=0.92, 3.76, p=0.086), moderate or great self-perceived HIV risk (aOR=1.81, 95%CI=0.98, 3.42, p=0.063), report-

ing recent PrEP use at enrollment (aOR=2.01, 95%CI=1.65, 12.1, p=0.020), and positive urine TFV result with biofeedback counseling at enrollment (aOR=4.17, 95%CI=1.65, 12.1, p=0.004), and negatively associated with gestational age (aOR=0.95, 95%CI=0.91, 1.00, p=0.033) (Table 1).

Characteristic	Overall (N=224, %)	Positive urine TFV (N=130, %)	Negative urine TFV (N=94, %)	p-value ¹	Unadjusted OR (95% CI), p-value	Adjusted OR ² (95% CI), p-value
Maternal age (median, IQR) years	26 [21-32]	27 [22-34]	24 [21-28]	0.017	1.05 (1.01, 1.10), 0.011	1.05 (1.01, 1.10), 0.011
Gestational age at enrollment (median, IQR), weeks	27 [23-34]	26 [23-32]	30 [23-35]	0.025	0.94 (0.90, 0.99), 0.015	0.95 (0.91, 1.00), 0.033
Gravidity – Multigravida	133 (59%)	88 (68%)	45 (48%)	0.004	2.28 (1.33, 3.96), 0.003	1.85 (0.92, 3.76), 0.086
HIV risk perception: Moderate/Great chance	66 (29%)	46 (35%)	20 (21%)	0.026	2.03 (1.11, 3.79), 0.023	1.81 (0.98, 3.42), 0.063
≥1 day of PrEP use within last week at enrollment	80 (36%)	54 (42%)	26 (28%)	0.035	1.86 (1.06, 3.32), 0.033	2.01 (1.13, 3.64), 0.020
Urine TFV positive result at enrollment	37 (32%)	31 (41%)	6 (14%)	0.003	4.23 (1.68, 12.2), 0.004	4.17 (1.65, 12.1), 0.004

¹Each individual model adjusted for maternal age at baseline, Bold p<0.10

Table 1: Baseline demographic and health characteristics of pregnant and postpartum women at 1-month study visit, Cape Town, South Africa (N=224).

Conclusions: We found that approximately 60% of pregnant individuals on PrEP had positive TFV tests, indicating recent PrEP adherence and continuation, at 1-month follow-up. Older age, earlier gestational age, having multiple children, previous PrEP use, and self-perceived HIV risk were associated with recent PrEP use. Additional targeted interventions are needed to support pregnant individuals with PrEP adherence and continuation.

Product acceptability and adherence

TUPE035

Understanding preferences for pre-exposure prophylaxis (PrEP) among people who would benefit from PrEP in the United States

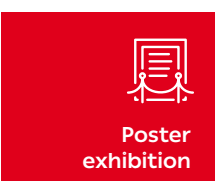
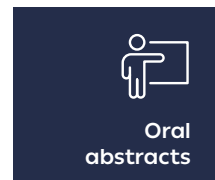
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Background: PrEP is effective in preventing HIV-1 infection; however, PrEP utilization is low, particularly among populations disproportionately impacted by HIV-1, with only 36% of people who would benefit from PrEP (PWBP) in the US utilizing PrEP.

To better understand PrEP modality preferences among PWBP and provide insights for increasing PrEP utilization, we conducted a cross-sectional survey.





Oral abstracts



Poster exhibition



E-posters



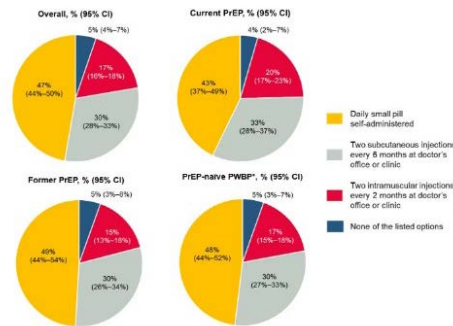
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Methods: Concept elicitation interviews among PWBP informed development of an online discrete choice experiment survey for participants to rate attributes of daily and long-acting PrEP. Using resulting preference weights, share of preference for different PrEP options were simulated. Recruitment via patient advocacy groups and HCP referrals ensured a diverse US sample inclusive of disproportionately affected populations across PrEP-use status: current PrEP user (CP), former PrEP user (FP), and PrEP-naïve PWBP (PN).

Results: Overall, 546 participants completed the survey (112 CP; 150 FP; 284 PN): mean age (39.2 years); assigned female at birth (46%); cisgender (91%); transgender (5%); White/Caucasian (57%); African American/Black (32%); Hispanic/Latinx (20%); and from Southern states (45%). Most respondents (84%) described a small oral pill as good/very good, decreasing to 66% if the pill was described as large. Most participants described good/very good PrEP administration frequencies of once per year, twice per year, every 2 months (75% for each), and once per week (72%), decreasing to 50% for daily administration. Share of preference estimations for PrEP options with combined attributes were as follows: 47% of respondents preferred a small daily pill, 30% twice-yearly subcutaneous injections, 17% bi-monthly intramuscular injections, and 5% none of these options; preferences were similar in all PrEP-use subpopulations (Figure).



*Respondents qualified as PrEP-naïve PWBP if they were HIV negative, had never used PrEP, and were either from a jurisdiction with high HIV-1 prevalence (according to the CDC) or indicated that they participated in at least one behavioral trait associated with PWBP. PrEP, pre-exposure prophylaxis; PWBP, people who would benefit from PrEP.

Figure. Share of preference for PrEP administration options in overall population and PrEP-use subgroups.

Conclusions: These results demonstrate the importance of PrEP options for PWBP and an unmet need for longer-acting PrEP. While daily oral PrEP remains an important choice for HIV-1 prevention, additional longer-acting PrEP options are critical to meet the needs of all PWBP.

TUPE036

Acceptability of the live biotherapeutic LACTIN-V (*Lactobacillus crispatus* CTV-05) among young women at high risk of HIV acquisition in South Africa: data from the Phase 2 placebo-controlled trial

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Background: Live biotherapeutics containing *Lactobacillus crispatus* may optimize the vaginal microbiome, reduce genital inflammation and protect against HIV. Determining acceptability of these products among African women at high risk of HIV acquisition is essential.

Methods: The trial recruited cis-women aged 18-23 with vaginal dysbiosis from the parent FRESH (Females Rising through Education, Support and Health) study.

Following metronidazole, participants were randomized (2:1) to receive eleven doses of LACTIN-V (2X10⁹ *L. crispatus* CTV-05) or matched placebo over 4 weeks. A questionnaire determining product acceptability was administered.

Results: Among 45 Black South African women randomized to LACTIN-V (N=32) or placebo (N=13), the median age was 21. Forty-two (94%) had a regular male partner, none reported use of vaginal agents prior or during the study and only two used tampons for menstrual hygiene. Adherence was high with 36 participants (80%) completing 11 doses, and 40 (89%) completing at least 9 doses. Of 43 participants who completed acceptability questionnaires, 38 (88%) were satisfied using the vaginal applicator and 41 (95%) confirmed ease of use.

Fourteen participants (33%) agreed that product use without partner knowledge was important and 31 (72%) disagreed that partner approval was important. Partners' reaction to product use was positive with 12 (28%) women, while 15 (35%) reported partner unawareness of product use. Among women reporting side effects, all were likely to use the product again. On Likert scales of 0-10, agreement with positive product attributes scored at means of ≥ 6.7, while importance of negative product attributes scored at ≤ 3.2. (Table 1).

Overall, 75% of participants would use the product again, with no significant difference between study arms.

	LACTIN-V (N=32)	Placebo (N=13)	All Participants (N=45)
POSITIVE PRODUCT ATTRIBUTES.			
On a scale of 0 to 10, with 0 being ,not at all' to 10 being ,extremely', I found the product to be:			
Effective	6.9 (1.72)	6.5 (2.44)	6.7 (1.94)
Comfortable	7.8 (2.01)	8.1 (1.32)	7.9 (1.82)
Easy to use	8.8 (1.55)	8.5 (1.45)	8.7 (1.50)
NEGATIVE PRODUCT ATTRIBUTES. On a scale of 0 to 10 (with 0 being ,not at all' to 10 being ,extremely'), the following things made the product hard for you to use:			
Frequency or timing of using the product	3.4 (2.53)	2.5 (2.33)	3.2 (2.48)
Vaginal dryness	2.4 (2.69)	1.3 (1.65)	2.1 (2.46)
,Messiness' or leakage / discharge of the product	3.0 (2.99)	1.2 (1.54)	2.4 (2.74)
Partner's disapproval	2.1 (3.09)	0.5 (0.66)	1.7 (2.70)

Table 1: Product Attributes (Likert Scale 0-10). Mean (Standard Deviation).

Conclusions: Young South African women at high risk of HIV found the vaginal applicator and study product highly acceptable and easy to use. Partner approval was high but not deemed critical. (clinicaltrials.gov: NCT05022212).

TUPE037

Awareness and willingness to use a 6 monthly long-acting injectable PrEP among men who have sex with men and transgender women in Asia

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Background: Pre-exposure prophylaxis (PrEP) scale-up in Asia lags other regions and is not on track to meet regional 2025 targets. Offering long-acting injectable (LAI) PrEP as an additional choice could help accelerate PrEP uptake.

Methods: We conducted an online cross-sectional survey among HIV-negative men who have sex with men (MSM) and transgender women (TGW) aged ≥ 18 years, in 15 and 11 Asian countries/territories respectively in May- November 2022. Survey items included PrEP awareness and willingness to use and top preference for different PrEP modalities.

Multivariable logistic regression was used to examine factors associated with preference to use 6-monthly LAI versus other PrEP modalities; we present adjusted odds ratios (aOR) and 95% confidence intervals (CI).

Results: Among 15,345 MSM (mean age=31.2) and 1,260 TGW (mean age=28.3), PrEP awareness was 80.0% and 77.8%, ever having taken PrEP was 26.2% and 47.6%, currently taking PrEP was 18.3% and 36.6%, and willingness

to take any PrEP modality was 92.3% and 96.1% in MSM and TGW, respectively. Willingness to take 6-monthly LAI-PrEP was 33.9% among MSM and 31.8% among TGW (compared with 60.8% and 59.4% for oral PrEP) and varied by country (MSM: Lao PDR=22.7% to Singapore=42.4%; TGW: Lao PDR=19.4% to Malaysia=54.6%). 6-monthly LAI-PrEP was the top preference for 17.0% of MSM and 19.4% of TGW.

Among MSM, preferring 6-monthly LAI-PrEP (compared to all other PrEP modalities) was associated with: older age (aOR=1.01, 95%CI=1.00-1.01), gay identity (aOR=1.18, 95%CI=1.07-1.30), university education (aOR=1.28, 95%CI=1.16-1.41), working full-time (aOR=1.12, 95%CI=1.01-1.23), ever having taken PrEP (aOR=1.42, 95%CI=1.29-1.57), and in the last 6 months: not having done sex work (aOR=1.18, 95%CI=1.01-1.38), reporting >10 sex partners (aOR=1.18, 95%CI=1.03-1.35), and having an STI (aOR=1.28, 95%CI=1.10-1.48).

Among TGW, 6-monthly LAI-PrEP preference was associated with: older age (aOR=1.02, 95%CI=1.00-1.04), general PrEP awareness (aOR=1.54, 95%CI=1.01-2.34), and any sex work in the last 6 months (aOR=1.38, 95%CI=1.01-1.90).

Conclusions: Although not yet available nor promoted, one-third of Asian MSM and TGW were willing to use 6-monthly LAI-PrEP and it was the top preference for almost 20%. The addition of a safe and effective 6-monthly LAI could increase PrEP uptake and help meet unmet PrEP demand in Asia.

TUPE038

Reasons for PrEP choice at enrolment: the DREAMS PrEP choice study in Johannesburg Health District, South Africa

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Background: Oral Pre-Exposure Prophylaxis (PrEP) is effective in reducing HIV however, daily pill burden may affect continued use. Long-acting HIV prevention methods may offer continuation benefits. However, understanding why clients choose one method over the other is needed. We describe the reasons for selecting a PrEP method at enrolment among participants in the DREAMS PrEP Choice study conducted in Johannesburg, South Africa.

Methods: The DREAMS PrEP Choice study is an implementation science study offering oral PrEP and PrEP ring to women 18 years and older receiving services at community sites. We analysed survey responses obtained at enrolment between October 2023 and March 2024. The survey collected information on sociodemographic, PrEP knowledge and perceptions, sexual behaviour, and reasons for method choice. Descriptive statistics described uptake and reasons for selecting a PrEP method (i.e., Oral PrEP and PrEP ring) offered at enrolment.



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Results: We analysed data for 570 females, the majority (n=409,72%) were aged 18-24 years, currently a student (n=362, 64%), 68% (n=389) were in a causal relationship with at least one sexual partner and 70% with no prior PrEP use. The majority of the participants chose oral PrEP (408, 72%) and 27% (n=156) chose PrEP ring. Reasons for choosing PrEP ring at enrolment were ease of use (42%, n=65); having autonomy over method use (20%, n=31), 35% stating no need to swallow pills and 9% (n=14) stating that they chose it because its discreet.

Furthermore, participants felt confident in their ability to use ring (60%) and 97% believed that PrEP would improve their ability to prevent HIV.

Participants who chose oral PrEP similarly stated that ease of use (46%) and having autonomy over method use influenced their choice (17%). In addition, they stated that it works/protects them well (38%) and interestingly protects them when not having sex (n=58, 14%).

Conclusions: The study shows that method choice is influenced by a myriad of reasons, particularly client's ability and confidence to use the product, ease of use, product characteristics and formulation including ability to protect them outside of only sexual exposure. Participants seem to understand their role in using PrEP to protect them from HIV acquisition.

WEPE032

Exploring HIV prevention products and acceptability among men who have sex with men aged 18-25 years in Kenya

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Background: Young men who have sex with men (MSM) aged 18-25 years represent a critical demographic in the HIV epidemic, facing heightened vulnerability and unique challenges in accessing prevention tools.

This abstract investigates the exploration and acceptability of HIV prevention products among young MSM in Kenya, aiming to inform tailored interventions and strategies to address their specific needs.

Methods: A mixed-methods approach was employed, combining quantitative surveys and qualitative interviews conducted among young MSM aged 18-25 years across the three major cities of Kenya. Participants were recruited through community-based organizations, social media platforms, and peer referrals.

Quantitative data were analyzed using descriptive statistics, while qualitative data underwent thematic analysis to elucidate patterns and themes related to HIV prevention product exploration and acceptability.

Results: Preliminary findings reveal a multifaceted landscape of HIV prevention product exploration among young MSM in Kenya.

While traditional methods such as condoms are widely recognized, interest and curiosity exist regarding emerging biomedical interventions including pre-exposure prophylaxis (PrEP), long-acting injectables, and rectal microbicides. Factors influencing acceptability include perceived effectiveness, ease of use, privacy concerns, stigma, and access barriers. Additionally, preferences vary among individuals, highlighting the importance of offering diverse prevention options tailored to individual needs and preferences.

Conclusions: Understanding the exploration and acceptability of HIV prevention products among young MSM in Kenya is essential for designing effective interventions and programs. By incorporating diverse prevention options and addressing barriers to access and acceptability, tailored approaches can be developed to meet the unique needs of this demographic.

Furthermore, community engagement, education, and stigma reduction efforts are critical for promoting uptake and adherence to HIV prevention products.

This abstract underscores the importance of youth-centered approaches in HIV prevention research and programming, aiming to empower young MSM with the knowledge and tools to protect their sexual health and well-being.

WEPE033

Pre-Exposure Prophylaxis preferences of young women of reproductive ages in a Nigerian rural community: a comparative assessment between dapivirine vaginal ring and long-acting cabotegravir

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Background: Pre-exposure prophylaxis (PrEP) is used to reduce the risk of HIV acquisition among vulnerable individuals. Whereas dapivirine vaginal ring (DPV-VR) and long-acting cabotegravir (CAB-LA) are the most recently approved PrEP strategies, the preferences for either of the two among young women have not been assessed. The aim of this study was to determine the acceptability and willingness to pay (WTP) for either PrEP option among women of reproductive ages in a rural Nigerian community.

Methods: A cross-sectional design was adopted to obtain responses from women of 18-35 years old in Umuoji, Nigeria in 2023 after Institutional Review Board approval. The acceptability and WTP for DPV-VR and CAB-LA of 370 randomly sampled respondents were assessed using a 23-item validated questionnaire. WTP was obtained through a contingent valuation method in Naira (N) (\$1=N957.51). Appropriate statistical analysis was conducted on the data, with significance set at p<0.05.

Results: A total of 262(70.81%) respondents returned validly completed questionnaires. Majority of them, [209(79.8%)], were aged 18–24 years, with 229(87.4%) being unmarried. Less than half of the respondents, [116(44.27%)], knew their HIV status, with three (2.59%) identifying as living with HIV. Also, 107(40.8%) respondents were unaware of the HIV status of their sex partners. DPV-VR and CAB-LA were the preferred PrEP choices of 137(52.3%) and 134(51.1%) respondents, respectively ($p=0.0001$). Affordability [22(8.4%)] and non-invasiveness [31(11.8%)] were the main reasons for respondents' preferences, although 102(38.93%) respondents would use either of the two ($p=0.0001$). Respondents that indicated a positive WTP for DPV-VR and CAB-LA were 128(48.9%) and 119(45.4%), respectively. Duration of action informed the WTP for CAB-LA, [7(2.7%)], although 95(36.26%) would pay for either of the two ($p=0.0001$). The mean WTP amount for each PrEP strategy was N6070.42±843.99 (DPV-VR) and N417697.18±116504.24 (CAB-LA); $t(df)=-3.541(70)$, $p=0.0001$.

Conclusions: The women of reproductive ages in the community preferred DPV-VR over CAB-LA, even though about half of them would use and pay for both PrEP strategies. Those willing to pay indicated values that were below the market prices of the two. It is recommended that public health education should be employed to increase the awareness and acceptance of PrEP among young women in Nigeria.

WEPE034

PrEP product acceptability and service satisfaction among CATALYST clients offered choice between oral PrEP and PrEP ring

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Background: Understanding client acceptability and service satisfaction as additional PrEP products become available will accelerate the design of successful PrEP choice programs. The PEPFAR/USAID-supported CATALYST study offers choice of PrEP ring and oral PrEP to a cohort of women in public service delivery sites across Kenya, Lesotho, South Africa, Uganda, and Zimbabwe.

Methods: We describe method acceptability (perceived burden, self-efficacy, and perceived effectiveness) and service satisfaction among 2,643 women interviewed from May to December 2023 at their enrollment visit. Chi-square tests compare results between PrEP naïve and PrEP experienced (ever used PrEP) participants and between people choosing oral PrEP and PrEP ring.

Results: Of 1,657 PrEP naïve respondents, 73% chose oral and 27% chose ring; among 894 experienced, 55% chose oral and 45% chose ring. Fifty-five percent of experienced participants said taking oral PrEP requires no effort (low perceived burden), compared to 46.7% of PrEP naïve participants ($p<0.05$).

The anticipated burden of ring use was even lower in both groups (61% experienced vs. 56% naïve; $p=0.13$). Experienced users, compared to naïve, had greater self-efficacy to use oral PrEP correctly (94.3% vs 90.6%, $p<0.05$); anticipated self-efficacy to use the ring was similar (94.8% vs. 90.7%; $p=0.08$).

Over 78% of oral PrEP and PrEP ring participants felt the products would work very well (perceived effectiveness), with no significant variation by experience. Oral PrEP was completely acceptable to 83% of experienced and 77% of naïve participants ($p=0.02$); ring showed a similar, though non-significant, pattern (83% vs 77%; $p=0.11$).

Service satisfaction was high, with over 97% of respondents reporting providers gave clear information, respectful treatment (>98%), and adequate privacy (>99%). Among those not completely satisfied, reasons were wait time and negative provider interactions. Method satisfaction was high (>95%) across both methods.

Conclusions: Clients perceive the ring to require less effort than oral PrEP and method acceptability (particularly perceived effort, self-efficacy, and overall satisfaction) is higher for those with prior exposure to PrEP.

With greater exposure to PrEP ring, acceptability may increase. Introducing PrEP choice services yielded high client satisfaction appropriate for scale-up.

WEPE035

Considerations for future prep use from qualitative sub-study participants of a Phase 2 trial of daily oral prep regimens among adolescents and young women in Southern Africa

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Background: Adolescent girls and young women (AGYW) in southern Africa face high HIV risk, yet PrEP use is suboptimal for multiple reasons including poor product acceptability. We explore acceptability of future daily oral PrEP use by AGYW aged 15–24, who participated in a qualitative sub-study nested within a six-month, Phase 2 randomized trial of F/TAF (Descovy®) and F/TDF (Truvada®) in two South African and one Zimbabwean site.



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Methods: Between 2022-2024, 60 of 330 trial participants were recruited for serial, in-depth qualitative interviews. We used preliminary, blinded clinical and demographic variables to classify sub-study participants' HIV risk, including self and partner sexual concurrency, intimate partner violence, and baseline and incident STI diagnosis. We compared acceptability of future PrEP use across sub-study participants in the high (2+ indicators) and low (0-1 indicators) risk group; analysis per product group is ongoing.

Results: Participants (N=60) were evenly split across risk groups with large differences across sites. Desire to continue use of daily PrEP beyond the trial was common, although women with fewer risk indicators were more likely to be undecided and/or want to use condoms together with daily PrEP; many imagined PrEP as a reliable backup to condoms, which they liked for broader STI prevention. Lower risk participants shared more concerns about accessing PrEP through public clinics after the trial, fearing potential mistreatment and HIV-related stigma. Higher-risk AGYW were more likely to want to use daily PrEP alone, explaining that they or their partner disliked condoms and/or liked that PrEP could be used discreetly. They expressed fewer concerns about accessing PrEP via public clinics and discussed that PrEP was easy to take and had become part of a daily routine.

Conclusions: While sub-study participants were interested in using daily PrEP beyond the trial, concerns remain over availability and accessibility beyond the trial. Long term, delivering PrEP outside HIV care and treatment settings and strategic promotion may reduce barriers for some women. Given higher-risk participants appeared more enthusiastic about future PrEP use compared to condoms, approaches such as point of care STI testing and contraceptive services at PrEP delivery sites, should be investigated.

Methods: We analyzed data from the community-based USAID-funded ACHIEVE project in Tanzania. The analysis was conducted on HIV-positive orphaned and vulnerable children (OVC) aged 0-17 years, who were on ART, and had at least two viral load tests spaced at least six months apart between 2021 and 2023. A total of 4,809 OVC whose first test indicated that they were virally detectable (≥ 50 copies/mL) were included in the analysis. Three project services with notable coverage gaps were considered in this analysis: economic empowerment through WORTH Yetu groups, teen club attendance, and health insurance. Other project services such as ART adherence support, case management visits, enhanced adherence counseling, etc. had universally reached the OVC. Data analysis involved a multivariable logistic regression model and propensity-score matching (PSM) to assess the project impact on achieving undetectable viral load at the second test.

Results: At the second test, 70.9% of the OVC had attained undetectable viral load. In the regression analysis, OVC who had received at least one of the ACHIEVE project interventions were 32% more likely to be undetectable compared to those who had received none (aOR=1.319, 95% CI 1.059-1.643, $p=0.014$).

After matching on ART regimen type, duration in the ACHIEVE project, OVC sex, OVC age, caregiver sex, caregiver age, caregiver education, OVC school enrolment status, household hunger, place of residence, family size, and whether the OVC had changed ART regimen in the last 6 months, the PSM revealed that the ACHIEVE project interventions were significantly effective in the attainment of undetectable viral load among the OVC ($\beta=1.103$, 95% CI 0.044-0.162, $p=0.001$).

Conclusions: The ACHIEVE project exhibits promise in accelerating the attainment of undetectable viral load for OVC, highlighting the importance of consistently delivering effective community-based interventions complementing clinical services for the holistic well-being of every HIV-positive child.

Treatment as prevention

TUPE040

Influence of community-based interventions in attaining an undetectable viral load in HIV-positive children and adolescents receiving antiretroviral treatment in Tanzania

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Background: Achieving and maintaining an undetectable HIV viral load in children and adolescents poses unique challenges due to various factors, including social and psychosocial issues, emphasizing the ongoing need for targeted interventions and support.

TUPE041

Sexually transmitted infections in men-who-have-sex-with-men with HIV resistant to tenofovir/emtricitabine and/or cabotegravir

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Background: Our aim was to explore the incidence of sexually transmitted infections (STIs) in men-who-have-sex-with-men with HIV (MSMWH) and resistance (R) to tenofovir/emtricitabine (TXF/FTC) and/or cabotegravir (CAB).

Methods: Cohort study on MSMWH on antiretroviral treatment (ART) with ≥ 1 genotyping resistance test (GRT) including integrase. Follow-up accrued from the first GRT [at or after ART initiation; baseline (BL)] to death/loss-to-follow-up/freezing date (February 28th, 2024). MSMWH who developed TXF/FTC- and/or CAB-R during the follow-up were excluded from the analysis.

The following STIs were included in the analysis: *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma/Ureaplasma spp.* (only if symptomatic), early syphilis (primary, secondary, or early latent), and mpox infections.

Poisson regression modeled incidence rates (IR) and 95% confidence intervals (95%CI).

Results: Overall, 638 MSMWH [554 (86.8%) without R, 71 (11.1%) with TXF/FTC-or-CAB-R, and 13 (2.0%) with TXF/FTC+-CAB-R] evaluated (Table 1).

Baseline characteristics	Overall (n=638)	No TXF/FTC- or CAB-R (n=554)	Either TXF/FTC- or CAB-R (n=71) ¹	TXF/FTC- and CAB-R (n=13)	P-value [§]
Age (years), median (IQR)	38.1 (30.8-45.2)	37.2 (30.0-43.7)	46.4 (40.4-52.1)	51.4 (44.1-53.9)	<0.001
Pre-baseline ART initiation, n (%)	137 (21.5%)	65 (11.7%)	59 (83.1%)	13 (100%)	<0.001
HIV VL (copies/mL), median (IQR)	44010 (8459-140462)	57000 (13491-159100)	4195 (742-21286)	3570 (1127-12006)	<0.001
CD4 ⁺ T-cell count (cells/mm ³), median (IQR)	393 (260-566)	385 (252-550)	506 (302-686)	392 (328-538)	0.011
CD4 ⁺ nadir (cells/mm ³), median (IQR)	338 (195-495)	359 (229-510)	200 (55-340)	137 (64-202)	<0.001
Positive HBsAg, n (%)	29 (4.5%)	23 (4.2%)	6 (8.5%)	0 (0%)	0.261
Positive HCV serostatus, n (%)	40 (6.3%)	26 (4.7%)	9 (12.7%)	5 (38.5%)	<0.001

¹67 TXF/FTC-R and 4 CAB-R [§]by Kruskal-Wallis test (continuous variables) or chi-square test (categorical variables), as appropriate

Table 1. Baseline characteristics of men-who-have-sex-with-men with HIV included in the analysis.

During a median follow-up of 9.6 [interquartile range (IQR)=7.3-11.7] years 307/638 (48.1%) individuals developed ≥ 1 STI (Figure 1). Specifically, 744 STIs were diagnosed during 5908 person-years-of-follow-up (PY), IR=12.6 (95%CI=11.7-13.5)/100-PY; 23/744 (3.1%) STIs occurred at viral load (VL) ≥ 200 copies/mL.

Notably, 60/744 (8.1%) STIs were diagnosed in 29/71 (40.8%) MSMWH with TXF/FTC-or-CAB-R [1/60 (1.7%) at VL ≥ 200 copies/mL], IR=8.2 (95%CI=6.2-10.5)/100-PY, and 4/744 (0.5%) STIs in 3/13 (23.1%) MSMWH with TXF/FTC+CAB-R [0/4 (0%) at VL ≥ 200 copies/mL], IR=2.9 (95%CI=0.8-7.3)/100-PY.

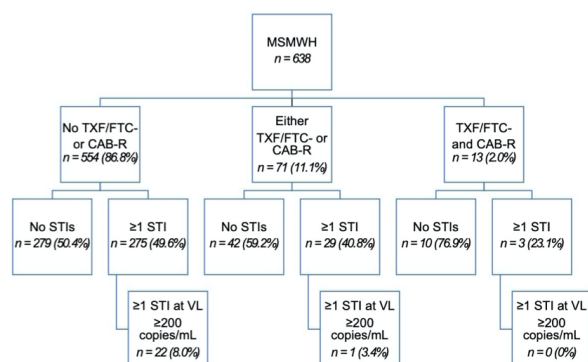


Figure 1. Occurrence of sexually transmitted infections (STIs) in men-who-have-sex-with-men with HIV (MSMWH) included in the analysis.

Conclusions: In our cohort of MSMWH, STI incidence was high, even in presence of TXF/FTC- and/or CAB-R. Discussion of resistance test results in these individuals is important, even in light of potential HIV transmission uncontrolled by pre-exposure prophylaxis.

TUPE042

Loss to follow up among first Ecuador PrEP program users in community-based centers between 2019 and 2023

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Background: Pre-exposure prophylaxis (PrEP) was first implemented in Ecuador in 2019 by Kimirina, a community-based non-governmental organization focused on comprehensive health promotion and response to HIV epidemic. The program was set up in conjunction with the Ministry of Public Health allowing for medication to be free of charge. Once PrEP is initiated, patients should return for their first follow-up within a month, then within two months and finally every three months. After four years, the objective of the analysis was to determine the loss to follow up (LTFU) and associated variables.

Methods: A retrospective longitudinal analysis of the database of Kimirina's PrEP users was carried out from the 21st of August of 2019 to 31st July of 2023. Users were divided into active follow up and lost follow up, and then correlated with sexual orientation, nationality and age.

Results: During the first four years of program implementation, 1345 users have received PrEP at Kimirina community centers. The main age was 31.5; 75% were homosexual, 20% bisexual and 5% heterosexual. 60% of the users were Ecuadorian and 40% migrants -Venezuelans (145) and non-Venezuelans (392). The average number of monthly new users increased each year, from 19 users in 2019 to 48 in 2023.

According to nationality, Ecuadorians had the highest average PrEP use (12.23 months); Venezuelan users averaged 10.74 months of use and, those of other nationalities, 9.18 months (ANOVA gl=2, F=3,962 y Sig.=0.019). Regarding age, users under 26 years had the shortest average PrEP use (6.46 months), followed by users between 26 and 35 years with 11.80 months and 14.5 months for users over 36 years (ANOVA analysis test gl=2, F=19,250 and Sig.=0.000). There were no significant differences between the follow up according to sexual orientation.

Conclusions: PrEP program in Ecuador is in expansion, the first experience showed that non-Venezuelan migrants and users under 26 years of age had the greater LTFU.



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WEPE037

Effects of the timing of maternal antiretroviral therapy initiation, CD4 count, and HIV viral load on birth outcomes in the Eastern Cape province of South Africa: a secondary data analysis

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Background: Antiretroviral therapy (ART) use during pregnancy reduces the vertical transmission of HIV but is associated with adverse neonatal outcomes. This study aimed to evaluate the impact of maternal HIV and the timing of ART initiation on pregnancy outcomes.

Methods: This secondary data analysis examined the dataset from an earlier cohort study involving 1709 HIV-positive women who delivered their babies at three major maternity centres in the Eastern Cape province of South Africa between September 2015 and May 2018. The associations between adverse pregnancy outcomes (stillbirth, preterm birth, very preterm birth, and low birth weight) and the timing of maternal ART initiation, peripartum CD4 count, and HIV viral load were examined using logistic regression analysis.

Results: The observed rates of stillbirth, preterm birth, very preterm birth, and low birth weight were 1.4%, 33.5%, 5.4% and 18.0%, respectively. In the multivariable analysis, low birth weight was associated with ART initiated during the second trimester (adjusted odds ratio [aOR] 1.38; 95% confidence interval [CI], 1.03-1.85), low-level viraemia (21-999 copies/ml) (aOR, 1.62; 95% CI, 1.17-2.22), and high-level viraemia (≥ 1000 copies/ml) (aOR, 1.66; 95% CI, 1.66-2.38) during the peripartum period. Preterm birth was associated with low-level viraemia (aOR, 1.44; 95% CI, 1.16-1.79) and a CD4 count of less than 200 cells/mm³ (aOR, 1.35; 95% CI, 1.01-1.82). Very preterm birth was associated with detectable maternal viraemia.

Conclusions: Adverse birth outcomes are common among pregnant women with HIV, especially those with unsuppressed viraemia. Clinicians and programme managers should prioritise timely ART initiation and virological suppression in all pregnant women.

Adaptive immunity

TUPE043

Imaging of SHIV immune complexes in animal lymph nodes to study T cell priming

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Background: Administration of two HIV-1 Envelope-specific broadly neutralizing antibodies, 3BNC117 and 10-1074, during acute acquisition with an HIV-1 Envelope containing SIV virus (SHIV) resulted in durable CD8⁺ mediated control of SHIV replication (Nishimura, *Nature*, 2017). However, the mechanism by which antibodies might contribute to an effective lentiviral-specific CD8⁺ T cell response has not been defined. It is possible that one effect of antibodies may be the lowering of viral load, potentially reducing a negative impact on CD8⁺ T cells. In addition, it is possible that virion-antibody immune complexes are processed in lymph node antigen presenting cells and cross-presented to CD8⁺ T cells resulting in an effective CD8⁺ T cell response. Understanding the interplay and dynamics of these effects may provide critical information for induction of an effective lentiviral CD8⁺ T cell response.

Methods: Plasmids containing fluorescent (mCherry) SIV_{mac239} gag, SIV_{mac239} Denv, and SHIV_{AD8} stabilized env were co-transfected into 293Expi cells to produce virus-like particles (VLPs) displaying SHIV_{AD8} Env. VLPs were sucrose purified, bound to 3BNC117 and 10-1074, and inoculated into the upper extremities of rhesus macaques. Axillary lymph nodes were excised at different timepoints following inoculation and live, thick sections were cut and stained. Sections were imaged using Leica Stellaris SP8 DIVE (Deep In Vivo Explorer) microscope.

Results: Images showed co-localization of the mCherry immune complexes with antigen presenting cells such as CD11b⁺ and CD123⁺ cells indicating macrophage and dendritic cell involvement in presenting these immune complexes. Ongoing quantification of colocalization with CD8⁺ T cells should further detail the priming events during lentiviral acquisition in the presence of virus-specific antibodies.

Conclusions: These images are providing a detailed spatiotemporal examination of the host immune response to SHIV VLPs in the context of antibodies, which has the potential to inform the development of novel therapies and vaccines for HIV-1.

TUPE044

Efficacy metrics of epitope breadth, depth, and specificities of early CD8 T cell responses to HIV-1 gag antigens in natural infection

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Background: The natural transition from peak viremia to viral set point of primary HIV infections potentially represents spontaneous control, howbeit impermanent. This initial down regulation of viremia is characterized by an early HIV-specific cytotoxic T lymphocytes response.

Methods: We set to determine efficacy metrics of early CD8 T cell responses by comparing the breadth and depth of HIV-1 specific responses to multivalent HIV-1 gag antigen peptides using samples (n=15) collected at 3-6 months and 9-12 months post Estimated Date of Infection (EDI). We optimized an in-vitro polyclonal CD8 T-cell expansion procedure using isolated PBMC for the extension of limited one-time-point clinical samples for IFN- γ ELISPOT. These were subsequently used to screen a large library of multivalence complemented consensus peptides representative of local viral strains within the PBMC sampling population.

Results: Analysis of CD8 T cell responses magnitudes above the pre-specified threshold for a positive response of 38 SFU/10⁶ cells, a significantly higher magnitudes of T cell responses at 3-6 months was observed (mean \pm SD; 874.01 SFU \pm 1204.10 vs 474.34 \pm 469.90), despite CD4 counts, an indicator of immune function and status, being averagely similar. Overall, we also identified more epitopes and epitope variants from 3-6 months compared to 9-12 months sample responses (breadth: 5 vs 4, depth 11 vs 9). Breadth and depth change dynamics were different between samples, some registering a loss of viral antigen specific CD8 T cell responses (loss of breadth and/or depth, n=10) and some gaining antigen specific responses at 9-12mon (increase of breadth and/or depth, n=5). Increased breadth and/or depth was further indicated with improved CD4 and VL measures from 3-6 months to 9-12 months post EDI.

Conclusions: Considering that HIV-1 is always evolving and presenting new antigenic challenges to the immune system, it makes sense that a CD8 T cells response de-

finied by a high magnitude and an incrementally adaptable breadth and/or depth should have better disease outcomes. These results offer critical insight for strategic development of heterologous prime- 'augmented' boost regimens to ensure immunes responses that are effectively additive to the initial priming epitopes.

WEPE038

The frequency of HIV-specific activated memory B cells associates with antibody durability following vaccination

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Background: Vaccinations aspire to induce enduring antibody responses that offer protection years after immunization. However, the waning efficacy of the HIV-1 RV144 vaccine corresponded with diminishing levels of plasma binding antibodies. The magnitude and durability of RV144-elicited antibodies were boosted with a subsequent immunization in a follow-up study, RV306.

Understanding the mechanism of durable antibody responses after immunization is key to devise vaccine strategies that can exploit these mechanisms to maintain sufficient levels of antibodies for long-lasting protection.

Methods: Specimens from RV306 participants who received the RV144 regimen followed by an additional boost at month 12 were used to define immune signatures of durable antibody responses. Sorted HIV-specific B cells from pre-vaccination, 2 weeks (peak), or one year following the final boost were processed for single cell multiomics assessment of the transcriptome, surface protein expression, and antigen recognition to elucidate factors that contribute to antibody durability.

Results: Twenty participants with similar peak antibody responses were segregated into two groups; those who maintained higher (durable, N=10) or lower (non-durable, N=10) antibody magnitudes one year following the final boost (p<0.001). The durable responders maintained a longer antibody half-life (p<0.001) and slower rate of antibody decay (p<0.001) compared to non-durable responders who were on par with the lack of durability elicited by RV144 vaccination.

Transcriptomic clustering analysis of HIV-specific B cells revealed a unique class-switched activated memory B cell population that comprised >50% of HIV-specific B cells 2 weeks following the last vaccination.



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Durable responders maintained higher frequencies of these unique HIV-specific activated B cells at peak and year one compared to non-durable responders ($p < 0.05$). The frequencies of this unique B cell population associated with binding antibody levels at year 1 ($p < 0.006$) and slower antibody decay rates ($p < 0.003$), indicating that higher levels of these HIV-specific B cells associate with antibody durability.

Conclusions: These data provide evidence that the magnitude of a specific activated memory B cell subpopulation induced by vaccination plays an important role in the production of long-lived antibody responses.

Developing vaccine platforms or adjuvants to preferentially harness these pathways following vaccination may improve the durability of antibody responses against HIV Env.

WEPE039

HIV-1 broadly neutralizing antibodies in SHIV-infected macaques recapitulate structurally divergent modes of human V2 apex recognition with a single D gene

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Background: Broadly neutralizing antibodies (bNAbs) targeting the V2 apex of the HIV-1 envelope trimer are among the most common specificities elicited in HIV-infected humans and in simian-human immunodeficiency virus (SHIV)-infected macaques.

Here, we conduct a systematic analysis of the immunogenetics and structures of a repertoire of rhesus V2 apex-targeted bNAbs isolated from SHIV-infected macaques to gain insight into their prevalence and to assess the relevance of the rhesus model for V2 apex-targeted HIV-1 vaccine design and testing.

Methods: HIV-1 Env-pseudotyped viruses with and without V2 apex epitope substitutions were used to phenotypically map heterologous neutralization of rhesus plasma and monoclonal antibodies. Antigen-specific single-cell sorting with HIV-1 SOSIP trimers was used to isolate V2 apex-specific lineages from memory B cells of SHIV-infected macaques with V2 apex-targeted responses. Single-particle cryo-EM was used to determine the high-resolution structures of rhesus bNAbs in complex with HIV-1 SOSIP trimers.

Results: We recovered 11 monoclonal rhesus lineages which exhibited potent heterologous neutralization of a panel of 19 tier-2 HIV-1 and SIV strains. Each rhesus lineage had atypically long ≥ 23 residue HCDR3s with an overall electronegative charge due to an enrichment of anionic residues, similar to the HCDR3 features of human V2 apex-targeted bNAbs. Rhesus lineages segregated into five distinct phenotypic neutralization groups – two newly identified – based on their sensitivity to specific V2 apex epitope substitutions.

Strikingly, all rhesus V2 apex-targeted bNAb lineages, including those previously published, were invariably derived from the rhesus DH3-15*01 gene in reading frame two. Immune repertoire analysis identified the rhesus DH3-15*01 gene to have unique and favorable biochemical features for V2 apex recognition compared to all other rhesus and human D genes.

Cryo-EM analysis of ten rhesus lineages revealed structural and functional plasticity of the DH3-15*01 gene segment, which enabled three reproducible structural classes that mimicked the three HCDR3-dominated modes of human V2 apex recognition.

Conclusions: While many immunogenetic and structural features of broad V2 apex-recognition are conserved across species, the DH3-15*01 gene can yield highly advantageous rhesus-specific paratopes for V2 apex-recognition, which may make the induction of these antibodies more prevalent in this preclinical model.

Antibody functions (neutralizing and non-neutralizing)

TUPE046

Deciphering HIV vaccine induce antibody response according to ethnicity

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Background: Should HIV-1 preventive vaccines be adapted to geography and/or ethnicity? Recently HVTN 702 failed to show efficacy, despite its attempt to tailor the RV144 vaccine for the HIV clade circulating in South Africa. Amongst multiple potential reasons ethnic differences may play a role. We evaluated the association of ethnicity with HIV vaccine-induced humoral immune response. We also assessed the specific effect of sex assigned at birth, age, geographic location, and crystallizable fragment receptor (FcR) polymorphism frequencies of single nucleotide polymorphisms (SNPs are single nucleotide differences in paired chromosomes).

Methods: We retrospectively analysed data from the HVTN 204 vaccine trial, a multiclade HIV-1 DNA Plasmid Vaccine, VRC-HIVDNA016-00-VP, followed by a Multiclade Recombinant Adenoviral Vector HIV-1 Vaccine boost, VR-CHIVADV014-00-VP conducted in HIV-1 uninfected adult participants from South Africa and the United States. We performed multivariate analysis of antibody responses induced in both countries according to ethnicity, Fc-receptor polymorphism, sex assigned at birth, age, and geographic location.

Results: We found that Black South Africans displayed higher total Igs (mean 22 mg/mL vs 9 mg/mL, $p < 0.001$) and IgA (mean 6 mg/mL vs 5 mg/mL, $p = 0.026$) compared to White Americans. Moreover, they showed significantly lower HIV-specific IgG responses against the envs MN/LAI ($p < 0.001$) and TH023/LAI ($p = 0.02$) and against the peptide V1V2 92TH023 ($p < 0.001$) post-vaccination. As they also showed lower background at baseline, differences between ethnic groups were narrowed after baseline background subtraction, referred to as delta values for the vaccine response outcome.

Conclusions: We found that Black South Africans displayed distinct antibody profile compared to White Americans. It is not clear whether these population differences are due to ethnicity or some other geographic factors. The observed impact of genetics, geographic location and ethnic background on HIV-specific Ab immune responses to the HVTN 204 vaccine warrants further investigation of additional vaccine-induced humoral responses.

In particular, analysis of genetic and ethnicity effects on new, improved vaccines able to induce high and sustained levels of HIV-specific Abs should be explored. Results of such studies may give additional insights for future specific-designed vaccine strategies, customized according to ethnicity or country specificities, such as currently envisaged personalized medicine.

bNAbs and HIV prevention

TUPE048

High-throughput HIV broadly neutralizing antibody discovery from the United States Military Natural History Study cohort

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Background: The discovery of HIV broadly neutralizing antibodies (bNAbs) remains a key focus in the HIV vaccine and therapeutics fields. bNAbs have demonstrated potential for protection from viral acquisition in the Antibody-Mediated Protection (AMP) study and have proven effective in suppressing viral load when administered as passive therapy. Many gaps in our current arsenal of HIV-directed bNAbs exist, however, including suboptimal potency, lack of reactivity against entire clades, and atypical features that may hinder re-elicitation by vaccination.

Here we screened samples from a large cohort of U.S. Military service members with HIV for their potential for bNAb discovery.



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Methods: Subjects were selected from the U.S. Military HIV Natural History Study (NHS) based on availability of matched PBMC and serum/plasma, along with clinical criteria associated with neutralization breadth including viral load >1000 copies/ml over ≥2 years and ART-naïve or off ART for ≥ 6 months. Samples were screened initially against 6 Env-pseudotyped viruses for neutralization using the TZM-bl assay, and those samples that neutralized ≥2 viruses were further assessed for neutralization against a 20-virus panel. Samples that demonstrated ≥75% breadth against the 20-virus panel were computationally epitope mapped using a neutralization fingerprinting algorithm.

Results: Of >6400 HIV+ subjects, 856 were identified for screening based on our selection criteria (median cumulative days VL > 1000 copies: 2329; range 733-9262). 121 serum samples have been screened so far. 46 (38%) neutralized ≥2/6 viruses and were further assessed against the 20-virus multiclade panel. 11 of these 46 samples (24%, or 9% of all 121 samples screened to date) neutralized ≥75% of the 20 viruses. Of these, 6/11 were computationally predicted to have VRC01-like neutralization activity and 3/11 exhibit PG9-like activity. Strong HJ16-like, 8ANC195-like, PGT128-like, and 10E8-like activity was also detected among the 11 broad neutralizers.

Conclusions: The detection of ≥75% neutralization breadth in nearly 1 in 10 screened serum samples bodes well for isolating bNAbs from individuals in this cohort. Screening of an additional >700 sera, and confirmation of epitope specificity by functional mapping neutralization assays using epitope mutants will assist in selection of subjects for high-throughput recovery of antibodies.

TUPE049

Assessing the suitability of HIV env trimers as booster immunogens to facilitate affinity maturation of VRC01 class bNAb response

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Background: The current preventive tools for HIV-1 disease are sub-optimal. With the discovery of Germline Targeting (GT) immunogens new hope for getting an effective vaccine against diverse strains of HIV viruses lit up. Therefore, it is now essential to identify and evaluate the Env trimer immunogens as late-stage boost candidates in parallel to further accelerating the affinity maturation

of the immune response elicited because of GT immunogen immunization. In the present study, 11 env sequences were down selected from HIV+ individuals based on their neutralization profiles against VRC01 class antibodies. Soluble env trimers in their near native closed prefusion conformation were produced using these sequences and characterized extensively so that they can be used as potential booster immunogens.

Methods: Different designs (SOSIP only, BG505SOSIP chimera, DS-BG505SOSIPchimera) of the env trimers from the selected sequences were codon optimized. Expi 293 cells were transfected with the codon optimized DNA of different designs. The pure trimeric protein was then purified either by affinity column or lectin column followed by size exclusion chromatography (SEC).

The purified trimeric env proteins were then characterized by using native PAGE to confirm the size and their closed conformation was confirmed by negative stain electron microscopy (NSEM).

The thermal stability of the trimers was confirmed by differential scanning calorimetry. Their antigenicity was tested against the matured known broadly neutralizing antibodies (bNAbs), inferred germline antibodies (iGLAbs) and intermediate antibodies (int. Abs) using BLI-Octet.

Results: All these characterizations indicate that 3 env soluble trimers can be expressed in their near native prefusion conformation with ~>70% trimers in closed state. Lesser extent of binding to iGLAbs, moderate binding to int. Abs and higher binding to the VRC01 class matured Abs, observed in Octet determines their potential as booster immunogens in the germline targeting vaccine approach to elicit VRC01 class bNAb responses.

Conclusions: Out of all the env trimers so far produced from the given sequences, three have been found to be in the near native closed trimeric conformation. Though the immunogenicity of these trimers is further needed to be validated in animal model, these env trimers could be the potential booster immunogen candidates in the future.

TUPE050

In vitro affinity maturation of the HIV-1 bnAb N49P7-FR for increased neutralization breadth and potency

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Background: HIV-1 broadly neutralizing antibodies (bnAbs) have been powerful tools to inform HIV-1 vaccine design and there is growing interest in using them for prophylactic and/or therapeutic indications. The Antibody Mediated Prevention (AMP) trials found that prophylactic administration of VRC01, a CD4bs-targeting bnAb, provided protection against strains of HIV-1 that were sensitive to VRC01 neutralization. This demonstrated the potential for bnAb-mediated prevention; however, it highlighted the need for bnAbs with improved neutralization potency. N49P7 is a VRC01-class bnAb that displays near pan coverage across a 117-pseudovirus global panel of HIV-1 isolates. While N49P7 neutralizes HIV more potently than VRC01, data from the AMP study suggests that N49P7 lacks the requisite potency to be useful for prophylactic indications. Here, we work to engineer a variant of N49P7 with improved neutralization breadth and potency.

Methods: N49P7-FR, a variant of N49P7 that contains the extended heavy-chain framework region 3 loop of VRC03, was designed and selected as the starting bnAb for engineering. We then utilized an interdisciplinary multistate optimization strategy that integrates yeast surface display screening of barcode-enhanced saturated mutagenesis scanning libraries and combinatorial libraries of the N49P7-FR heavy and light chain variable regions, combined with deep sequencing and bioinformatics analysis. The optimized N49P7-FR variants were produced as IgG1 to test their functionality by neutralization assay; developability by PSR-ELISA, HPLC-SEC, and thermal shift assay; and pharmacokinetics in the human FcRn transgenic mice.

Results: Our strategy resulted in an engineered N49P7-FR bnAb variant with neutralization breadth improved 6- and 2-fold ($IC_{80} \leq 0.1 \mu\text{g/mL}$), and median potency increased 36- and 5-fold compared to VRC01 and the parental N49P7-FR bnAb, respectively, against 149 HIV-1 pseudoviruses selected from the Seaman global panel and VRC01 AMP trials. The optimized N49P7-FR lead candidate did not show major developability problems, such as polyreactivity, manifested notable improvements in

production yield and thermal stability, and had a comparable pharmacokinetic profile to that of the parental bnAb in mice.

Conclusions: Our bnAb optimization campaign maximized the potency and breadth of N49P7-FR, with the created enhanced bnAb variant constituting a promising clinical candidate for future AMP trials and therapeutic regimens.

TUPE051

Applying a statistical model to define the differential trajectory of cell-cell communication to identify factors driving the maturation of broadly neutralizing antibodies by HIV vaccination using single-cell RNA sequencing data

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Background: The induction of broadly neutralizing antibodies (bnAbs) by vaccination remains a major hurdle in the design of a protective HIV vaccine. We have demonstrated that immunization of infant rhesus macaques (RM) with the germline-targeting BG505 GT1.1 SOSIP trimer adjuvanted with 3M-052-SE is more effective in inducing CD4 binding site (bs) bNAb precursors than immunization of juvenile RMs with the same vaccine. However, there is a gap in understanding what factors promote the maturation of bNabs.

Here, we will apply a novel statistical method to define interactions between cell types critical in the activation of B cells towards the production of bNabs.

Methods: Intercellular interactions (so called "Cell-Cell Communication"), mediated by ligand-receptor complexes, are important to many biological processes, including immune responses.

The single-cell RNA sequencing (scRNA-seq) technologies allow the measurement of the gene expression of ligand and receptors. We have developed a novel statistical method to identify differential intercellular ligand-receptor (L-R) interactions from single-cell RNA sequencing data.

The method firstly introduces a novel connection score to quantify ligand-receptor interactions between two cell types while accounting excess zeros in scRNAseq data. It then fits a two-component generalized linear mixed model to the connection scores.



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Results: Applying this approach, we previously demonstrated upregulation of TRAIL by innate immune cells, such as Innate lymphoid cells (ILCs) and Plasmacytoid Dendritic Cells (pDCs), played a major role in CD4 depletion in an *in vivo* model of HIV infection in humanized mice.

Here, we apply this statistical method to dissect the interactions between dendritic cells, follicular T helper cells and germinal center B cells in longitudinally collected lymph nodes of infant *rhesus macaques* (RM) (n=10) vaccinated with the germline targeting BG505 GT1.1. SOSIP adjuvanted with 3M052-SE to assess the time trajectory effect on the maturation of antibodies with broadly neutralizing function.

Conclusions: Application of the new statistical method of cell-cell communication in single-cell RNA sequencing data of samples longitudinally collected from lymph nodes of infant RM, can identify key ligand and receptor genes that drive the maturation of broadly neutralizing antibodies by HIV vaccination.

TUPE052

Human CD4-binding site antibody elicited by polyvalent DNA prime-protein boost vaccine neutralizes cross-clade tier-2-HIV strains

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Background: One of the bottlenecks to an effective HIV-1 vaccine is the difficulty in raising protective antibody responses, capable of neutralizing the diverse resistant-to-neutralize viral isolate especially the tier-2 neutralization-resistant viruses.

Methods: A CD4-binding site (CD4bs) specific monoclonal antibody, HmAb64, from a human volunteer immunized with a polyvalent DNA prime-protein boost HIV vaccine (PDPHV) was isolated and characterized for the binding specificity, breadth of neutralizing activities, and structure in complex with HIV-1 Env.

Results: HmAb64 is derived from heavy chain variable germline gene IGHV1-18 and light chain germline gene IGKV1-39. It has a third heavy chain complementarity de-

termining region (CDR H3) of 15 amino acids. On a cross-clade NIAID VRC panel of 208 HIV-1 pseudo-virus strains, HmAb64 neutralized 20 (10%), including tier 1B and tier-2 strains from clades B, BC, C, and G. The cryo-EM structure of the antigen-binding fragment of HmAb64 in complex with a CNE40 SOSIP trimer revealed details of its recognition; HmAb64 uses both heavy and light CDR3s to recognize the CD4-binding loop, a critical component of the CD4bs.

Conclusions: This study demonstrates that a gp120-based vaccine can elicit antibodies capable of tier 2-HIV neutralization.

TUPE053

Characterization of novel monoclonal antibodies targeting HIV-1 envelope V3 isolated from an Indian donor with Subtype C Infection

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Background: Broadly neutralizing antibodies (bNabs) are an alternative approach to treat and prevent HIV acquisition. Identifying novel vulnerable epitopes on the HIV-1 envelope is key for complementing the bNab-based intervention to combat emerging HIV-1 resistance. HIV-1 Subtype C accounts for about half of global acquisitions and >90% of acquisitions in the Indian population. Hence, it is important to have a better understanding of antibodies elicited by subtype C infection. Here we report the characterization of novel antibodies isolated from an Indian donor with Subtype C acquisition.

Methods: TZM-bl based neutralization experiments were done to identify plasma with broad and potent neutralizing antibodies against pseudoviruses expressing Envs of diverse HIV-1 subtypes. Further mapped specificity of plasma and suitable bait for the isolation of antibody by antigen-specific single B cell sorting and cloning method. Single B cells IgG variable regions were amplified and cloned into respective vectors to express the IgG. The antigen-specific IgGs in ELISA were further characterized for their genetic characteristics using IMGT tools and breadth, potency as well as specificity mapped by using chimeric constructs by TZM-bl based neutralization assay.

Results: We have isolated a total of 50 HIV-reactive human monoclonal antibodies isolated from an ART naïve HIV-1 subtype C acquired Indian donor with V1V2-directed specificity. Two antibodies HVTR-PG9-030 and HVTR-PG09-103 have been found to demonstrate cross-neutralization of HIV-1 subtype C of Indian origin. The genetic properties indicated these two antibodies derived from

district V-genes like VH-1-69*18 and VH5-51*01 respectively having >15% divergence from their respective germlines. Both the mAbs have been tested against a panel of 40 Indian and 15 non-Indian viruses including global panel viruses and both the mAbs showed partial neutralization against majorly Indian viruses with less breadth and potency. Further mapping specificity indicated V3-directed specificities of these two antibodies.

Conclusions: The information on novel antibodies isolated from HIV-1 subtype C acquired Indian donor will give an idea about the kind of antibodies elicited and B cell repertoire used will have its ultimate implications in the design of effective vaccine design and therapeutic interventions.

TUPE054

Topical vectored broadly neutralizing antibodies prevent *ex vivo* HIV-1 infection of human cervicovaginal tissue

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Background: Vectored delivery of broadly neutralizing antibodies (bnAbs) using adeno-associated virus (AAV) has shown success in preventing HIV/SIV infection in different animal models. However, assessment of AAV-bnAb efficacy in human female genital tract tissues *ex vivo* has not been reported. We tested this concept with the ultimate aim of developing a vectored topical immunoprophylaxis tool for women.

Methods: Vectors expressing PGT121 or VRC07 bnAb genes were transformed into E. Coli cells, amplified and packaged as recombinant AAV2. AAV localization in cervicovaginal (CV) tissues and cells was performed by immunofluorescence analysis after 24h exposure to AAV2-GFP. Anti-HIV-1_{Bal} activity of AAV-bnAbs was assessed in TZM-bl cells following a 6 or 24h incubation with AAV prior to HIV-1 infection. CV tissues collected from HIV-1-negative women were exposed to AAV2-VRC07 and AAV2-PGT121 for 1 to 4 days before *ex vivo* challenge with HIV-1_{Bal} and then cultured for 21 days. Infectivity was monitored by measurement of luciferase expression in TZM-bl cells and p24 production in tissue.

Results: TZM-bl cells exposed to AAV2-bnAbs showed time-dependent accumulation of specific anti-gp120 IgG and complete neutralization of HIV-1_{Bal} infection. Using specific markers, smooth muscle, fibroblasts, epithelial cells and leukocytes in CV tissues were identified as expressing AAV-GFP, 1 day after exposure. Complete HIV neutralization was observed in vaginal and/or cervical tissues exposed to either AAV2-PGT121 or AAV2-VRC07 4 days prior to HIV-1_{Bal} challenge in 4 out of 7 donors. Specific anti-gp120 IgG levels significantly correlated with HIV-1_{Bal} neutralization in CV tissues (p=0.0037).

Conclusions: We show proof-of-concept that AAV vectored bnAbs can transduce, replicate, and induce sustainable and sufficient production of HIV-specific Abs in human CV tissues to prevent *ex vivo* HIV-1 infection and potentially serve as a long-acting topical immunoprophylactic tool for HIV prevention in women.

TUPE055

Rational design of immune complex immunogens to target the bnAb epitopes of gp120 V1V2

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Background: The beta-barrel V1V2 domain of the HIV-1 gp120 envelope glycoprotein in the prefusion trimer harbors epitopes of broadly neutralizing antibodies (bnAbs), such as PG9 and PG16, located at the β -hairpin formed by strands b and c and their associated glycans. However, developing a V1V2-based immunogen to focus the antibody responses against these bnAb epitopes remains challenging due to the structural metastability of V1V2. We hypothesize that the complex of V1V2 and a non-neutralizing mAb can stabilize the formation of bnAb epitopes, and serve as an immune complex vaccine.

Methods: We structurally characterized the complex of the V1V2 domain with V1V2-specific mAb 2158, whose binding is known to enhance V1V2 recognition by bnAb PG9, by determining a cryo-EM structure of PG9 Fab in complex with a 2158 Fab-bound V1V2_{ZM109}-1FD6.

Results: Structural results revealed that 2158 binds to the conserved hydrophobic side of V1V2 and, most importantly, preserves the β -hairpin structure compatible with PG9 binding. The structural details allowed us to design a covalent link at the V1V2/2158 interface to further stabilize the complex, hence creating a stable immune complex ready to be tested in animal experiments.

Conclusions: Our results provide an example of the rational design of an immune complex V1V2 subunit vaccine that may direct antibody responses to the bnAb epitope vulnerable site.



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WEPE041

Evaluation of the kinetics of systemic distribution of i.v. injected bNAbs of various IgG subclass in the rhesus macaque model

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Background: Antibody-mediated protection against HIV/SHIV transmission has been illustrated in non-human primates (NHP) with IV injection of broadly neutralizing monoclonal antibodies. To gain insight into the kinetics and dynamics of the distribution and localization of passively transferred antibodies we previously utilized fluorophore-labeled VRC01 IgG1 to understand how broadly neutralizing antibodies (bNAbs) distribute and localize to mucosal tissues. We developed a platform to track passively infused fluorescently labeled antibodies in the living NHP model, without compromising antibody function. After injection, we could follow the distribution of antibodies over time, providing a unique perspective to observe how antibodies reach different anatomical sites. As it has been shown that IgG subclass drives antibody functionality and may influence antibody effector functions, we are now further utilizing this platform with VRC01 IgG subclasses (IgG2, IgG3, IgG4) to explore the potential influence of IgG subclass on the distribution of labeled antibodies to different anatomical sites.

Methods: To assess IgG subclass antibody distribution, eight female rhesus macaques were IV-administered fluorescently tagged VRC01 IgG2, IgG3, or IgG4 (10mg/kg) in conjunction with VRC01 IgG1 (10mg/kg), each antibody of a different color fluorophore. Two male rhesus monkeys were also IV-injected Cy5 or Cy3 fluorescently labeled VRC01 IgG2 and IgG4. Animals were necropsied 1-week post-injection, tissues were collected, frozen down in OCT or paraffin-embedded, and imaged with deconvolution microscopy.

Results: By analyzing animals that received fluorescently labeled VRC01 IgG subclass antibodies, we can now begin to discern the differences in localization and distribution in the *in vivo* system. Although studies are still ongoing, we can visualize differences in VRC01 IgG subclass distribution and localization amongst different tissues, including, but not limited to the spleen, small intestine, large intestine, and lymph nodes.

Conclusions: These data build on our previous data examining the distribution and localization of fluorescently labeled anti-HIV bNAbs. Importantly, these studies provide novel insights into IgG subclass-associated mechanisms of antibody delivery to various organs and tissues following IV injection. These experiments will provide critical insight into the mechanism(s) of distribution and localization of systemic antibodies by following the time course of distribution of passively transferred antibodies.

WEPE042

Contemporary HIV-1 subtype C from India shows resistance to env V1/V2 loop directed broadly neutralizing antibodies

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Background: Broadly neutralizing antibodies (bnAbs) has been found to be effective as a preventive measure globally in absence of an effective vaccine against HIV-1. However, this faces a major concern of generation of escape variants. Thus, to intervene suitable prevention strategies, it is important to characterize the circulating viruses at a given geographical area.

In this study, we did functional characterization of contemporary HIV-1 isolated from different risk groups and disease stages of HIV-1 infected patients across India against such lead bnAbs.

Methods: Towards this, 161 plasma of HIV-1 infected patients (2019 to 2023) from 5 clinical sites of India were collected. Viral RNA were isolated, followed by envelope amplification, deep sequencing and pseudovirus generation. 88 unique pseudoviruses of subtype C were synthesized followed by TZMBL neutralization assay against a panel of lead bnAbs of different classes (V1/V2, CD4bs, V3, MPER and Interface).

Results: Majority of the Indian viruses were resistant to V1/V2 class of bnAbs specially CAP256-VRC26.25 (50%), which were effective against subtype C viruses from India (historical viruses reported earlier). Further, some of the viruses (12.5%) were resistant to both CAP256 and PGDM1400 and some (15.9%) were resistant to all of the studied V1V2 bnAbs (CAP256-VRC26.25, PGDM1400, PG9 and PGT145). Interestingly, PG9 Ab showed a marked increase in sensitivity (29.5%) towards resistant viruses over and above PGDM1400 (19.31%) and PGT145 (15.9%). Sequence analysis showed enrichment of resistance associated signatures at the key positions (e.g. R166K) for these bnAbs.

Conclusions: Our study showed emergence of bnAb resistant HIV-1 amongst Indian population. This emphasizes the importance of continued virus surveillance towards bnAb sensitivity of circulating HIV-1 from India for appropriate preventive measures.

WEPE043

Innovative *défense*: harnessing bNAbs to combat HIV among vulnerable communities

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Background: People who inject drugs (PWIDs) and female sex workers (FSWs) face significant HIV risk due to their behaviours and socio-individual characteristics, with condoms being their primary protection. This study assesses the acceptance and willingness among these groups to use broadly neutralizing antibodies (bNAbs), and their preferences regarding product attributes, positioning bNAbs as a complementary prevention method to existing options, potential alternative to conventional prevention methods.

Methods: Conducted in Chennai and Delhi, the study comprised six focus group discussions (FGDs) and eight in-depth interviews (IDIs), with recordings transcribed, translated, coded, and analysed thematically using a qualitative data analysis tool.

Results: Initial reliance on condoms for HIV protection was universal among participants. Introduction to bNAbs sparked interest and willingness to adopt, contingent on factors such as cost, side effects, dosage frequency, and administration logistics. The preference was influenced by concerns over privacy, ease of use, side effects, and the logistics of consistent medication adherence amidst unpredictable lifestyles.

Oral formulations were not preferred due to lack of privacy to take and store, side effects, adherence challenges like frequent travels and unpredictable work schedules conflicting with the time sharing with clients or drugs intake, forgetting under the influence of alcohol. Injectable bNAbs were favoured for their longevity and fast action, despite fears of dependency on healthcare facilities and injection-related discomfort.

Conclusions: The study underscores a critical demand for innovative HIV prevention solutions beyond condoms, tailored to the unique needs of high-risk populations. bNAbs emerge as a promising avenue, meriting consideration for broader application across diverse groups and geographies.

By offering a complementary option to enhance choice, bNAbs could significantly reduce the transmission rates among the most vulnerable groups, such as PWIDs and FSWS. bNAbs provide long-lasting protection with fewer

dosages aligning with the need for more accessible and less frequent regimens, overcoming barriers of stigma, inconvenience, and healthcare access are more welcomed by the high risk groups. As we envision a future where HIV is no longer a global health crisis, bNAbs stand out offering hope for a more effective, inclusive, and adaptable approach to prevention.

WEPE044

Development and evaluation of a lipid nanoparticle-encapsulated mRNA encoding a broadly neutralizing antibody in the vervet monkey model

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Background: While combination antiretroviral therapy (cART) has dramatically improved the quality of life for people living with HIV, cART requires life-long strict adherence and consistent medical care access. After cART is discontinued for more than a few weeks, viremia rebounds, increasing transmission risk and immunodeficiency.

Moreover, broadly neutralizing antibodies (bNAbs), potential therapeutic alternatives, are short-lived and transiently suppress viral replication.

Therefore, we are investigating the therapeutic potential of LNP-encapsulated mRNA encoding the bNAb ePGD-M1400v9 (v9).

Methods: To assess the *in vivo* distribution of unencapsulated v9, two female vervets were IV-administered Cy5 or Cy3-tagged v9, and we collected sequential blood, vaginal or rectal fluid, and tissue samples over 7d.

Following, we developed mRNA strands encoding v9 heavy and light chains with different lipid ratio encapsulation, and evaluated LNP size, electrokinetic potential, particle heterogeneity, LNP encapsulation and content, and mRNA stability by DLS, FFF-MALS, and fluorescence and bioanalyzer analysis.

To assess mRNA delivery and v9 production, we co-IV-injected four additional animals with v9 mRNA and Cy3-tagged unencapsulated v9, collected sequential blood, vaginal/rectal fluids, and tissues over 8d, necropsied animals at 14d, and IF stained and imaged mucosal tissues.

Results: Tissue analysis showed robust v9 infiltration in rectal and vaginal epithelia 7d post-infusion. The presence of stromal v9 4d post-infusion suggested passive biodistribution through the lymphatics. Bioanalyzer and fluorescence analyses indicated that the v9 mRNA is stable and encapsulated with a RIN score between 7.5-8.5 with ~96% LNP encapsulation efficiency.



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Particle size, zeta potential, polydispersity index, and total mRNA content per LNP were consistent amongst lyophilized and non-lyophilized samples. In mucosal tissues, we found v9 mRNA bNAb production in the stratum basale 11d post-injection.

Conclusions: These data establish a workflow for the production and analysis of LNP-mRNA therapeutics and advance our evaluation of LNP-encapsulated v9-mRNA (Lv9) as a novel vaccine.

In addition, we plan to further evaluate the biodistribution and pharmacokinetics of Lv9 in 4 SHIV-positive female vervet monkeys by IV and IM administration to improve our understanding of the *in vivo* dynamics of Lv9 and to evaluate the viability of Lv9 as an alternative HIV-1 therapeutic.

WEPE045

The unmet challenges in the development of indigenous HIV-1 immunogens in LMICs: bridging the gap between research and tangible solutions

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Background: The HIV-1 Envelope glycoprotein (Env) facilitates viral entry and is a key target for broadly neutralizing antibodies (bnAbs). Soluble Env trimers, mimicking the virus native form, are pivotal as immunogens and tools for antibody isolation and B-cell response assessment. Despite not yet inducing broad neutralization consistently, Env trimers are pivotal in HIV vaccine research. LMICs encounter capacity constraints in product development. Strengthening resources and facilitating technology transfer via partnerships is essential to expedite discovery and ensure LMICs contribute equitably to HIV-related interventions.

Methods: A series of conceptual training modules (3-4), seminars/webinars (2-3), hands-on workshops, global expert consultation, and site assessments were meticulously organized and conducted (between 2022- 2024) in India and Africa to facilitate cross-learning of HIV-1 Env trimer design, purification and characterization strategies among young researchers. The initiative sought to catalyze sustainable progress towards HIV R&D.

Results: Key Lessons Learned:

Persistent Challenges and Gaps

1. Protein Production Capacities: Establishing robust protein production capacities in Africa remains arduous, primarily due to scarcity of trained personnel. This deficiency

spans across both laboratory-scale operations and manufacturing capabilities. Therefore, India's expertise and capacity were utilized to bolster capabilities in Africa through trainings.

2. Navigating Viral Diversity for immunogen Development:

The intricate landscape of contemporary circulating viruses and emerging recombinants in both India & Africa presents obstacles in the identification of sequences crucial for immunogen selection such as stabilization strategy and purification tools. This complexity underscores the critical need for sustained monitoring of viral strains.

Opportunities for Impact:

Integrating Computational Tools for accelerated immunogen Development:

The inclusion of computational tools emerges as a pivotal strategy in expediting the development of next-generation vaccines. Leveraging computational models and algorithms streamlines the identification of potential vaccine targets, accelerates the design process, and enhances the overall efficiency of vaccine development initiatives.

Conclusions: This multifaceted approach aims to bridge existing disparities in scientific capacity, foster collaboration across borders, and pave the way for LMICs with high HIV burden to emerge as key players in HIV-related research and development. This will set a model for indigenous, cost-effective & integrated research also aiding in pandemic preparedness benefiting countries in both the global north and south.

WEPE046

A redesigned HIV-1 Env V1 hypervariable loop renders CRF01_AE Env sensitive to 10-1074

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Background: Some of the most potent broadly neutralizing antibodies (bnAbs) can penetrate the glycan shield and target the V3-glycan epitope of Env, yet the efficacy of these V3-glycan bnAbs for treatment or prevention also depends on the prevalence of HIV-1 circulating strains that are resistant to these bnAbs. Previous studies showed that the recognition of the glycan at site 332 was critical for V3-glycan bnAbs, explaining the common resistance of CRF01_AE viruses, which lack the N332 glycan, to V3-glycan antibodies. Here we investigated the mechanisms behind V3-glycan bnAbs resistance in CRF01_AE.

Methods: We designed HIV-1 Env consensus sequences based on 174 independent CRF01_AE sequences sampled since 2010. Protein structures were predicted using AlphaFold2. Infectivity and neutralization were tested with pseudoviruses in a TZM-bl assay.

Results: Structure predictions of CRF01_AE Env showed that the residue I147 in the conserved Env motif ('IGNITD', site 147-152) occupies the hydrophobic pocket that is targeted by the CDR-H3 of 10-1074, thereby preventing 10-1074 from binding. Structural examination shows that other PGT121/10-1074-family antibodies recognize the same hydrophobic sites, while PGT128, which can neutralize half of CRF01_AE viruses, does not recognize this hydrophobic pocket. We redesigned the V1 hypervariable loop of the CRF01_AE consensus to create two versions of Env, in which the V1 hypervariable loop was shortened from 24 to 19 AAs (with IGNITD motif) or 9 AAs (IGNITD motif removed). None of the redesigns introduced a glycosylation at site 332.

Consensus CRF01_AE Envs with and without the loop modification were infectious *in vitro*, with higher infectivity to Gag-p24 ratio for the redesigned Env. Env with the IGNITD motif were resistant to 10-1074 (IC₅₀ > 50 µg/ml), while the redesigned Env without the motif became sensitive to 10-1074 (IC₅₀ = 0.139 µg/ml).

Conclusions: Our results show that the frequent resistance to 10-1074 among CRF01_AE viruses depends on a conserved V1 loop motif. With the motif removed, CRF01_AE Env can be sensitive to 10-1074 in the absence of the 332 glycan.

These results highlight that AI-models are valuable tools for vaccine design and that redesigned hypervariable loops can optimize bnAb epitope accessibility on HIV-1 Env antigens.

WEPE047

Discordant VRC01 sensitivity phenotype in participants with HIV-1 multi-lineage infections from the AMP trials

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Background: The Antibody Mediated Prevention (AMP) study [HVTN703/HPTN081 and HVTN704/HPTN085] demonstrated the efficacy of broadly neutralizing antibody VRC01 in preventing acquisition of viruses that were very sensitive to VRC01, with breakthrough viruses in the treatment group being more VRC01-resistant compared to the placebo group. We compared VRC01 virus phenotype when individuals were infected with multiple founder viruses, and the acquisition barrier was consistent in the same transmission event.

Methods: HIV env was sequenced from the first HIV positive sample, using the SMRT-UMI PacBio protocol. Sequences representing different infecting lineages were synthesized. Pseudoviruses (PSV) were tested for VRC01 sensitivity using the TZM-bl neutralization assay. Recombinant lineages were excluded.

Results: Sixty-four participants with multi-lineage infection were identified in both trials (HVTN703 n=74 mostly subtype C; HVTN704 n=98 mostly subtype B). Neutralization data was available for 50 of these participants (HVTN703 n=21; HVTN704 n=29). PSV representing different lineages from participants in the treatment arm had significantly higher differences in IC₈₀ compared to placebo (Wilcoxon test: p=0.026; Jonckheere-Terpstra test for trend in dose response: p=0.025, placebo to low dose VRC01 to high dose VRC01). Almost a third of participants (16/50) harboured viruses that had discordant VRC01 sensitivity, which we define as >3 fold (IC₈₀). Viruses with discordant



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VRC01 sensitivity was higher in the treatment arms (12/16, 75%) versus placebo (4/16, 25%). Of these, 3 individuals were infected with both hypersensitive (IC80 <1ug/ml) and resistant viruses (IC80 >10 ug/ml), all of which were in the treatment arm (see Figure).

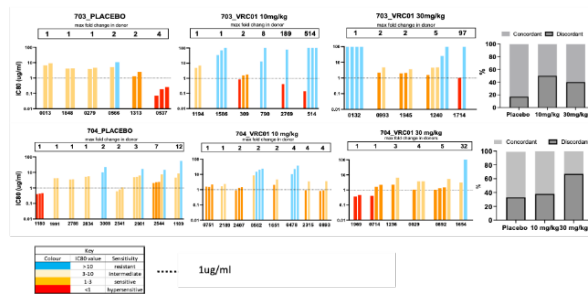


Figure.

Conclusions: We found that during the same transmission event, infection occurred in the treatment arm with both viruses that were highly sensitive to VRC01 and those that were resistant to VRC01. While this suggests that VRC01 provided a selection pressure pre- or post acquisition, other factors including donor virus population and viral fitness may also play a role.

WEPE048

Eliciting VRC01-class neutralizing antibodies from transgenic mice with low VRC01-class antibody precursor frequency

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Background: VRC01-class broadly neutralizing antibodies (nAbs) targeting the conserved CD4 binding site (CD4bs) of HIV-1 envelope is a major target of vaccine development. We previously demonstrated that sequential immunization regimens robustly elicited VRC01-class nAbs with >50% breadth in knock-in mice expressing VRC01-class precursors in ~25% of IgG+ B cells.

However, it is unclear whether these regimens can still elicit broad neutralization in more stringent mouse models expressing as low levels of VRC01-class precursors as humans.

Methods: We optimized the sequential immunization regimens by 1) replacing the eOD-GT8 priming immunogen with Mut49, an improved glycan masking mutant of eOD-GT8, and 2) replacing the late sequential trimer boosts with two shots of trimer cocktails.

We also tested four different gp120 core nanoparticles to determine which one is the best first boosting immunogen. We applied the optimized sequential immunizations to two different stringent VRC01 germline V-gene rear-

ranging mouse models: SE13 and SE09xSE16 mice. Both express human VH1-2/VK1-33 or VH1-2/VK3-20 paired VRC01-class precursors with diverse CDR3 regions at 0.008% and 0.0002% frequency, respectively. Immune sera and B cells were analyzed for CD4bs-specific binding and neutralization against a sentinel panel of viruses.

Results: Post prime serum and B cell analyses indicated that Mut49 elicited higher CD4bs-specific responses than eOD-GT8_60mer. C13.G4.1-Ferritin gp120core nanoparticle elicited higher CD4bs-specific response than three other boosting immunogens. Finally, sequential immunizations elicited both N276 glycan-sensitive and insensitive cross-strain serum neutralization in several mice of both models. Isolation of these nAbs is ongoing.

Conclusions: The immunization studies in two stringent VRC01 germline rearranging mouse models identified Mut49 and C13.G4.1-ferritin as better 1st and 2nd immunogens for sequential immunization and demonstrated that these vaccine regimens elicited cross-strain N276 glycan-sensitive serum neutralization, consistent with elicitation of broad VRC01-class nAbs, in a fraction of immunized animals even when the VRC01-class precursor frequency was as low as in humans.

Correlates of protection (including immunogenetics) and restriction factors

TUPE056

Three year durability and boosting of T cell responses in the ASCENT study utilizing two HIV-1 vaccine regimens comprising of Ad26.Mos4.HIV and either clade C gp140 or bivalent gp140

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Background: In limited resource settings, maintaining sustained immune responses following vaccination is particularly critical. This study aimed to assess T-cell immunogenicity of two HIV vaccine regimens 3-year post completion of primary regimen, with the provision of an optional booster vaccine, among participants of the ASCENT trial (NCT02935686), as conducted in adults in Rwanda and the USA. This trial administered vaccine regimens identical to those used in the Imbokodo and Mosaico efficacy trials.

Methods: Participants were randomized to Ad26.Mos4.HIV at weeks 0 and 12, and Ad26.Mos4.HIV with Aluminum phosphate adjuvanted gp140 Env protein (clade C gp140 or bivalent clade C-Mosaic gp140) at weeks 24 and 48 or placebo. A Long-Term Extension phase up to 192 weeks was added at the end of the study for volunteers from both vaccine arms; participants were offered an optional late boost vaccination (Ad26.Mos4.HIV and gp140-bivalent protein) at Wk192.

Long-term immunogenicity was evaluated in late boost participants at Wk52 (n=28), Wk192 and Wk196 (n=29). HIV-specific Env/Gag/Pol T-cell responses were evaluated using a validated 28-color intracellular cytokine staining assay based on IFN- γ and/or IL-2 expression.

Results: Cellular immune responses were maintained in both mono- and bi-valent gp140 vaccine groups, but were higher for the latter group. IFN- γ and/or IL-2 CD4+ T-cell response rates (RR) to any Env peptide pool were 85.7% at Wk52 versus 82.6% at Wk192. RR were further increased to 91.3% after the late boost vaccine (wk196). Median magnitudes among responders' CD4+ T cells by time point were 0.15%; 0.09% and 0.20% respectively. CD8+ T cell Env responses also remained consistent with 0.1% median responses across the three time points with RR of 66.7%, 60.9% and 60.9% respectively. Similarly consistent over time, albeit lower responses were observed against the other antigens tested.

Conclusions: In this 3-year post-vaccination follow-up of ASCENT with additional late boost, we observed durable cellular immune responses in the participants receiving the Ad26.Mos.HIV plus gp140 bivalent vaccine regimen. Responses after the final boost at Wk192 were even higher than after the 4th primary dose. This demonstrates robust durable cellular responses induced by the Ad26/protein platform, highlighting a compelling feature where prolonged cellular responses would be desirable.

TUPE057

Unveiling the correlation of protection and restriction factors in HIV prevention: exploring immunogenetics and beyond

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Background: This abstract presents a comprehensive examination of the correlation between protection factors, including immunogenetics, and restriction factors in HIV prevention. By elucidating the interplay between host genetic factors and innate immune responses, the study aims to enhance understanding of HIV susceptibility and inform targeted prevention strategies.

Methods: Through a multidisciplinary approach, this study integrates insights from immunogenetics, virology, and epidemiology. Utilizing both in vitro and clinical data, the research explores the role of host genetic variations,

such as HLA alleles, in modulating immune responses and influencing HIV acquisition and progression. Additionally, the study examines the impact of restriction factors, such as APOBEC3G and TRIM5 α , on viral replication and transmission.

Results: Preliminary findings indicate a complex interplay between host genetics and HIV susceptibility, with certain HLA alleles conferring protective effects while others increase vulnerability to infection. The study also highlights the role of restriction factors in inhibiting viral replication and transmission, underscoring their potential as targets for novel prevention strategies, such as gene editing and therapeutic interventions.

Conclusions: The study delves into the intricate mechanisms underlying HIV prevention, elucidating the synergistic effects of protection and restriction factors. By integrating immunogenetic insights with the understanding of innate immune responses, the research sheds light on novel pathways for intervention and highlights the importance of personalized approaches in HIV prevention. This abstract advocates for a paradigm shift in HIV prevention strategies, moving beyond traditional approaches to embrace the complexity of host-pathogen interactions.

By unraveling the correlation between protection and restriction factors, the study paves the way for innovative interventions tailored to individual genetic profiles. The presentation at the HR4P 2024 Conference aims to foster dialogue, inspire collaboration, and catalyze the development of next-generation HIV prevention modalities grounded in immunogenetics and innate immunity.

WEPE049

SERINC5-mediated enhancement of patient-derived envelopes sensitivity to neutralization by bNAbs and autologous plasma antibodies

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Background: A host protein SERINC5 restricts HIV-1 infectivity by impeding the viral entry to the target cells when incorporated to the nascent virions, and augments the potency of broadly neutralizing antibodies (bNAbs) toward HIV-1 Envelopes of laboratory strains. Here, we aimed at elucidating the extent and correlates to which



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SERINC5 enhances the neutralization of both, bNAbs and autologous plasmas toward Envelope sequences isolated from Tanzanians living with HIV-1.

Methods: A total of 20 treatment-naïve Tanzanians with HIV-1 infection were enrolled. Envelope clones were isolated from plasma viral RNA and used to produce *nef*-deficient pseudoviruses from HEK 293T cells in the presence and absence of SERINC5. Resultant pseudoviruses were tested for infectivity toward TZM-bl cells in the presence and absence of bNAbs (4E10, 2F5, VRC01 and 3BNC117) and autologous plasma antibodies.

Results: The infectivity of all pseudoviruses bearing patient-derived Envelopes was reduced by less than 20% with SERINC5 alone, and neutralized to no more than 60% with bNAbs alone at a concentration of 10µg/ml. When tested in combination, neutralization by bNAbs was significantly increased (Wilcoxon matched pairs, $p < 0.001$). Of note that this effect was more pronounced for bNAbs targeting the epitopes within the Envelopes' MPER region (4E10 and 2F5) than those targeting epitopes within the CD4 binding sites. Moreover, as expected, infectivity of the pseudoviruses were less sensitive to autologous plasma antibodies. In the presence of SERINC5 however, neutralization capacity of autologous plasmas was significantly improved as the half-maximal plasma neutralizing titer (NT_{50}) was increased by $\geq 50\%$ for majority plasma samples (Wilcoxon matched pairs, $p = 0.01$). No correlation was observed between plasma viral load and neutralization sensitivity or SERINC5-enhancing effect in bNAbs or autologous plasma (Spearman's correlation, all $p > 0.1$).

Conclusions: Our study reveals that SERINC5 enhances the sensitivity of patient-derived Envelopes to neutralization by both bNAbs and autologous plasmas. These findings underscore the potential of SERINC5 and host restriction molecules for enhancing antibody effectiveness against HIV-1 in vivo.

Novel vaccines (preventive or therapeutic)

TUPE058

Association between reactogenicity and received but not perceived intervention assignment in HIV Vaccine Trials Network (HVTN) HIV vaccine efficacy trials

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Background: Disaggregating reactogenicity by received and perceived interventions may inform interpretation. We analysed if perceived and received interventions were associated with reactogenicity in HIV vaccine efficacy trials.

Methods: For our retrospective analysis, eligible participants were:

- Enrolled in HVTN randomized double-blinded preventive HIV vaccine efficacy trials published by 05 Mar 2024, and
- Injected, and completed perceived intervention assignment assessments at month 6-6.5. We collated demographics at baseline, intervention assignment perceived at 6-7.5 months, intervention received at 6-6.5 months, and any local or systemic reactogenicity at 6-6.5 months. We determined frequencies for categorical measures, compared proportions by chi-square test and performed univariate multinomial regression assessing if reactogenicity was associated with perceived assignment.

Results: Participants eligible for analysis ($n = 5165$) were from HVTN 502, HVTN 503, and HVTN 702 trials. Median age was 24 (interquartile range 21-28) years; 69% ($n = 3552$) were assigned female at birth. At month 6-6.5 (after the third injection time point), 19% ($n = 1002$) reported any reactogenicity. Perceived interventions were 27% ($n = 1413$) vaccine, 8% ($n = 429$) placebo and 64% ($n = 3323$) unsure. Received interventions were 50% ($n = 2574$) vaccine and 50% ($n = 2591$) placebo.

Received and perceived interventions were concordant for 19% ($n = 961$) of participants. Vaccine recipients reported reactogenicity significantly more than placebo-recipients (23% vs. 16%, $p < 0.0001$).

Participants who perceived and received placebo reported the lowest proportion of reactogenicity (14%) (Table). Reactogenicity was similar in vaccine-recipients regard-



less of perceived vaccine or placebo assignment (25% vs. 31%, $p=0.4027$). In univariate analysis, reactogenicity was not significantly associated with perceived placebo (OR 0.926, 95% CI: 0.713-1.203) or perceived vaccine (OR 1.093, 95% CI: 0.936-1.277) assignment, relative to perceived unknown assignment.

Group	Any reactogenicity
Perceived assignment	
vaccine (n=1413)	290/1413 (21%)
placebo (n=429)	77/429 (18%)
unknown (n=3323)	635/3323 (19%)
Received vaccine (n=2574)	600/2574 (23%)
Received placebo (n=2591)	402/2591 (16%)
Received vaccine while perceiving vaccine assignment (n=736)	187/736 (25%)
Received vaccine while perceiving placebo assignment (n=204)	46/204 (23%)
Received vaccine with perceived unknown assignment (n=1634)	367/1634 (22%)
Received placebo while perceiving vaccine assignment (n=677)	103/677 (15%)
Received placebo while perceiving placebo assignment (n=225)	31/225 (14%)
Received placebo with perceived unknown assignment (n=268)	268/1689 (16%)

Conclusions: HIV vaccine reactogenicity differs by received, but not perceived, intervention assignment. Reactogenicity reported by placebo-recipients was only one-quarter less than vaccine-recipients; thus reactogenicity cannot be automatically presumed to be related to study vaccines. Conceivably, the acts of injection/measurement or comorbidities explain a considerable proportion of reactogenicity events.

TUPE059

Boosting HIV-1 immunity: unveiling the impact of antigen delivery systems in vaccination strategies

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Background: In the field of HIV vaccination, prime/boost heterologous strategies have been a focus of research due to their potential to enhance immune responses. Several strategies have been tested unsuccessfully in phase 2b/3 trials. This underscores the importance of further optimizing these strategies, potentially by exploring new vaccine platforms.

We investigated vaccine combinations containing the same antigens but using different platforms to enhance DNA-primed immune reactions:

- i) DNA-PT123 encoding HIV-1 Env(ZM96)-/Gag/Pol;
- ii) MVA-HIV-B encoding Gag/Pol/Nef;
- iii) Antigen-presenting cell (APC) targeting vaccines: anti-CD40 mAb fused with a string of 5 HIV-1 peptides (Gag/Pol/Nef: CD40.HIV5pep) or HIV-1 Env(ZM96) (CD40.HIVRI. Env) (tested in a recent phase I clinical trial NCT04842682).

Methods: Female hCD40-transgenic mice were given prime injections of DNA-PT123 (50 mcg, i.m.) boosted either with:

- i) MVA-HIV-B alone (10⁷ PFU, i.m.; Gr1);
- ii) MVA-HIV-B plus CD40.HIVRI.Env (10 mcg, i.p.; Gr2);
- iii) CD40.HIV5pep (10 mcg, i.p.) plus CD40.HIVRI.Env (10 mcg, i.p.)(Gr3) at week-3 (w3) and -5.

Mock animals were injected with PBS (Gr4). Humoral and cellular responses were evaluated using blood (w0/w3/w5/w6, IgG-ELISA) and cells from the spleen (w6, B- and IFN γ -ELISpots, phenotyping) and from the mucosal vagina (w6, phenotyping).

Results: In both booster regimens, the CD40.HIVRI.Env vaccine significantly enhanced the levels of circulating Env-specific IgG antibodies and the presence of Env-specific antibody-secreting cells. Groups 1 and 2 showed a significant increase in effector memory CD8⁺ T cells and Gag-specific CD8⁺ T-cell responses (AIM and IFN γ -Elispot assays) compared to groups 3 and 4.

However, only group 2 exhibited a notable expansion of tissue-resident CD8⁺ T cells in the vaginal mucosa. Group 3 had more effector CD4⁺ T cells and Gag/Env-specific CD4⁺ T cells than the other groups.

Conclusions: Our results revealed a key role of vaccine platforms in eliciting specific immune responses regardless of antigens and confirmed the potency of a heterologous DNA prime/boost vaccination approach. We demonstrated the tuning effect of the boost combining MVA and CD40 targeting platforms in eliciting systemic and mucosal CD8⁺ T cell responses, along with Env-specific antibody responses.

These findings underscore the potential for optimizing vaccine prime/boost to induce multifaceted immune responses crucial for combating HIV-1 infection.



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TUPE060

Targeting Langerhans cells with HIV trimeric Env induces a Tfh/germinal center (GC) reaction with a rapid and strong Env-specific IgG response and NeutAb

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Background: Despite the success of licensed vaccines in generating lasting antibody responses, HIV vaccine development faces challenges. While the RV-144 trial showed modest protection by targeting specific HIV antigens, subsequent studies struggled to replicate these results. Innovations targeting antigens directly to dendritic cells (DCs) and activating the cutaneous immune system offer promising strategies. Previous studies targeting epidermal Langerhans cells (LCs) with anti-Langerin mAbs fused to HIV-1 Envelope monochains (LC.Env) induced antigen-specific humoral responses in mice and human LC:T/B co-cultures. Here, we aim to refine LC targeting by designing trimeric Env constructs (LC3.Env3) or BG505-like structures (LC3.SOSIP) to investigate their potential to stimulate germinal center (GC) and Tfh cell reactions, leading to enhanced Env-binding IgG and production of HIV neutralizing antibodies (NeutAb) in vivo.

Methods: LC.Env, LC3.Env3 and LC3.SOSIP were produced in CHO cells and quality-controlled. B6 mice were intradermally immunized with LC3.Env3 or control LC.Env mAb (5 mcg of Env antigen) at day (D) 0 and D21 without adjuvant. Antibody and cellular responses were assessed post-prime (PP) and post-boost (PB) using Luminex and FACS. GC/Tfh reactions in draining lymph nodes (dLN) were monitored through immunofluorescence. Additionally, rabbits were subcutaneously immunized with 30 mcg of LC3.Env3 or LC3.SOSIP without adjuvant, and serum NeutAb levels were evaluated.

Results: LC3.Env3 immunization induced specific changes in Tfh and B-cell populations in the dLN, with significant expansion of Env-specific GC B-cells post-boost ($P < 0.01$) and the rapid formation of structured GC indicative of a robust immune response. Post-prime, Env IgG were detectable, with LC3.Env3 immunization showing an increase in IgG avidity over time. Notably, Env IgG titers were higher compared to non-targeting Env3 HIV-1 trimer. Fluorescent

vaccine studies demonstrated LC-specific antigen uptake associated with potent T- and B-cell Env-specific immune responses. Rabbit immunization with LC3.Env3 and LC3.SOSIP showed elevated Env-specific IgG and sera neutralizing tier-1 HIV-1 viruses.

Conclusions: This study introduces a novel strategy for advancing HIV vaccine development by targeting Langerhans cells as a delivery mechanism, resulting in enhanced humoral responses and production of neutralizing antibodies. These findings emphasize the need for ongoing optimization and exploration of diverse strategies for comprehensive and effective immunization against HIV.

TUPE061

Adherence to a HIV vaccine dose schedule and associated factors among adults enrolled in a HIV vaccine trial in Uganda

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Background: Ensuring the completion of multiple-dose vaccine schedules is vital for establishing a protective immune response. We examined adherence to the vaccine schedule and associated factors within an HIV vaccine trial conducted in Uganda.

Methods: A cohort study was conducted among 508 at-risk adults (18-40 years) participating in a Phase IIb three-arm, two-stage HIV prophylactic vaccine trial with a second randomisation to compare Descovy to Truvada as pre-exposure prophylaxis from December 2020 to November 2023. Participants were required to receive 4 vaccine doses at specific intervals: visit 2 (week 0), visit 4 (4 weeks), visit 8 (24 weeks), and visit 12 (48 weeks). Each dose, containing a combination of two vaccines, was administered intramuscularly in the deltoid area of each arm. If a participant missed a dose, they did not receive the subsequent doses. Good adherence was defined as receiving all four doses. Data on demographics, vaccination and reasons for non-adherence were collected via paper case report forms and entered into OpenClinica database. Demographic characteristics were summarized descriptively, and a logistic regression model was fitted to identify associated factors.

Results: A total of 508 participants were enrolled, with 80.9% being female, and a median age of 25 years (interquartile range 21-29). Regarding vaccine adherence, 74.6% received all four doses (considered good adherence), 11% received three doses, 9.8% received two doses, and 4.5% received only one dose. Participants aged 25 years and

older were 1.6 times more likely to demonstrate good adherence compared to those aged 18-24 years [adjusted odds ratio (aOR)=1.57, 95% Confidence Interval (CI) 1.04 – 2.40]. Female participants had lower odds of adhering to the vaccine schedule compared to males (aOR=0.21, 95% CI 0.09 – 0.47).

Conclusions: Adherence to the vaccine schedule was generally high. Nonetheless, there is a need to develop strategies specifically targeting improved adherence among women and younger individuals.

TUPE062

A comparison of humoral immune responses induced by infant HIV BG505 germline-targeting SOSIP envelope trimer vaccination across immunogen platforms

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Background: mRNA-based vaccines encoding immunogenic antigens have proven safe and effective in triggering long-lasting immunity. They provide immense potential for rapid antigen design and production for a variety of pathogens, including HIV vaccines designed for engagement of broadly neutralizing antibody (bnAb) B cell lineages. Additionally, the encapsulation of mRNA in lipid nanoparticles (LNP) is self-adjuvating, a property which protein-based vaccines lack.

In this study, we sought to determine effective priming strategies to develop an HIV vaccine that induces protective bnAbs in early life to prevent the ~410,000 new cases that annually occur among adolescents worldwide.

Methods: Groups of infant rhesus macaques (RMs) were immunized with matched antigen-design HIV Env BG505 germline-targeting (GT)1.1 SOSIP trimer using two different vaccine platforms: 50mg of protein-only trimer adjuvanted with 3M-052-SE (n = 5) and 15mg of mRNA-LNP (n = 6). Each group received their respective vaccine at weeks 0, 6, and 12 followed by several boosters. All groups received a booster of either BG505.GT1.1 SOSIP or BG505.664 SOSIP at weeks 24 or 26, 52, and 78.

Results: Across platforms, BG505 GT1.1 SOSIP trimer protein immunization elicited higher plasma IgG binding responses following the 2nd immunization compared to the mRNA-immunized RMs. Furthermore, the median autologous tier 1 and 2 neutralization titers elicited by protein-based vaccine were a log higher (p<0.05) at weeks 14 and 28. Notably, by week 28, two of five protein-immunized infants exhibited a plasma neutralization signature indicating CD4 binding site-specific (CD4bs) bnAb precursor development, while none of mRNA-immunized RMs had developed this response.

Conclusions: While our data suggests that protein-based priming immunization with germline-targeting SOSIP trimers may induce higher-magnitude vaccine-specific antibodies and induce CD4bs bnAb precursors at a higher rate than sequence-matched mRNA-based vaccination in early life, a new antigen design could better harness the advantages of mRNA and produce more optimal results.

Future work will include the optimization of intermediate immunogens that can facilitate the maturation of development of bnAb B cell lineages initiated by GT immunogens.

TUPE063

Chromatin vaccine

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Background: Developing effective vaccines against viral infections have significant impacts on human health and social economy. Built on the knowledge and empirical data from previous research and study of HIV/AIDS, we propose to apply HIV DNA in its chromatin form, i.e., the end product of aborted viral DNA integration in LTR (long terminal repeat)-circle formats, as the chromatin vaccines (cVacc). cVacc elicits the host cell epigenetic silencing and immune memory to prevent HIV infection.

Methods: We will apply ChIP-seq tool kits, Colony formation tests, Multi-omics big data analyses, RNAseq, Methylation-specific PCR, and Humanized mouse model to generate and test the cVacc.

(A figure of the workflow can't be shown here due to the word count)

Results: The concept of cVacc eliciting the host immunity originated in 2017, and the proposed bench process was published in 2023 ¹. cVacc induces epigenetic immunity. Such epigenetic immunity consists of three elements: DNA methylation, histone modification, and noncoding RNA function.

Applying assays to examine biomarkers of C4 T cells in the above three aspects identifies the colonies of HIV specific C4 T cells, which will reveal the efficacy of cVacc as both preventive and therapeutic AIDS vaccines.



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Similar to trained immunity, however, basic characterization of epigenetic immunity markers of CD4 T cells vaccinated by cVacc is currently lacking. The descriptive results here proceed to seek definition of the phenotype and immune signaling pathways of CD4 T cells mediating epigenetic immunity that prevents HIV infection.

¹Zhang J, et al. Approaches to pandemic prevention - the chromatin vaccine. *Front Immunol.* 2023 Dec 8;14:1324084.

Conclusions:

1. The production and validation of a cVacc is built on the knowledge and technology of the NIH Roadmap Epigenomics Project, ENCODE consortium, and big Omics data, enabling an analysis with a systems vaccinology approach.
2. Such induced autologous vaccinated CD4 T-cells can be infused back into patients to elicit an autologous immunization, embodying both prophylactic and therapeutic functions of the cVacc.
3. Since cVacc elicits cell enhancer decommisioning that is the molecular mechanism governing cell differentiation and cell type, a cVacc may also act against cancer stem cells as an anticancer vaccine.

WEPE051

Non-therapeutic leukapheresis in the HVTN 305 HIV vaccine trial in South Africa

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Background: Trials assessing whether HIV vaccines can expand rare (~1/20,000,000) precursor B-cell populations require more peripheral blood mononuclear cells (PBMCs) than obtained in routine peripheral whole blood sampling (~1,000,000 PBMCs/ml). Leukapheresis, a procedure removing up to 10 billion PBMCs without depleting other blood components, is emerging as useful for immunoge-

nicity evaluations of germline-targeting vaccines. We describe leukapheresis outcomes in an HIV vaccine trial in South Africa (SA).

Methods: HVTN-305, the HIV Vaccine Trial Network's first trial to conduct leukapheresis in SA, is a phase 1 open-label clinical trial of synthetic DNAs encoding NP-GT8 and IL-12, with or without a TLR-agonist-adjuvanted HIV Env Trimer 4571 boost in adults without HIV. The 3 SA trial sites partnered with nearby apheresis institutions which performed leukapheresis at screening and week 14. Trial consent forms included leukapheresis-specific information about procedure steps, risks and reimbursement per Ethics committees' requirements; instruction leaflets guided participants' preparations and post-care. Apheresis professionals also obtained institutional consent. Leukapheresis eligibility included institution requirements, no pregnancy nor contraindications. We collated demographics, pre-leukapheresis haematology and chemistry, collection volumes, and leukapheresis-related withdrawals and adverse events. We performed descriptive analysis and Wilcoxon signed-rank tests.

Results: SA sites screened 56 and enrolled 26/46(57%) of the trial's participants: 17/26(65%) aged 21-30 years, 16/26(62%) assigned-male-at-birth. Haematology (n=26 available) medians of differences between the two leukapheresis procedures were: haemoglobin (-1g/dl, p=0.005), haematocrit (-2%, p=0.030), white blood cell count (-0.6x10⁹/l, p=0.027), monocytes (0x10⁹/l, p=0.353), lymphocytes(-0.1x10⁹/l, p=0.208), neutrophils (-0.6x10⁹/l, p=0.033), platelets (3.5x10⁹/l, p=0.882). Sodium, potassium, chloride, urea, calcium and magnesium (n=16 available) did not change significantly. PBMC specimens were collected for 29/32(91%) participants attempting screening leukapheresis and 25/25(100%) at week 14. Volume was >40mL for 52/54(96%) specimens. Reasons for specimens not collected were: peripheral intravenous cannulation failure (n=2) and insufficient flow rate (n=1). No trial withdrawals and 3 adverse events [grade 2 leukapheresis site pain (n=2), grade 1 headache (n=1)] were leukapheresis-related.

Conclusions: Non-therapeutic leukapheresis for PBMC collection was feasible and safe in SA in a small HIV vaccine trial. Small median reductions of haemoglobin, haematocrit, white blood cells and neutrophils were not clinically significant. Specimens will be assayed for VRC01-class B cells.

WEPE052

A CH505TF envelope trimer targeting CD4 binding site neutralizing antibody precursors and adjuvanted with 3M-052-AF + Alum is safe, generally well-tolerated, and immunogenic (HVTN 300)

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Background: Induction of Env-specific broadly neutralizing antibodies (bnAbs) is considered a key objective for HIV-1 vaccine development. One approach is to recreate the Env immunogens that successfully induced a CD4 binding site (CD4bs) bnAb in a person with HIV.

We hypothesized that the CH505 TF chTrimer vaccine that has high affinity for CH103-like CD4bs bnAb precursors could expand CD4bs B cell precursor lineages capable of producing tier 2 bnAbs.

Methods: HVTN 300 is a first-in-human, open-label Phase 1 study evaluating the safety and immunogenicity of 300 mcg CH505 TF chTrimer admixed with 5 mcg 3M-052-AF + 500 mcg Alum. The vaccine is a stabilized chimeric Env trimer protein with the N-terminal sequence of CH505 TF gp120 Env transplanted into the BG505 SOSIP sequence. 3M-052-AF is a toll-like receptor (TLR) 7/8 agonist combined with Alum as an adjuvant. Participants received the adjuvanted protein administered in both deltoid muscles at months 0, 2, 4, 8, and 12.

Results: Adults (n=18) aged 18 to 55 were screened at a single site in Boston, USA, and 13 were enrolled. Participants reported local and systemic reactogenicity that was typically mild to moderate, but one participant had severe pain/tenderness and five participants reported severe systemic symptoms at least once. CD4+ T cell response rates were 82% two weeks post third vaccination and 71% two weeks post fifth vaccination. Vaccine-specific B cell response rates reached 100% two weeks post third and fifth vaccinations. Serum binding antibody response rates to autologous Env constructs were high (up to 100%) with correspondingly high magnitudes.

Moreover, differential binding to a Δ 371 mutated Env suggested that the CD4bs had been targeted. Autologous tier 2 nAb responses were detected in 6/11 participants and four participants had robust serum neutralization signatures for CD4bs bnAb precursors.

Conclusions: Overall, the vaccine was safe. Although transient reactogenicity was common, the adjuvanted CH505 TF chTrimer successfully elicited CD4bs directed responses and tier 2 autologous nAbs. HVTN 300 Part B has been launched to examine dose modifications to the 3M-052-AF + Alum adjuvant to determine if the promising immunogenicity results can be recapitulated with a lower dose of adjuvant.

WEPE053

Preclinical development and testing of a Chimpanzee Adenoviral HIV vaccine candidate comprised of highly networked CD8+ T cell Epitope regions

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Background: Adenoviral vectors have been a mainstay in the HIV vaccine field for the induction of CD8+ T cell responses. However, several adenoviral vaccine trials have not led to protective efficacy due to anti-vector immunity, generation of immunodominant T cell responses and the subsequent emergence of viral escape variants.

Here, we present our findings on the development of a novel vaccine candidate that leverages highly networked CD8+ T cell epitope regions and an immunogenic chimpanzee adenoviral (ChAd) vector.

Methods: A replication-incompetent chimpanzee adenovirus serotype 68 (ChAd68) vector was synthesized by utilizing recombination to excise the E1 gene from viral genome into a bacterial artificial chromosome. To improve vector immunogenicity and production, the viral E3 and E4 genes were eliminated and modified, respectively, through bacterial recombineering.

A T cell vaccine cassette comprised of an endoplasmic reticulum insertion signal sequence, 23 highly networked regions (46 highly networked epitopes) with broad HLA coverage and universal CD4+ T cell helper epitope (with intervening furin cleavage sequences) was inserted into the E1 locus.

This vaccine was then administered to BALB/c mice and HLA-A*0201 knock-in (KI) mice, prior to the evaluation of epitope-specific CD8+ T cell responses in vaccinated mice by interferon-g ELISpot and intracellular cytokine staining (ICS).

Results: Single vaccination of BALB/c mice with ChAd68 vector encoding the highly networked epitope cassette elicited strong and polyfunctional CD8+ T cell responses against two known KdDd-restricted networked epitopes in Gag (AI9) and protease (VI9).

The same vaccine vector was then delivered to HLA-A*0201 KI mice and was found to similarly generate robust CD8+ T cell responses against established HLA-A*0201-restricted



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networked epitopes derived from functionally important regions at the reverse transcriptase active site (YV9), envelope V1V2 stem (KL9) and protease core (LI9).

Conclusions: These data demonstrate that the ChAd68 highly networked T cell vaccine can elicit robust CD8⁺ T cell responses towards networked epitopes, in an appropriate MHC-restricted manner, in two distinct murine backgrounds. These data now serve as the basis for further pre-clinical testing of a highly networked simian adenoviral vector vaccine that is currently advancing towards a human clinical trial in sub-Saharan Africa.

WEPE054

Sex-specific immune responses to ALVAC-HIV and bivalent subtype C gp120/MF59 in the HVTN 100 clinical trial in South Africa

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Background: Innate and adaptive immune responses differ between individuals assigned male and female at birth, and these differences may impact vaccine-induced immunity. Little is known about sex-specific immunogenicity to HIV-1 vaccine candidates.

Methods: HVTN 100 was a phase 1-2 randomized controlled, double-blind trial conducted in South Africa. Participants aged 18-40 years without HIV received either

vaccine regimen (intramuscular injection of a canarypox vector (ALVAC) at 0, 1, 3, 6, and 12 months plus bivalent subtype C envelope gp120 and MF59 adjuvant at 3, 6, and 12 months) or placebo. Immune responses at month 6.5, including IgG binding antibodies (bAb), neutralizing antibodies (nAbs), antibody-dependent cell-mediated cytotoxicity (ADCC), and CD4⁺ IFN γ and/or IL2 intracellular cytokine staining (ICS) responses, were compared between per-protocol vaccine-recipients assigned male at birth (AMAB) and assigned female at birth (AFAB). T-cell ICS responses to cytomegalovirus (CMV) pp65 and staphylococcal enterotoxin B (SEB) at month 6.5 were also compared between AMAB and AFAB vaccine- and placebo-recipients. Response rate comparisons were conducted using Barnard's test and response magnitude comparisons using Wilcoxon Rank Sum test. *P*-values were Holm-adjusted for multiple comparisons.

Results: Of the 185 vaccine-recipients, 73 were AFAB, 112 AMAB. AFAB had a higher ADCC response rate (57.5% vs 29.5%; *p*=0.0003) and greater peak granzyme B activity (10.8% vs 7.3%; *p*=0.04) to a vaccine-matched TV1.C virus compared to AMAB.

In contrast, despite having similar CD4⁺ IFN γ and/or IL2 ICS response rates among both sexes, CD4⁺ magnitude among positive responders to TV1.C was significantly higher among AMAB vaccine-recipients (medians of 0.212 vs 0.113; *p*=0.002). There were no differences in response rate or magnitude of IgG bAb to vaccine-matched antigens (1086.C, ZM96, TV1.C) or in nAbs to TV1C8.2 or MW965.26. Among 185 vaccine-recipients and 37 placebo-recipients (18 AFAB, 19 AMAB) no sex differences were observed in CD4⁺ or CD8⁺ responses to CMV or SEB.

Conclusions: We found selected differences in immune responses by sex assigned at birth for the HVTN 100 vaccine regimen; however, these varied by immune response type. Although this regimen proved inefficacious regardless of sex-assigned-at-birth, future HIV vaccine trials should investigate whether there are sex-specific differences in immunogenicity and efficacy.

WEPE055

Validation of a 28-color intracellular cytokine staining assay in preparation for the M72/AS01_E TB vaccine trial immune correlates study

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Background: The GSK TB-018 M72/AS01_E TB vaccine trial demonstrated 49.7% efficacy in reducing progression to active TB disease in adults with *Mycobacterium tuberculosis* (*M.tb*) infection. Immune correlates of protection (CoP) conferred by this vaccine remain unknown. The Gates Medical Research Institute initiated a program to evaluate immunoassays for their potential to identify CoP in this trial. Our laboratory was selected to assess cellular immune responses by intracellular cytokine staining (ICS).

Methods: A 28-color ICS staining panel was developed to measure responses to mycobacterial antigens in T-cell populations. Two peptide pools matched to the antigens in the M72 vaccine (Mtb32A and Mtb39A), were characterized by the ICS assay using peripheral blood mononuclear cells (PBMC) isolated from volunteers in our control cohort from Cape Town. Antigen-specific expression of IFN- γ and/or IL-2 by CD4+ and CD8+ T-cells was evaluated as the primary readout. The 28-color panel was validated using parameters for accuracy, linearity, and precision. For accuracy testing (n=60), samples were stimulated with *M.tb* lysate, CMV and the Mtb32A peptide pool, stained with 17- and/or 28-color panels, and the frequency of antigen-specific CD4+ and CD8+ T-cells expressing IFN- γ and/or IL-2 was measured. For linearity testing (n=3), samples were stimulated with PMA/ionomycin; for precision testing (n=6), PBMC were stimulated with *M.tb* lysate, CMV and the combined M72 peptide pool.

Results: For accuracy, the Concordance Correlation Coefficient (CCC) and the 95% lower bound of the CCC for the CD4+ and CD8+ IFN- γ and/or IL-2 T-cell response magnitudes met the pre-specified criteria for establishing agreement between the two panels ($R^2 > 0.7$). The panel passed the preset criteria for linearity with a slope of $R^2 > 0.8$ and the 90% confidence interval (CI) of the slope of the line between 0.8 and 1.25. Precision testing passed the criterion of a coefficient of variation (CV) 35% for 80% of the data across all experiments and sample replicates.

Conclusions: The newly developed 28-color assay passed the criteria for accuracy, precision and linearity and is fit for purpose for the planned immune correlates studies. The assay includes a range of functional and phenotyping markers to fully characterize TB-specific T-cell responses.

WEPE056

RV546: impact of late boost with IHV01 and A244 gp120 proteins with fractional dosing and/or ALFQ on immune responses in previously vaccinated volunteers

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Background: RV546 assesses immunogenicity 6-8 years after the RV306 vaccine series with a heterologous vaccine boost with or without the Army Liposomal Formulation with QS21 (ALFQ) adjuvant and/or fractional dosing.

Methods: Eighty-one participants without HIV who had previously received a late boost of AIDSVAX[®]B/E with or without ALVAC in RV306 were enrolled at two sites in Bangkok, Thailand to receive IHV01 (gp120-CD4 chimera subunit HIV-1 in aluminum phosphate) and A244d11 gp120 at full or fractional (one-fifth) dose with or without ALFQ (ALFQ+/ALFQ-) or placebo.

Interim immunogenicity analysis evaluated binding and neutralizing antibodies, CD4+ T-cell and innate responses at days 0 through 14. Interim blinded data include placebo recipients.

Results: 50/81(61.7%) participants were female. Four participants were excluded from analysis. 40/81(49.4%) participants reported at least one local reactogenicity event; most mild (28/40) and unrelated to study products (32/40) with no related serious adverse events.

Significant increases in binding antibody responses were observed in full dose compared to fractional dose recipients starting at day 7, mainly driven by IgG1, with no differences between ALFQ+/ALFQ- groups. Full dosing elicited increased tier 1 neutralization compared to fractional dosing.

No differences in tier 1 or 2 neutralization were observed in ALFQ+/ALFQ- groups. 19/81(23.4%) participants experienced a transient >30% decrease in CD4+ T cell count from baseline at days 1, 7 and/or 14 post-vaccination with rapid normalization. Th023 and IHV01-specific CD4+ T



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cell responses increased day 14 post-vaccination with no clear difference between ALFQ+/ALFQ- or full or fractional dose groups. Interestingly, Ki67+ proliferating NK and CD4+ T cells increased by day 7 after full dose vaccination ($p=0.0009$ for NK and $p=0.005$ for CD4+ T cells in ALFQ-) with trends toward earlier (day 1) proliferation in ALFQ+ participants. Similarly, we observed a more rapid (day 1) increase in frequency of CCR7+ dendritic cells in ALFQ+ participants.

Conclusions: Preliminary blinded data indicate that the RV546 vaccine regimen was safe and well-tolerated, with dose-dependent binding and neutralizing antibody responses. In vaccine-experienced participants, inclusion of ALFQ with the protein boost did not improve magnitude of antibody responses or T cell responses but accelerated the development of some innate responses.

WEPE057

WIN332, a novel immunogen to elicit a new class of V3-glycan bNAbs

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Background: Sequential immunization is a promising approach to eliciting broadly neutralizing antibodies (bNAbs) against HIV-1.

The V3-glycan epitope is the most common specificity for broadly neutralizing activity in studies of cohorts with bNAb responses. Human canonical V3-glycan bNAbs are defined based on binding to the GDIR motif and the N332 glycan of Env.

However, we hypothesize that precursors and early intermediates of V3-glycan bNAbs may not require this glycan for binding and that N332-glycan-independent antibody lineages can mature into canonical (N332-dependent) and non-canonical (N332-glycan-independent) V3-glycan bNAbs. We thus hypothesize that Env immunogens lacking the N332 glycan would be more efficient at activating V3-glycan bNAb precursors.

Here, we present WIN332, a novel priming immunogen rationally designed to broadly elicit V3-glycan antibody responses including a new class of non-canonical V3-glycan bNAbs.

Methods: We used WIN332 to immunize humanized DH3-3/JH6 mice and nonhuman primates (NHPs). After a prime immunization, we characterized the serologic responses by ELISAs, EM polyclonal epitope mapping (EMPEM) and neutralization assays. We isolated single WIN332-specific B cells from lymph node biopsies and produced a battery of monoclonal antibodies that we characterized using ELISAs, neutralization assays, nsEM and Cryo-EM.

Results: Remarkably, WIN332 binds to human canonical V3-glycan bNAb precursors. Excitingly, WIN332 also shows binding to inferred precursors of EPTC112, a recently isolated human V3-glycan bNAb with non-canonical, N332-glycan-independent binding to Env. These results suggest that WIN332 could be efficient at activating both types of human bNAb precursors.

Prime immunization with WIN332 in humanized mice and NHPs induced N332-glycan independent antibody responses to the V3-glycan epitope as determined by ELISA and EMPEM. Remarkably, the serum collected 3 weeks after one immunization with WIN332 in NHPs showed low but detectable neutralization activity against the autologous BG505 pseudovirus. N332-glycan independent monoclonal antibodies isolated from WIN332-immunized mice and NHPs showed sequence features of human canonical V3-glycan bNAbs including PGT121 and BG18. Excitingly, WIN332 also elicited N332-glycan independent antibodies that closely resembled the non-canonical V3-glycan bNAb, EPTC112.

Conclusions: In summary, we present WIN332, a first-in-class Env immunogen that elicits human V3-glycan bNAb-like antibodies with a novel N332-glycan independent mechanism of binding.

Community engagement in prevention research

TUPE065

Enhancing community engagement in prevention research for people living with HIV (PLHIV) and young women and girls (YWGS) aged 15-24 in Uganda

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Background: Uganda continues to face challenges in HIV Prevention, particularly among YWGS aged 15-24 disproportionately affected. And according to Uganda AIDS commission (U A C) statistics in 2022 showed 570 young women and girls acquired HIV every week. Stigma as limited access to health care and also PLHIV also face challenges in accessing prevention services to reduce onward

transmission and achieving viral suppression, and also gender inequality contribute to these issues. so community engagement is crucial for designing and implementing effective HIV prevention research that addresses these specific needs.

Methods: This study explores different approaches to community engagement in Ugandan HIV prevention research targeting YWGS (15-24) and PLHIV. We have analyzed existing research initiatives and highlighted successful strategies used in studies like the DREAMS partnership (USAID 2023) and the Kisoboka Mukwano intervention (Clinical Trails.gov, 2024). and these include;

1. **Community Advisory Boards (CABs):** YWGS and PLHIV representatives collaborate with researchers to shape research questions, interventions and dissemination plans.

2. **Community Mobilization Activities:** Workshops, dialogues, and peer education sessions raise awareness about HIV prevention research, address stigma, and encourage participation.

Results: Studies that prioritize community engagement demonstrate positive outcomes cause data revealed 75% of PLHIV and 80% of YWGS aged 15-24 expressed willingness to engage in prevention research within their communities, however, only 40% of both groups reported being actively engaged in such activities.

For instances, the DREAMS program and CABs report, they heavily involve community mobilization which as shown success in reducing HIV incidence, stigma and lack of awareness among YWGS. And Capacity building as empowered communities to become active partners in research and advocate for improved HIV prevention services.

Conclusions: Meaningful community engagement is vital for effective HIV prevention research in Uganda. By incorporating the voices and experiences of YWGS and PLHIV, researchers can develop culturally appropriate interventions that will empower communities and ultimately contribute to reducing HIV transmission.

And also fostering collaboration and capacity building, community engagement can bridge the gap between research and real-world application, ultimately accelerating progress towards an AIDS free future. By prioritizing community voices, Uganda can accelerate progress towards achieving the UNAIDS goal of zero new HIV infections.

TUPE066

Dostana initiative for scaling up HIV self testing in Lahore Pakistan for MSM/MSW community

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Background: Dostana is Sub-recipient of Global Fund Project managed by UNDP launched an Initiative in Lahore, it was aimed to enhance HIV testing facility to those who feel reluctant in health care services specially key population of MSM and MSW which is hidden due to cultural and social barriers in Pakistani Society through HIV self testing (HIVST) kits.

Methods: Over a period of 10 Months till Feb-2024, a total of 2000 HIV self testing kits were distributed to Key population of MSM/MSW in Lahore. This distribution approach encompassed primary and secondary channels, directly reached 988 individuals and involving 1400 clients in distributing kits to their sexual partners and sexual encounters in same sex behaviors. The organization encouraged clients to report their HIVST results and facilitated confirmatory testing.

Results: The Program achieved its 98.27% of its distribution targets, disseminating all 2000 HIVST kits. apparently 61.2% of recipients reported their results of HIVST. That indicate the robust engagement. Eight clients reported confirmatory testing following HIV positive. out of which seven linked to Government treatment centers in Lahore Pakistan.

Conclusions: Dostana's initiative, bolstered by Global Fund support through UNDP, demonstrated effectively the pilot and later implemented largely at Provincial level to other districts and sites of Dostana and with High client engagement. while 2.40% of HIV Positive cases identifies and 2.10% successfully linked to Government Treatment centers.

Further extension through other service delivery points will maximize its impact on HIV prevention all across Pakistan within the targeted MSM/MSW community. These findings offer valuable insights for similar interventions within global health framework.



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TUPE067

Engaging community stakeholders in preparation for HPTN 091, a study integrating HIV prevention, gender-affirming medical care, and peer health navigation to prevent HIV among transgender women in the Americas

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Background: Transgender women (TGW) worldwide are disproportionately affected by HIV, with an estimated prevalence of 19.9%. Additionally, TGW suffer high rates of trauma and violence, as well as stigma and discrimination, resulting from transphobia. Often, these experiences are exacerbated by intersecting stigmatized attributes (race and ethnicity). Multiple sociocultural and structural barriers contribute to adverse HIV prevention outcomes. While research indicates that TGW have positive attitudes toward pre-exposure prophylaxis (PrEP), a biomedical HIV prevention strategy, awareness and uptake are low. Uptake barriers include HIV-related stigma, sexual behavior stigma, and drug-hormone interaction concerns. Given TGW's unique/individualized HIV prevention needs, it is critical that TGW be consulted and have direct input throughout the research process for HIV prevention interventions.

Methods: HPTN 091 conducted 5 community consultations (New York, Houston, San Francisco, Philadelphia, Rio de Janeiro) with n=138 transgender attendees. Consultations facilitated diverse audience dialogue, detailed explanations of TGW's HIV prevention needs, and elicited stakeholder questions/recommendations regarding study design and implementation of HPTN 091 prior to protocol finalization.

Results: Participants discussed facilitators and barriers to study participation based on their lived experiences and local knowledge of community norms, including the need for non-stigmatizing gender-affirming healthcare and trauma-informed strategies to optimize HPTN 091 participation for TGW.

The interactive, participatory processes enabled stakeholders to express strong concerns related to the study design and work with researchers to redesign the proto-

col to include access to gender-affirming hormone therapy for all participants and strengthen strategies related to PrEP provision and strengths-based peer health navigation. Better than expected screening to enrollment ratios and retention rates were attributable in part to proactive interactions with community representatives and feedback received.

Conclusions: HPTN recognizes that research success requires partnerships with local implementers, potential participants, and community advocates. These partnerships facilitate early ownership of research by key stakeholders. Inclusion of local perspectives of TGW provided the research team generous insights into the development and implementation of a culturally appropriate HIV prevention integrated strategy and added value to a wide range of trial considerations through transparent, authentic dialogue. Community engagement was key to achieving enrollment goals and high retention rates for the study.

TUPE068

The role of PrEP advocacy focal persons in enhancing acceptability for PrEP enrollment and repeat HIV testing among key populations in the slummy settlements of Kampala and Wakiso districts

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Background: Despite KCCC rolling out PrEP to prevent new HIV among Key and Priority Population, there was low enrollment for KPs on PrEP and low turn-up for HIV testing after PrEP initiation due to stigma, discrimination and Isolation, because of their gender identity. KCCC medical team launched a campaign to increase enrollment for new clients and ensure repeat testing for all enrolled KPs and break social barriers.

Methods: We mapped dwelling places for Sex Workers (SW) and LGBT and trained leaders of SWs/LGBT as **PrEP Advocacy Focal Persons (PAFP)** to woo fellow LGBT/SW and access PrEP, HIV testing and to distributed ARVs to LGBT/SW as PrEP in their clusters; Each PAFP was given targets for individual to reach out to; while using self-testing HIV Kits, PAFP, assisted clients to retest for HIV.

Weekly performance review meetings were held to track progress on the individual targets. Data was collected and entered in the KP tracker for analysis. KCCC medical team were trained in breaking social barriers to HIV services.

Results: In 2018, 1 KP was enrolled for HIV services, and in 2019, the number of KPs enrolled increased from 1, to 361, while in 2020, it increased to 604 KPs, 67.3% increase compared to 2019; similarly, in 2021 we enrolled 545 KPs. Overall, 1006 SWs had been enrolled from 2018-2021, 271 MSM, 184 People who Inject Drugs, and Transgender.

In 2019, 17 MSM were tested for PrEP initiation, the number of MSM tested increased by 158.8% in 2020, and in 2021 we registered a significant increase of 372.7% compared to 2020. Similarly, the number of SW tested for PrEP initiation increased from 1 in 2018 to 250 in 2019, while in 2020 it increased from 250 to 448 SWs, 79.2% increase. Overall 370 KPs were enrolled on PrEP since 2018-2022.

Conclusions: The participation of PAFPs in HIV serves as a reminder of our collective responsibility to ensure that every person, regardless of their sexual orientation or gender identity, has unimpeded access to HIV prevention drugs. By embracing this principle, we can make meaningful strides in reducing HIV transmission rates and nurturing a healthier and more inclusive society.

TUPE069

Investigation of the form and patterns of misinformation and stigmatizing narratives related to HIV prevention: content analysis of YouTube videos

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Background: The Human immunodeficiency Virus (HIV) is a significant global health burden with misinformation and stigma surrounding the disease still being prevalent. In today's digital age, YouTube has become an increasingly important source of health information with over 1.8 billion users globally.

However, the proliferation of misinformation and stigmatizing narratives regarding HIV prevention can hinder effort to end this epidemic by 2030.

Therefore, this study conducted a content analysis to identify and examine the forms and patterns of misinformation and stigmatization present in the fifty most viewed YouTube video on HIV prevention.

Methods: We conducted a systematic search on YouTube using the keyword 'HIV prevention'. The search results were filter to limit to those 4 minutes or less, posted in the past five years and available in English language. Subsequently, the identified videos were ranked based on the number of views, with the top fifty videos selected for inclusion in the analysis. These videos were then transcribed and segments containing potentially misinforming or stigmatizing content were extracted. Thematic analysis was performed using Nvivo 12 software to identify recurring themes and patterns in the extracted content.

Results: The analysis of the fifty eligible YouTube videos revealed various forms of misinformation and stigmatizing narratives surrounding HIV prevention. Some videos suggest that HIV can be transmitted through activities like kissing or sharing toilets. In some videos, there's a sensationalizing of HIV diagnosis, with doctors delivering the news in a dramatic and emotionally charged manner. Notably, there was a lack of comprehensive information in some videos about testing, treatment options, and

preventive measures. Furthermore, some video imply bias toward individuals who engage in certain behaviors associated with HIV transmission, such as drug use or homosexuality.

Conclusions: This study revealed the pervasive presence of misinformation and stigmatizing narratives within YouTube videos on HIV prevention. Addressing these issues is imperative if we are to end the HIV epidemic by 2030. Efforts to mitigate misinformation and stigma (such as promotion of accurate and non-judgmental videos on HIV prevention) must be prioritized.

TUPE070

Assessing the impact of an integrated community service delivery approach in improving case identification, HIV viral suppression and other health outcomes at Community level

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Background: The HIV epidemic continues to be a public health challenge and cause of vulnerability in Uganda. With 1.4 Million people living with HIV of which 82,000 are non-suppressed. Approaches to support them suppress are siloed and the country continues to struggle in reducing new infections.

The Integrated Community Service Delivery approach (ICSDA) has shown great improvement in treatment outcomes, identifying the undiagnosed HIV positives, addressing socio-economic issues and Directly Observed Treatment and Support (DOTS). We assessed the impact of the model to improving health outcomes in Uganda.

Methods: A comprehensive analysis was conducted using data collected from various districts within 3 sub-regions. The study involved mapping all virally non-suppressed clients by village, Mapping all Community Health Workers (CHW) to determine the patient ratio attachment and effectiveness, success of socioeconomic support programs and DOTS.

We attached all Non suppressed clients to mapped CHWs/peers within the proximity of a radius of 2 kilo meters on a ratio of 1:4, provided them with treatment literacy handbooks and a package which included DOTS, screening and testing of family members for HIV, TB, Malaria and linkage to livelihood programs. They followed the households attached for 30 days.

Results: A total of 11,243 unsuppressed clients were attached to 2,955 CHWs during the study. 3,373 Males and 7,870 females. Of which 75% were on 1st Line, 25% on 2nd Line. Interventions led to a notable increase in viral load suppression rates of 97%, index testing for the contacts of non-suppressed individuals resulted in 13% yield, referral of 2,430 malaria cases.

Additionally, Socioeconomic interventions showed varied success, with strides in vocational training and kitchen gardens, suggesting a beneficial role of these programs



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in supporting HIV-positives. CHWs identified information fatigue and stigma created from different program peers/CHWs and lack of a supportive environment as major factors for non-suppression.

Conclusions: ICSDA in Uganda has shown promising results in improving viral suppression, case identification for HIV and Malaria. It is cost effective to use 1 peer/CHW to support a household with an integrated service package, reduces duplication, improves efficiency and coordination and if scaled, it can support the country to achieve epidemic control.

TUPE071

Bridging continents, advancing health: the Appalachia to Africa Project

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Background: The Appalachia to Africa project by the Community Education Group is a pioneering initiative aimed at addressing common public health challenges in Appalachia, USA, and several African countries, including Cote d'Ivoire, Mozambique, and South Africa.

The project employs the four pillars of collaboration, knowledge exchange, capacity building, and cultural exchange to combat issues such as HIV/AIDS, hepatitis, substance use disorders, and other transferrable diseases.

Methods: The project's methodology is structured around four core pillars:

- 1) Collaboration, which involves establishing partnerships between various stakeholders in both regions;
- 2) Knowledge Exchange, which focuses on sharing successful strategies and interventions;
- 3) Capacity Building, which aims to strengthen local organizations and healthcare systems; and,
- 4) Cultural Exchange, which promotes mutual understanding and respect between the regions.

These pillars guide the project's activities, including workshops, training sessions, research collaborations, and community engagement.

Results: The Appalachia to Africa project has established over 15 partnerships in Appalachia and 7 in Africa, developed culturally appropriate training programs for approximately 500 healthcare providers and community leaders and initiated collaborative research projects. Preliminary results include a 15% reduction in HIV transmission rates in a targeted Appalachian community and a 10% increase in hepatitis C treatment uptake in an African study. Data disaggregation by age and gender has shown significant benefits for young adults and women, with a 20% increase in HIV testing rates among women aged 18-35 in both regions.

Conclusions: The Appalachia to Africa project demonstrates the potential of international collaboration in public health. By leveraging the strengths of diverse regions, the initiative has made strides in improving health

outcomes and building sustainable public health solutions. The project's innovative approach, grounded in collaboration, knowledge exchange, capacity building, and cultural exchange, holds promise for advancing health equity and outcomes in Appalachia and Africa.

TUPE072

Retention in the MOSAICO study: experience in one site from Argentina

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Background: With few HIV vaccine models having made it to Phase III, lessons learned from sites implementing such studies are essential. The implementation of MOSAICO in Argentina has also withstood the challenges of the COVID-19 pandemic and its subsequent socioeconomic crisis. In that context, 117 participants were recruited by our organization for its 30-month vaccination and follow-up process.

Methods: The retention strategy implemented included transportation via a ride-hailing app, a standardized messaging package to participants, invitations to educational and recreational events, delivery of merchandising, a monthly newsletter reinforcing protocol information and services offered by the organization, and a social media campaign where participants shared their experiences as volunteers.

Contact with participants was maintained through peer navigators, informational materials, trained receptionists and a medical on-call line; frequently allowing for coordination of unscheduled STI screenings and answering questions about prophylaxis, COVID-19, vaccinations, mental health, hormone therapy, and human rights.

Results: By the time MOSAICO was stopped in January 2023, 89,7% (n=105) of participants were active, with a median follow-up time of 21 months. The reported HIV incidence was 4,2% (5). PrEP use among participants was low (n=20, 17%) but increased after study interruption: 51.2% (n=60) by month 6, and 60,6% (n=71) by month 12.

The most frequently reported reasons for missed study visits were COVID-19 related (vaccine application, compatible symptoms or disease), changing personal and professional schedules, travel, and mental health problems. Among the 11 discontinued participants, internal or external migration accounted for almost half of discontinuation reasons (46%; n=5).

Conclusions: Low loss to follow up rate was observed, as well as a high number of participants still opting not to take oral PrEP after study interruption. Environmental factors may be the main challenge to retention, for which establishing proximity with participants upon recruitment is crucial to accomplish study goals.

Further HIV vaccine research in low and middle income countries, targeting populations subjected to stigma and social exclusion, should consider the impact of socioeconomic context and people mobilization in recruitment strategies, retention analysis and post-study considerations.

TUPE073

PrEParados: an innovative social network strategy and community-based participatory research approach to engaging Latino men who have sex with men in HIV prevention programs

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Background: Latino men who have sex with men (LMSM) are disproportionately impacted by HIV but underutilize PrEP. Social network strategies (SNS) and community-based participatory research (CBPR) approaches are effective ways to engage LMSM and their sexual partners (SP). These approaches allow us to explore what HIV prevention strategies LMSM use and discuss while accounting for emotional closeness.

This presentation focuses on the *PrEParados* strategy which combines CBPR approaches with innovative SNS to explore LMSM's HIV prevention behaviors and discussions.

Methods: From February 2022 to August 2023, we partnered with a community-based sexual health clinic to collect responses from LMSM in South Florida. LMSM (n=488) provided information about their SP (n=1,065), PrEP discussions, and condom use. Multilevel models explored LMSM's PrEP discussions with their SP based on emotional closeness.

Results: HIV prevention strategies and discussions varied across LMSM. Figure 1 highlights that PrEP discussions were not always occurring, even among LMSM who engaged in condomless sex without PrEP. In each multilevel model, emotional closeness was positively associated with increased odds of having had PrEP discussions or disclosing PrEP use status in the previous 6 months.

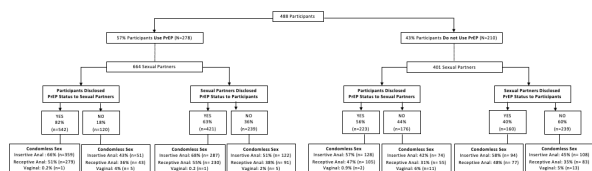


Figure 1. Diagram detailing LMSM respondents (n=488), their current PrEP use status (n=278), PrEP disclosure, and condom use during sexual activities.

Conclusions: The *PrEParados* strategy successfully engaged LMSM who were behaviorally vulnerable to HIV acquisition, 43% of which were not using PrEP. *PrEParados* is a promising strategy to engage SP, including women, who may have an increased susceptibility to HIV acquisition but who are not engaged in prevention programs.

The *PrEParados* strategy identified 38 women who may benefit from PrEP; indicating that the *PrEParados* strategy can be expanded to reach women, a priority population that is not often engaged in US-based programs.

Lastly, our results emphasize the importance of emotionally strong bonds in PrEP information dissemination and discussions. Future interventions can utilize the *PrEParados* strategy to engage and educate LMSM and their SP about PrEP for HIV prevention.

WEPE060

Peer-led HIV self-testing among men in Ugandan fishing communities: implementation experiences and implications for scale-up

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Background: Peer-led HIV self-testing (HIVST) has got the potential to improve HIV testing rates in unreachable men in diverse settings, including fishing communities. We describe our HIVST implementation experiences in two rural fishing communities in Uganda in order to inform future programming and scale-up.

Methods: Between May and July 2022, we implemented a social group-based, peer-to-peer model in which 22 trained "peer-leaders" in two rural fishing communities in two island districts within the Lake Victoria region in Uganda were given oral fluid HIVST kits to distribute to male members within their groups. Men were eligible to receive HIVST kits from their peer-leaders if they were initially HIV-negative or of unknown HIV status, and last tested for HIV at least three months from the time of the interview.

Each peer-leader referred to the study team up to 20 members from their groups; eligible men were administered a baseline interview and asked to pick kits from their peer-leaders. A follow-up interview was conducted in September 2022 to determine users' experiences and challenges, if any. Data were analyzed using STATA, version 16.0.

Results: Of 400 men interviewed at baseline, 252 (63%) were aged between 15 and 24 years. Ninety per cent (n=361) were interviewed at follow-up. Of these, 355 (98.3%) picked HIVST kits from their peer-leaders; 352 men (99%) used them to self-test for HIV. Of these, 340 (96.6%) performed unsupervised HIVST. A few men experienced challenges in conducting the HIVST exercise: 43 men (12.2%) found difficulties in understanding the user instructions; 38 (10.8%) found it difficult to read the test results while 21 (6%) read the results before the required 20 minutes of waiting. Thirty-seven per cent (n=131) reported that they needed pre-test counselling; 119 (33.8%) needed post-test counselling; while 102 (29.0%) needed help in interpreting the results.



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Conclusions: Our study confirms that the peer-led HIVST model can successfully improve HIV testing uptake among men in rural fishing communities. However, challenges in the use of kits and interpretation of results still abound, suggesting a need for additional sensitization of potential users before the model is scaled-up to other fishing communities.

WEPE061

Impact of gender-based violence (GBV) on the increase in the HIV/AIDS prevalence rate among men who have sex with men (MSM) in the city of Douala

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Background: Human rights are fundamental principles that guarantee the equality, dignity and freedoms of every individual, regardless of race, gender, sexual orientation, religion or HIV status. However, in many countries, including Cameroon, MSM human rights in relation to HIV/AIDS are often violated. To prevent GBV, mitigate its effects on HIV outcomes and promote the well-being of MSM, Cameroon is hosting the "Community HIV/AIDS Investments for Longer and Healthier Lives In Cameroon" project funded by USAID, piloted by the Care and Health Program and implemented by community-based organisations including Alcondoms Cameroon (ALC), to be implemented in 2022.

Methods: Thanks to the prevention and management of GBV, empowerment is effective in the community through the message conveyed by peer educators (PL) to raise awareness and sound the alarm among peers, active referrals which are immediately triggered according to the client's needs if violence is recorded; talk sessions are also held with peers, the police, traditional and religious authorities, all with the aim of issuing a call to order on the increase in the prevalence rate if nothing is done.

Results: From October 2022 to September 2023, 375 cases of GBV were reported by the PLs, including 235 physical, 02 sexual and 339 social and emotional (23 family rejections, 61 threats, 30 arbitrary arrests, 13 scams, etc.). It should be noted that a survivor may have experienced several forms of GBV. During the same period, 11 authorities took part in advocacy sessions and 4,156 MSM were educated in the community, with 180 taking part in capacity-building and psycho-education/awareness-raising on GBV on our premises. In addition, with the support of donors, this year we were able to set up a shelter for cases of family rejection.

Conclusions: Respect for human rights is crucial not only to individual well-being, but also to the effectiveness of efforts to prevent and combat HIV/AIDS. It is essential that Cameroon recognises and protects the rights of all people, regardless of their sexual orientation, in order to achieve the UNAIDS vision of a future without HIV/AIDS by 2035.

WEPE062

Community engagement for CAB-LA PrEP implementation in Brazil

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Background: Community engagement is essential in implementation research to further community prevention literacy, to empower local stakeholders, and to ensure effective and sustainable interventions tailored to specific needs of the communities involved. Nonetheless, community involvement of sexual and gender minorities (SGM) in research projects remains a formidable challenge.

The purpose of the present work is to assess community engagement as a participatory process within the ImPrEP CAB-LA Brasil study.

Methods: ImPrEP CAB-LA Brasil is an implementation study of same-day delivery of injectable PrEP with cabotegravir for young SGM (18-30 years) in oral PrEP public health clinics in six Brazilian cities. We used good participatory practice (GPP) for effective community stakeholders' engagement since study inception and inclusion of SGM peer navigators in study clinics and Community Advisory Board (CAB).

Results: During the first year of study we developed:

1. Discussion groups with 34 SGM community members during the formative phase to ensure the development of more inclusive and culturally appropriate HIV prevention interventions;
2. Community work plans for each site including interventions tailored to SGM specific needs;
3. Dissemination of information about oral and injectable PrEP among SGM through live streaming and face-to-face interventions in SGM venues;
4. Inclusion of 12 SGM as peer-navigators in the study clinics to promote welcoming and safe environments, and to build trust between researchers and participants;
5. Awareness raising of all healthcare professionals to address language barriers and to leverage local community resources for specific social and healthcare needs of participants.

Conclusions: Community engagement through GPP provided extremely significant outcomes during the first year of study implementation. The inclusion of SGM on study inception allowed to forefront their needs and preferences aligned with existing resources. Having SGM as peer navigators and prevention educators in the clinics provid-

ed person-centered participant support and enhanced trust throughout study procedures, increasing the likelihood of successful implementation.

The dissemination of PrEP literacy among SGM was crucial to dispel distrust, myths, and stigma related to HIV and STI prevention to facilitate the implementation and scale-up of PrEP technologies.

WEPE063

Enhancing engagement of men who have sex with men in HIV prevention research studies in Kenya: strategies and lessons learned

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Background: Engaging men who have sex with men (MSM) in HIV prevention research studies is essential for developing effective interventions that address their unique needs and challenges. This abstract explores strategies and lessons learned in engaging MSM in HIV prevention research studies in Kenya, aiming to improve recruitment, retention, and meaningful participation.

Methods: Drawing on experiences from ongoing research projects and community-based initiatives, this abstract presents a synthesis of strategies employed to engage MSM in HIV prevention research studies in Kenya. Data sources include project reports, peer-reviewed literature, and insights from key stakeholders involved in research and community advocacy.

Results: Effective engagement of MSM in HIV prevention research studies requires a multifaceted approach that prioritizes community involvement, trust-building, and cultural sensitivity. Strategies include community outreach and mobilization, establishment of community advisory boards, capacity building of MSM peer educators and researchers, and leveraging digital platforms for recruitment and communication. Culturally tailored approaches, such as incorporating local languages and traditions, are critical for fostering rapport and participation among MSM communities.

Additionally, efforts to address structural barriers, including stigma, discrimination, and legal obstacles, are essential for creating enabling environments that support research engagement and uptake of HIV prevention interventions among MSM in Kenya.

Conclusions: Engaging MSM in HIV prevention research studies in Kenya requires a collaborative and culturally responsive approach that recognizes the diversity and complexity of MSM communities.

By incorporating community perspectives, building trust, and addressing structural barriers, researchers can enhance recruitment, retention, and meaningful participation of MSM in research studies. This abstract underscores the importance of community-driven approaches

in HIV prevention research, aiming to empower MSM with the knowledge, skills, and resources to contribute to the development of effective interventions and policies that promote their sexual health and well-being.

WEPE064

Enhancing Hispanic/Latino/a representation in clinical research: strategies, challenges and insights from the field through the Language Access and Justice Initiative (LAJI)

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Background: Hispanic/Latino/as in the United States are the second most impacted group by the HIV epidemic comprising ~30% of new HIV cases. Participation in clinical research needs to reflect the composition of the population most affected by the epidemic, thus, an increase in participation of Hispanic/Latino/a individuals in HIV research (<12%) is necessary to generalize research results. Our US-based study seeks to understand why participation of Hispanic/Latino/a individuals in HIV/AIDS clinical research is low, especially for monolingual Spanish speakers.

Methods: We conducted formative qualitative research by interviewing HIV investigators, clinicians, community educators and recruiters from different clinical research sites conducting HIV vaccine research to inquire about the strategies and challenges faced when engaging Hispanic/Latino/a participants at every stage of the clinical research cycle, including education, recruitment, and retention, with a focus on monolingual Spanish speakers.

Results: We interviewed 14 participants from 10 clinical research sites across the US. Participants' experience working in clinical research ranged from 3 to 30 years. Preliminary findings reveal that barriers to participation include a lack of bilingual staff, a need to adapt clinical research documents and procedures for monolingual Spanish speakers, misinformation about HIV and HIV clinical research in the Hispanic/Latino/a community, and a lack of sustained relationships with Hispanic/Latino/a-serving community groups.

Participants showed a nuanced understanding of the diversity within the Hispanic/Latino/a community and pointed to the need for strategies that reflect this complexity.

Participants underscored the need for institutional support, funding and network-driven initiatives to provide language services and cultural competency training.

Conclusions: Clinical research requires a holistic approach to language access that addresses cultural, linguistic, and structural barriers to participation of Hispanic/Latino/a



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individuals on a national scale. Institutions must prioritize and fund initiatives that build long term community relationships, facilitate language access, and reflect cultural diversity of the populations they aim to serve.

Collaborative and sustained efforts between research sites, community organizations and HIV/AIDS clinical research networks can facilitate the development of inclusive community engagement strategies that are essential for the advancement of equitable clinical research.

WEPE065

Enhancing accessibility to HIV prevention: a community-led approach for pre-exposure prophylaxis and self-testing in the National Capital Region (NCR), Philippines

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Background: The introduction of HIV self-testing and Pre-Exposure Prophylaxis (PrEP) marks a pivotal advancement in the Philippine HIV prevention program. However, the uptake by key populations (KP) has been constrained by protocols and perceived barriers to accessing services in clinics. In response, the HIV & AIDS Support House (HASH) has pioneered a community-level distribution and demedicalization of PrEP and self-testing kits in the National Capital Region (NCR) to mitigate stigma-related access barriers.

This initiative is especially critical in the context of the Philippines experiencing the highest and unabated rise in HIV cases among KP in the Asia-Pacific region.

Methods: Confronting stigma and access issues perceived in clinic settings in the Philippines, HASH initiated a direct community distribution model with e-PrEP from August 2023 to December 2023. Volunteers received training to streamline the PrEP process and improve counseling, enabling swift processing and issuance while e-PrEP facilitated remote management of clients.

Results: From August to December 2023, HASH distributed 1,798 HIV self-test kits, with 64.9% (1,167) reaching regions outside NCR. Among recipients, 819 were first-time testers, underscoring the initiative's success in expanding access. This community-led initiative successfully initiated 737 new PrEP clients, 95.52% (704) of whom were MSM and 77.88% (574/737) reporting unprotected penetrative anal sex in the last six months. Young key populations aged 15-24 accounted for 35.14% (259/737), highlighting a significant outreach to at-risk youth. Additionally, 70.28% (518/737) received daily PrEP regimens. The initiative contributed 11.52% (n=737) to the national PrEP enrollment of 6,396.

Despite achievements, challenges like self-test kit stock-outs and logistical burdens on volunteers emerged, along with the need for continuous training to mitigate turnover effects on PrEP distribution as volunteers transition to local government facilities.

Conclusions: The community-led demedicalized approach significantly improved access to PrEP and HIV self-testing and expanded the reach of KPs.

Future directions include strengthening collaborations with donor partners to support logistical needs and increasing PrEP access among young key populations.

WEPE066

Characterizing the levels of knowledge, attitudes, and behaviors regarding the use and risks associated with oral HIV-1 pre-exposure prophylaxis (PrEP) among people prescribed PrEP in Canada

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Background: People prescribed oral HIV-1 pre-exposure prophylaxis (PrEP) have access to educational materials and information on the safety and efficacy of PrEP. We assessed their knowledge, attitudes, and behaviors using a pre-tested self-reported survey in two waves in Canada; here, we report the results from Wave 1.

Methods: Wave 1 (November 2023–February 2024) surveyed people aged ≥18 years who were currently taking or had previously taken (within ≤30 days) oral PrEP and who agreed to participate.

Primary endpoint was adequate oral PrEP knowledge, defined as 75% correct responses regarding oral PrEP information use and risks. Secondary endpoints included attitudes and behaviors toward oral PrEP.

Results: Among 152 people invited, 69 completed the survey. Most respondents identified as male (87%). The majority (97%) had high school diploma or higher education; 57% were employed full-time. On average, respondents answered 77.7% of questions correctly; 4.4% scored <50% (Table).

Adequate knowledge was demonstrated by 75.4%. Regarding behaviors, most respondents (65%) initiated oral PrEP >1 year ago; 97% were prescribed daily oral PrEP and of these, 61% reported not missing any doses within ≤30 days. Most reported being tested for HIV-1 ≥3 times per year (81%) and were aware that oral PrEP initiation required a negative test (91%).

Current partners' HIV-1 status was known by 49%. Condoms were used sometimes (52%), most of the time (20%), or always (10%); 70% did not use condoms during their last sex encounter.

Respondents somewhat agreed or agreed (67%) with attitudes including being more likely to consider condomless sex while being on oral PrEP. They also viewed oral PrEP as equally important (42%) or the most important (52%) risk-reduction behavior.

Knowledge Level	Overall (N=69)*
Mean (SD), %	77.7 (17.4)
Median (IQR) [range], %	75.0 (75.0-91.67) [25-100]
Knowledge level $\geq 75\%$, n (%)	52 (75.4)
Knowledge level $\geq 50\%$ – $<75\%$, n (%)	14 (20.3)
Knowledge level $<50\%$, n (%)	3 (4.4)

*The denominator includes people prescribed oral PrEP who answered incorrectly and those who answered: "I do not know/I am not sure" or "Prefer not to answer". IQR, interquartile range; PrEP, pre-exposure prophylaxis; SD, standard deviation.

Table. Overall knowledge levels of people prescribed oral PrEP in Canada.

Conclusions: Despite 75% of surveyed individuals meeting the threshold for adequate knowledge regarding oral PrEP use and its associated risks, and over 90% being aware of a mandatory negative HIV test before initiating it, opportunities exist for further education to increase knowledge.

WEPE067

Evaluating an historically Black college and university (HBCU)-based initiative to promote careers in HIV prevention research

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Background: In support of efforts to diversify the HIV workforce in the U.S., Evidence2Practice (E2P) is a 3-day, in-person interactive workshop designed to promote careers in HIV to students at Historically Black Colleges and Universities (HBCUs). E2P introduces students to implementation science and its utility in HIV-related health disparities research. We implemented an evaluation to examine the program's impact during the first two years of implementing the E2P program.

Methods: We conducted a partially mixed-method concurrent equal status study design using a 35-item pre-program survey and a 31-item post-program survey. Questions focused on awareness of HIV and implementation science, perceptions of the HIV epidemic, experiences with the E2P program, and factors related to a career in HIV science. We used the Wilcoxon signed rank test to evaluate differences in pre-/post-program interest in and perceived difficulty in pursuing careers in HIV.

Results: A total of 120 students from 11 HBCUs participated in the E2P program and 102 completed both the pre- and post-workshop surveys. Median student age was 21 years (IQR 19-25), 78% were Black/African American, 69% were cisgender women, and 80% were undergraduates. Pre-workshop, 75 (62%) students reported at least mod-

erate familiarity with existing racial and ethnic disparities in HIV diagnoses in the U.S., 72 (60%) reported at least moderately familiarity with contemporary HIV prevention strategies, and 35 (29%) expressed moderate familiarity with implementation science. Comparing interest levels pre/post workshop, participating in the E2P program was associated with an increase in median interest in starting a career in HIV science ($p < 0.01$): interest increased in 61% ($n=62/102$) of students.

Additionally, participating in the E2P program was associated with a decreased perception of difficulty in starting a career in HIV in 45% (36/79) of students who reported perceptions before and after E2P ($p < 0.01$). The proportion of students interested in implementing HIV prevention strategies increased from 36% to 54% ($p = 0.01$). Overall, 93% of participants were "very satisfied" or "extremely satisfied" with the E2P program.

Conclusions: The E2P program increased HBCU students' interest in careers related to HIV prevention research and improved their self-efficacy to pursue such careers.

WEPE068

'When you have space, you can provide...' can pharmacies cater to women's HIV prevention needs during pregnancy? A qualitative analysis

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Background: Pharmacies are increasingly promising locations to deliver HIV prevention services for priority populations such as adolescent girls and young women. However, to date, there are no studies evaluating the effectiveness of such delivery models for women during pregnancy – a high-risk period for HIV acquisition. Effective design of delivery models requires prioritizing factors that influence pharmacy implementation and strategies to navigate potential challenges.

Methods: From February to April 2024, we conducted 15 semi-structured interviews with pharmacy providers in Western Kenya. A trained interviewer conducted the interviews in person or via phone. Each interview followed a structured topic guide that explored participants' capability, opportunity, and motivation to deliver HIV prevention services (PrEP and HIV, partner HIV and STI testing) to women during pregnancy. Interviews were audio-recorded; detailed reports documented key findings with supporting quotes. A thematic analysis of the reports identified key factors influencing implementation.

Results: The 15 participants included 8 men and 7 women who were pharmacy technologists (12), clinical officers (2), and nurses (1). The median age was 32 years (range: 25 to 45 years), and the median years of experience working in



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pharmacies was 4 years (range: 1 to 12 years). Participants had experience in providing HIV testing (mostly self-tests), partner HIV testing, and PrEP, but not specifically for pregnant women. Participants had no experience providing STI testing for Chlamydia or Gonorrhoea. To address these gaps, participants preferred offsite in-person training due to limited data access and for full engagement, supplemented by on-the-job training.

Resources available to participants included HIV self-test supplies, private space, and, in some instances, support from remote clinicians. Critical resource gaps included a lack of structured referral systems, proper waste disposal systems, and dedicated laboratory space.

Participants expressed interest in offering point-of-care STI testing, having on-site nurses to address time constraints and knowledge gaps, and acquiring support for subsidized HIV prevention products. Participants were generally receptive to providing services to pregnant women.

Conclusions: Expanding pharmacy-based HIV prevention services to pregnant women requires dedicated training programs specifically tailored to this population and investments to improve the infrastructural capacity (diagnostic tests, referral systems, waste disposal) of pharmacies.

WEPE069

Empowering adolescents and young people: a peer-driven approach to amplifying HIV Self-testing in Pwani, Kigoma and Shinyanga Regions of Tanzania, October 2021–December 2023

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Background: Tanzania has made remarkable progress in identifying people living with HIV, with 83% aware of their HIV status. Yet approximately half of adolescents and young people (AYP) aged 15–24 years living with HIV are unaware of their HIV status. Optimization of HIV self-testing (HIVST) among AYP is important to closing the identification gap.

Methods: From October 2021 to December 2023, we implemented a peer-driven strategy to enhance HIVST distribution among AYP. A total of 290 AYP including 205 (71%) key informants and 85 (29%) peer educators aged 15–24 years were trained for 5 days using the national training package to support the implementation of HIVST in both facility and community settings. Trained peers facilitated hotspot mapping, demand creation, bi-directional referrals/linkages for both community and facility services, and integration of HIVST into testing modalities such as community mobile testing, index testing, and social network testing.

The approach included tailored health education and communication strategies and age-appropriate materials including leaflets, brochures, posters, wristbands, and interpersonal communications job aids for peers.

Results: Between October 2021 and December 2023, there was a progressive increase in quarterly distribution of HIVST kits among AYP, rising from 1,586 from 01 October–31 December 2021 to 31,442 from 01 October–31 December 2023. A total of 139,693 HIVST kits were distributed to AYP during the entire period, with 82% (114,371) going to females and 18% (25,322) to males.

Of these, 98% (136,488) of the distributed kits were returned using peer active tracing. Among the returned results, 0.7% (915) tested reactive for HIV (372 in Kigoma, 423 in Pwani, and 120 in Shinyanga), with 98% (894) of confirmed cases being linked to services, including initiation of antiretroviral treatment. Of the confirmed cases, 131 females (15%) and 16 males (2%) were aged 15–19 years, while 657 females (73%) and 90 males (10%) were aged 20–24 years.

Conclusions: Peer-driven approaches can increase HIVST uptake among AYP, thereby contributing to case identification of AYP living with HIV. This underscores the importance of continued investment of peer-driven interventions as integral components of public health initiatives aimed at combating HIV/AIDS.

WEPE070

Expanding access to HIV services through combination of electronic health systems, community-based private public partnership and philanthropic participation

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Background: Zambia aims to achieve HIV epidemic control by 2025 in line with the UNAIDS 95–95–95 targets. Stigma continues to limit the provision and uptake of HIV prevention, diagnostic, and treatment services in Zambia, particularly for key populations (KPs). KPs are often unable or unwilling to access mainstream health services due to marginalization, criminalization of their behaviors, and structural factors. Person-centered innovative health service demand creation tools, like the virtual health hub

(VHH) designed and implemented by USAID DISCOVER-Health Project, can help to reach these groups and simultaneously help reduce stigma, discrimination, and long wait times at facilities.

Methods: To improve health service provision to KPs, USAID DISCOVER-Health (implemented by JSI) in January 2023 launched a virtual health hub to help clients access HIV services online in their safe spaces using the unstructured supplementary service data (USSD) information management system. This was because traditional methods of health service delivery exclude some HIV vulnerable population groups with high risk behaviours from accessing health services. In addition, the project introduced community based public private partnership and philanthropic health service programming to support social and behavioural change communication in local communities. The project worked with leaders of local NGOs and philanthropists who were trained in KP Sensitivity to enable them to work with both the Key Populations and Priority Populations wishing to access virtual and static health services.

Results: The number of KPs accessing virtual and static HIV services in the first six months of implementing the intervention increased by the following percentages: 49.1% for men who have sex with men, 25.9% for sex workers, 26.8 for transgender people, and 83% for people who inject drugs.

Furthermore, the total number of KPs accessing HIV services prior to implementing the intervention (May 2022 to January 2023) in comparison to the same period at the beginning of the intervention (February 2023 to October 2023) increased significantly from 4,111 to 8,393.

Conclusions: Building partnerships with local community stakeholders helps to develop a broad base of support for vulnerable and marginalized groups, increases access to HIV services by these groups and enhances sustainability of the services.

Demand creation, market research and human-centred design

TUPE075

Preferences for telePrEP among people who access HIV self-testing in Philadelphia

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Background: To end the HIV epidemic, novel strategies to deliver HIV services are necessary. Remote based health services, such as HIV self-testing and telehealth-based

PrEP (telePrEP), can reduce barriers to care and improve patient care experiences. The goal of this study was to evaluate preferences for obtaining telePrEP services among individuals utilizing an HIV self-test (HIVST).

Methods: We recruited individuals who obtained an HIVST through the Philadelphia Department of Public Health to complete an online survey between October 2022 and March 2024. To be eligible for the study, individuals had to live in Philadelphia county, be at least 17 years of age, and report a negative/unknown result from their HIVST. The survey included items on social determinants of health, prior health care engagement, and measures of PrEP stigma, norms, and self-efficacy. We evaluated preferences for telePrEP compared with in-person PrEP using linear regression.

Results: 277 people met inclusion criteria and completed the survey, of which 53% had a telehealth provider appointment in the past year. The median age was 27, 53% were cis-gender women, 38% reported non-Hispanic Black race, and 28% were men who have sex with men. We observed a preference toward obtaining telePrEP compared with in-person PrEP (mean 3.5, SD 1.1). In our multivariable model, preferences for telePrEP were higher among cis-gender women, those with increased PrEP norms, lower PrEP stigma, and lower levels of PrEP self-efficacy (Table 1).

Characteristic	Beta coefficient (95% CI)	p-value
Age (years)	0.002 (-0.01, 0.02)	0.55
Race/Ethnicity		
Black, non-Hispanic	Ref	
White, non-Hispanic	0.21 (-0.19, 0.20)	0.31
Hispanic, any race	0.42 (-0.02, 0.85)	0.06
Multi-racial, other	-0.06 (-0.63, 0.52)	0.85
Sex at birth and gender identity		
Cis-gender male	Ref	
Cis-gender female	0.38 (0.05, 0.71)	0.03
Transgender/nonbinary, any sex	0.20 (-0.40, 0.80)	0.58
Education		
High school or less	Ref	
Some college	-0.28 (-0.72, 0.15)	0.20
College or higher	0.23 (-0.25, 0.71)	0.35
Insurance		
Uninsured	Ref	
Public insurance	-0.38 (-0.83, 0.06)	0.09
Private insurance	-0.04 (-0.33, 0.66)	0.51
No prior test	Ref	
Last test >1 year ago	0.00 (-0.58, 0.59)	0.99
HIV test in the past year	0.18 (-0.27, 0.64)	0.42
PrEP self-efficacy	-0.39 (-0.70, -0.09)	0.01
PrEP social norms	0.22 (0.01, 0.43)	0.04
PrEP stigma score	-0.66 (-1.00, -0.31)	<0.001

Table 1: Factors associated with preference for telePrEP.

Conclusions: Multiple delivery models may be needed to support linkage to PrEP after self-testing. Offering telePrEP may facilitate individuals with low self-efficacy to obtain PrEP. However, the impact of telePrEP may be limited to reaching those who already have positive attitudes toward PrEP and lower levels of PrEP stigma. Additional research is needed to understand contextual barriers to PrEP linkage among self-testers.



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TUPE076

Future delivery pathways and costs for next generation HIV and pregnancy prevention products: exploratory analyses to inform early product development

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Background: Adolescent girls and women in sub-Saharan Africa are at heightened risk of HIV, STIs and unplanned pregnancy. The next generation of HIV prevention and dual indication products factors in novel delivery systems and active pharmaceutical ingredients. Economic evaluations early in product development can inform product design characteristics impacting costs, market potential, suitable pricing, and identify evidence gaps. As part of the MATRIX collaborative, a USAID-funded project to advance the research and development of innovative HIV prevention products for women, we estimated delivery costs and explored potential cost-effectiveness of novel HIV and pregnancy prevention product prototypes.

Methods: We identified nine products developed under MATRIX, including fast-dissolving vaginal inserts, non-ARV/non-hormonal vaginal rings, vaginal films, and implantable pellets. For each product, we consulted product developers to define target product profiles. Through expert elicitation, we explored future delivery pathways in Kenya and South Africa. Resource use and price data from a health service perspective were collated using peer-reviewed sources and primary data collection.

We present costs in the following categories for all delivery pathway and usage scenarios: above-service level costs (one-off start-up and annual recurrent) and delivery costs per client (initiation and annual recurrent direct delivery).

The cost-effectiveness model was adapted to account for plausible product-specific ranges of effectiveness and indications parameterized using country-specific data. Deterministic sensitivity and threshold analyses were carried out.

Results: Next-generation HIV- and dual-prevention products could be delivered through facility and community channels in both countries, and existing pharmacy-based routes in South Africa. Estimated one-off program start-up costs varied between US\$11 and 17.6 million and annual national-level program costs between US\$77,000–US\$209,000. Initiation costs per client and annual re-

current direct delivery costs per client varied between US\$2–US\$28 and US\$10–US\$108, respectively. Costs and cost-effectiveness are driven by the scope and location of consultations. In addition, we present areas where key characteristics (price and efficacy) drive cost-effectiveness in product delivery.

Conclusions: Delivering novel prevention products could potentially be cost-effective compared to existing products. Key drivers of cost and likely cost-effectiveness of delivery include testing requirements and over-the-counter designation, which may change by the time these products advance through regulatory pathways.

TUPE077

The effectiveness of user-centered demand creation interventions on PrEP initiation among Female Sex Workers (FSW) and Men who have sex with Men (MSM) in Kenya

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Background: Since Kenya launched a national oral pre-exposure prophylaxis (PrEP) scale-up program in 2017, uptake has been progressive but sub-optimal. We assessed the effectiveness of demand creation interventions developed by the *Jilinde* project through human-centered design in promoting PrEP uptake. Female sex workers (FSW) interventions included “*Glow in the Dark Bag*” – a peer educator bag branded “*Ask me about PrEP*”; and a poster branded “*I choose my job, I choose my life, I choose PrEP*”. Men who have sex with men (MSM) intervention included promotional events such as parties that integrated “*Let’s get Real*” PrEP messaging.

Methods: We conducted a non-equivalent control group post-test-only quasi-experimental study in fifteen counties. Participants were enrolled through respondent-driven sampling and data collected through interviewer-administered questionnaires. We used descriptive statistics to summarize the participant characteristics, and chi-square to identify differences in exposure.

We conducted a bivariate analysis of the outcome variable (PrEP initiation) using generalized linear models (GLM) with a logit link function. A multilevel mixed-effects GLM was employed to analyze factors associated with PrEP initiation.

Results: Between November 2020 and April 2021, 1299 FSW and 644 MSM completed the questionnaire. The median age was 32 [IQR 21–43] and 24 [IQR 18–30] years among FSW and MSM, respectively.

Overall, 609 FSW (46.9%) and 265 (41.1%) MSM initiated PrEP, respectively. Of these, 47.1% and 41.9% of FSW reported exposure to the bag and poster, respectively, while 75.1% of MSM reported attending a ‘*Let’s Get Real*’ event.

FSW exposed to the bag were 3 times more likely to initiate PrEP (a.O.R. = 2.95, 95% C.I. = 1.70; 5.09, p <0.0001), while those exposed to the poster were 1.8 times more likely to

initiate PrEP (a.O.R. = 1.82, 95% C.I. = 1.28; 2.60, p = 0.001). MSM who attended the event had significantly higher odds of PrEP initiation (a.O.R. = 2.28, 95% C.I. = 1.29; 4.02, p = 0.005).

Conclusions: Our findings suggest that FSW and MSM who reported exposure to user-centered demand creation interventions were more likely to initiate PrEP.

This underscores the importance of tailoring demand creation interventions to the unique characteristics and preferences of different populations.

WEPE071

Preference for HIV Pre-Exposure Prophylaxis modality among young people in rural South Africa: baseline insights from *Thetha Nami Ngithethe Nawe* cluster randomised trial of HIV prevention

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Background: Despite the increasing uptake of oral HIV pre-exposure prophylaxis (PrEP) among adolescents and young adults (AYA) in South Africa (SA), retention rates remain low. Long-acting injectable PrEP shows promise in improving retention, but data on its acceptability in SA are limited. We aimed to assess the preferred PrEP modality among AYA in an ongoing stepped-wedge cluster randomised trial investigating the effectiveness, implementation, and cost-effectiveness of peer-led social mobilisation into decentralised, integrated HIV and sexual and reproductive health (SRH) services in rural KwaZulu-Natal, SA.

Methods: Between May and December 2022, we conducted a baseline survey among a random sample of 15-30-year-olds from a health and demographic surveillance site. The survey covered demographics, individual sexual relationships, general health, and PrEP preferences: oral, injectable, and other (e.g. implant or dapivirine vaginal ring).

Additionally, we collected home-based, self-sampled urine and vaginal swab specimens for STI testing and dried blood spots for HIV and viral load (VL) testing. We fitted logistic regression models to assess factors associated with preference for injectable over oral PrEP, adjusted for demographics.

Results: 2090 AYA participated in the survey, and 2068 (99%) expressed a preference for either oral or injectable PrEP. Of these, 53.8% were female, median age was 22 (IQR: 18-26) years. HIV prevalence was 14.5%, higher in females (20.9%) than males (6.8%). Sexually transmissible HIV (VL \geq 400 copies/ml) was 6.7%, also higher in females (9.3% vs. 3.5%). Among females, 40.9% self-reported contraceptive use. Overall, 47.1% preferred injectable PrEP; this preference was higher among females (53.5%) than males (39.7%). Female sex (aOR 1.60, 95%CI: 1.31-1.95), age-groups: 20-24 (aOR 1.51, 95%CI: 1.16-1.97), 25-30 (aOR 1.41, 95%CI: 1.05-1.91), alcohol use (aOR 1.24, 95%CI: 1.02-1.51), contraception use (aOR 1.74, 95%CI: 1.29-2.35), and living with HIV (aOR 1.57, 95%CI: 1.09-2.26) were significantly associated with a preference for injectable PrEP compared to their counterparts.

Conclusions: Preference for injectable PrEP is considerably high among AYA, particularly females. Offering a choice of injectable PrEP within community-based SRH services, integrated with oral PrEP and post-exposure prophylaxis, could address the uptake and retention challenges of oral PrEP and lead to a population-level reduction of sexually transmissible HIV.

WEPE072

Effectiveness of audio advertising in influencing uptake of HIV Services in Kenya

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Background: In Kenya, HIV, HIVST and reproductive health programs have been using mass media to inform and educate the public about diseases, products and services, promote behavior change and healthy sexual practices. This effort has led to discrepancy between individuals reached and the desired target users who fit the audience profile. With a mobile phone ownership rate of 80%; 30% of the adults owning smart phones and 50% owning basic phones, we presumed that audio advertising now play a role in creating awareness of self-manageable conditions and available solutions for self-care health needs. Advertisers can target their specified audience based on content that trickles their fancy while measuring post-advertising data that is integral in evaluating the campaign.

Methods: Population Services Kenya in partnership with Safaricom PLC and Ad tones limited run an audio ad (replacing the call connection with the Ad) tailored to reach males and females of ages 18-55 years with HIV self-testing campaign and messaging. The campaign encouraged the intended audience to know their HIV status by purchasing HIV self-testing kits from the nearby physical pharmacies or order via online pharmacies. Safaricom PLC & Ad tones Ltd rewarded users who opted in and interacted with the campaign, users were able to redeem airtime or data bundles for listening to the audio ad developed.



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Results: The campaign reached 50,585 unique listeners in a period of 8 weeks, delivering 87,086 plays above 6 sec (billed) and 21,310 plays below 6 sec (Free plays). The average play time was 15.92 seconds with follow-up SMS text disseminated to 21,980 listeners. The number of unique users that clicked on the WhatsApp chatbot number, developed to support effective use of HIVST, linkage to treatment and prevention and services access, was 1,859 registering a CTR of 8.5%. The campaign contributed to 14.2% increase of HIVST kit sales among the project supported pharmacies.

Conclusions: Audio advertising is a game changing strategy to reach a more targeted and specific demographic characteristics such as age group, gender, calling location, device type, customer segments, 2g/3g/5g indicators hence a good platform for interventions to increase uptake of HIVST and HIV prevention among different populations.

WEPE073

Comparing trajectories of change in PrEP readiness across an intervention trial to increase uptake among young South African women: a Markov modeling approach

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Background: In South Africa, uptake of HIV oral pre-exposure prophylaxis (PrEP) has been slow among women, who account for 60% of new HIV diagnoses. A gender-enhanced (GE) online group workshop, Masibambane ("Let us Work Together") (N = 50), demonstrated greater increase in PrEP stage-of-change versus providing participants with individual access (IA) to online PrEP educational and motivational materials (N = 50).

We compared participants' trajectories of change to characterize who, given initial stage, was most impacted by the intervention.

Methods: Participants completed questionnaires at baseline ("pre-intervention"), post-intervention, and three months after baseline ("follow-up") and documented readiness through a 5-point stage-of-change (SOC) score. We used Markov transition matrices to calculate probabilities of different trajectories.

Results: Participants who reported 3 ("would like to speak to a counselor") were most likely to transition to 5 ("ready to initiate PrEP") at post-intervention in the GE arm ($P_{\text{post, pre}}(5|3) = 0.60$) but not the IA arm ($P_{\text{post, pre}}(5|3) = 0.17$) (Figure 1).

Those who scored 2 ("uncertain") at pre-intervention in the GE arm also exhibited greater probabilities of upward movement. Across arms, participants who scored 4 or above at post-intervention were most likely to progress or remain at 5 at follow-up; those reporting 2 were least likely to progress (not shown).

"GE" refers to the gender-enhanced workshop and "IA" to the individual access condition. Rows correspond to the score at pre-intervention and columns to the score at post-intervention.

$$P_{GE}(\text{post} | \text{pre}) = \begin{matrix} & \begin{matrix} 1 & 2 & 3 & 4 & 5 \end{matrix} \\ \begin{matrix} 1 \\ 2 \\ 3 \\ 4 \\ 5 \end{matrix} & \begin{bmatrix} 0.00 & 0.50 & 0.50 & 0.00 & 0.00 \\ 0.00 & 0.44 & 0.00 & 0.33 & 0.22 \\ 0.00 & 0.10 & 0.10 & 0.20 & 0.60 \\ 0.00 & 0.14 & 0.00 & 0.57 & 0.29 \\ 0.09 & 0.09 & 0.00 & 0.27 & 0.55 \end{bmatrix} \end{matrix}$$

$$P_{IA}(\text{post} | \text{pre}) = \begin{matrix} & \begin{matrix} 1 & 2 & 3 & 4 & 5 \end{matrix} \\ \begin{matrix} 1 \\ 2 \\ 3 \\ 4 \\ 5 \end{matrix} & \begin{bmatrix} 0.00 & 0.00 & 0.00 & 0.00 & 0.00 \\ 0.07 & 0.79 & 0.07 & 0.00 & 0.07 \\ 0.00 & 0.00 & 0.67 & 0.17 & 0.17 \\ 0.00 & 0.00 & 0.13 & 0.38 & 0.50 \\ 0.00 & 0.14 & 0.00 & 0.10 & 0.76 \end{bmatrix} \end{matrix}$$

Figure 1. Pre to post transition probability matrices.

Conclusions: The Markov approach revealed that compared to IA, the GE intervention demonstrated greater ability to shift women expressing uncertainty or a desire for counseling to a state of readiness. These results suggest the importance of interpersonal interaction in creating demand and facilitating belief change among women who are undecided about PrEP.

Overall, this analysis demonstrates how transition probabilities can give greater insight into change dynamics than mean values alone.

De-medicalization of prevention approaches

TUPE078

Leveraging university-based platforms to improve access to pre-exposure prophylaxis to prevent HIV transmission in Young Key Populations in Manila, Philippines

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Background: The prevalence of HIV in the Philippines, estimated at 215,400 people, is alarming, with over 40% of new cases occurring among young individuals. While pre-exposure prophylaxis (PrEP) offers a highly effective means of reducing HIV acquisition, accessibility remains a significant challenge. The PEPFAR-USAID-supported Meeting Targets and Maintaining Epidemic Control (EpiC) Project has played a pivotal role in strengthening the capacities of partner facilities to implement differentiated PrEP programs in the Philippines.

EpiC is addressing this critical issue through collaborations with its partner institution the Manila Social Hygiene Clinic (SHC) to provide PrEP access in universities to reach young key populations (YKPs).

Methods: EpiC conducted on-site capacity-building and training sessions for Manila SHC service providers on differentiated and de-medicalized PrEP service delivery. To provide non-clinic-based, same-day PrEP services, Manila SHC identified universities as gateways to reaching YKPs within Manila. Three universities were successfully engaged within February and March 2024: Philippine College of Criminology, Technological University of the Philippines, and Pamantasan ng Lungsod ng Maynila.

Results: Prior to providing university-based services, Manila SHC only initiates at an average of 7 clients aged 15-24 on PrEP every month. In two months of university-based PrEP implementation since February 2024, a 129% increase in YKP PrEP initiations was seen, wherein a total of 32 clients were initiated on PrEP across the three universities. All of the clients initiated on PrEP identify as either gay or MSM (men who have sex with men).

Conclusions: University-based PrEP implementation demonstrated a potential platform for reaching and improving access for HIV prevention among YKPs. Integrating PrEP services into university settings also provides an opportunity to reduce stigma associated with HIV prevention and foster greater awareness among young individuals.

Nevertheless, there remains a crucial need to assess the acceptability and feasibility of university-based platforms in enhancing PrEP accessibility among these populations. As EpiC advances in scaling up efforts, engaging more partner providers and more universities will ensure tailored comprehensive support and inclusive services for YKPs.

WEPE074

Community capacity project: a scientific approach to enhancing HIV prevention and care

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Background: The Community Capacity Project (CCP) aimed to strengthen the capabilities of 52 HIV-serving community organizations to improve HIV prevention and care outcomes. Recognizing the critical role of community organizations in addressing the HIV epidemic, the project sought to enhance their scientific knowledge and application of evidence-based practices while increasing the distribution of HIV-self-testing kits.

Methods: The CCP employed a multifaceted approach to capacity building, including the development of a comprehensive directory of over 4,400 HIV-serving community organizations. The project provided targeted technical assistance through one-on-one support, specialized training, and best practices webinars. A key component

was the distribution of HIV self-tests, which served as a tool for community organizations to engage in data collection and monitoring of HIV prevalence and prevention efforts. The project also facilitated the negotiation of discounted rates for HIV self-tests, enabling broader access and utilization.

Results: The project successfully distributed 12,888 HIV self-tests to community organizations, contributing to increased testing and early detection of HIV cases. The technical assistance component reached over 6,032 participants through 15 meetings and 39 webinars, enhancing the knowledge and skills of community organizations in evidence-based HIV prevention and care strategies. The comprehensive directory served as a valuable resource for networking, collaboration, and sharing of best practices among HIV-serving organizations.

Conclusions: The Community Capacity Project demonstrated the importance of a scientific approach to capacity building in the context of HIV prevention and care. By enhancing the knowledge, skills, and resources of community organizations, the project contributed to improved HIV outcomes and the overall effectiveness of the HIV response.

Future efforts will focus on expanding the project's reach, incorporating new scientific advancements, and continuously evaluating the impact of capacity-building interventions on HIV prevention and care outcomes.

Implementation science, including structural interventions, PrEP and VMMC

TUPE079

Improving uptake of pre-exposure prophylaxis among pregnant and breastfeeding women through integration in maternal and child health clinics; a case in Mombasa County

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Background: Pregnant and breastfeeding women (PBFW) face a three to four times higher risk of HIV acquisition compared to non-pregnant and breastfeeding women. Kenya has a national mother-to-child transmission (MTCT) HIV rate of 8.6%, with one-third of new pediatric diagnosis stemming from maternal transmission during pregnancy or breastfeeding. The use of Pre-exposure prophylaxis (PrEP) is one of the strategies for ending new HIV acquisition among PBFWs. Mombasa County in Kenya scaled up PrEP access beyond comprehensive care clinics (CCC) and integrated it into other service delivery points such as Maternal and Health clinics (MCH).



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Methods: Pre- and post-integration analysis compared PrEP uptake among PBFW aged ≥ 15 in 16 Mombasa public health facilities with PMTCT services. Pre-integration spanned (March-Aug 2023) and Post-integration (Sept 2023-Feb 2024). Facilities were selected based on PMTCT services' presence and willingness to integrate PrEP. Strategies included client flow review, PrEP champion engagement, provider training, HIV risk assessment, eligibility screening, and health education. The implementation also featured provider debriefs, recognizing top performers, progress updates, monthly reviews, feedback meetings, and joint-supervision.

The analysis focused on the number of HIV-negative women screened, eligible, and started PrEP excluding those who declined despite being at risk. This approach ensured enhanced PrEP accessibility within the existing healthcare system.

Results: Pre-integration, 83 PBFWs were screened for eligibility were all eligible, with 76 (92%) initiating PrEP. Among them, 45 (54%) of those screened and 41 (53%) who initiated PrEP were AGYW 15-24 years. PBFW aged 25 and above contributed to 38 (46%) of those screened and 35 (46%) of those who initiated PrEP.

Post-integration, the screening increased to 294 PBFW, of which 284 were eligible, and all 100% were initiated on PrEP. Among the screened, 127 (43%) were AGYW, and out of those eligible, 126 (44%) initiated PrEP. PBFW aged 25 and above contributed to 167 (56%) of those screened, and 157 (55%) of those who initiated PrEP.

Conclusions: Decentralization of PrEP contributed to increased access and uptake. More efforts are needed to further optimize the access and uptake of PrEP. This approach can combat the stigma associated with taking PrEP at CCC.

TUPE081

Missed opportunities for pre-exposure prophylaxis among women of reproductive age and pregnant and breastfeeding women in Zimbabwe: results from the Population-based HIV Impact Assessment, 2020

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Background: In Zimbabwe, pregnant and breastfeeding women (PBFW) are prioritized for pre-exposure prophylaxis (PrEP) due to elevated risk for HIV. To better understand PrEP in Zimbabwe we describe willingness to use PrEP and PrEP awareness and use among PBFW using data from the 2020 Zimbabwe Population-based HIV Impact Assessment.

Methods: Analysis was restricted to women aged 15-44 years who reported having had sex and had a negative HIV test. PrEP was described to survey participants followed by questions on awareness and willingness to use; only those who were aware of PrEP were asked about use, and all participants were asked about willingness, except for those who reported having used PrEP. We calculated weighted proportions of women aged 15-44 years who reported having had sex, had heard of PrEP prior to the survey, used PrEP (currently or ever), and willing to take PrEP, stratified by current pregnancy or breastfeeding status. We also examined differences in demographic characteristics between PBFW and non-PBFW.

Results: PBFW (n=1,821) were more likely than non-PBFW (n=3,946) to be younger (mean age 26.2 years [interquartile range (IQR) 20.1-30.2] vs 29.9 years [IQR: 22.9-35.5]), married (90.5% vs. 79.7%), and live in rural areas (70.5% vs 60.6%). A higher proportion of non-PBFW had heard of PrEP vs. PBFW (11.1%, vs. 8.4%; Table). Among those who had ever heard of PrEP, similar proportions of non-PBFW and PBFW reported currently using PrEP (3.2% vs. 3.0%) or having ever used PrEP (12.0% vs. 10.5%). Most women reported willingness to use PrEP (64.2% vs. 64.5%).

Status	Pregnant and Breastfeeding Women	Non-Pregnant or Breastfeeding Women	All Women of Reproductive Age
	N (%)	N (%)	N (%)
Total	1,821 (32.0)	3,946 (68.0)	5,767 (100.0)
Have ever heard of PrEP	152 (8.4)	446 (11.1)	598 (10.2)
Would be willing to use PrEP ¹	1,186 (64.5)	2,572 (64.2)	3,758 (64.3)
Ever used PrEP ²	15 (10.5)	47 (12.0)	62 (11.6)
Currently using PrEP ²	4 (3.0)	11 (3.2)	15 (3.2)

¹Among those who did not report ever having used PrEP

²Among those who have ever heard of PrEP

Table. Weighted estimates of PrEP awareness, willingness to use, and use by pregnant and breastfeeding status among women, 15 - 44 years, Population-based HIV Impact Assessment survey data, Zimbabwe, 2020.

Conclusions: Overall, there was low PrEP awareness and use among women of reproductive age, despite high willingness to use PrEP. PBFW reported lower awareness of PrEP compared to non-PBFW, indicating missed opportunities for PrEP engagement in maternal-child healthcare (MCH) settings. Integration of PrEP in settings that women commonly access, including MCH is recommended.

TUPE082

Improving continuation of oral pre-exposure prophylaxis for HIV prevention using the Ottawa Hospital Innovation Framework: a retrospective cross-sectional study among adolescents and adults in southern Nigeria

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Background: Uptake and continuation of oral pre-exposure prophylaxis (PrEP) remains a critical challenge to HIV epidemic control in sub-Saharan Africa. The Ottawa Hospital Innovation Framework (TOHIF) was introduced to improve PrEP continuation among individuals in Southern Nigeria. This study assesses the outcomes of this intervention.

Methods: This was a retrospective cross-sectional study using data collected from electronic medical records of individuals (≥15 years) who received oral PrEP between July 2022 and March 2024, at 154 health facilities supported by PEPFAR/USAID in Akwa Ibom and Cross River states. TOHIF was introduced in June 2023 at these facilities. The common barriers to PrEP continuity identified in steps 1 and 2 of the TOHIF included knowledge gaps among service providers, inadequate post-appointment follow-up of clients, and poor data use. Strategies were then deployed in steps 3 and 4 including capacity building for service providers, development of job aids, PrEP case management, use of a PrEP appointment diary, pre-appointment reminders, active tracking following missed appointments, and high-frequency granular data reviews. Data extracted include age (categorized as adolescent:15-24 years, adult:25-49 years, elderly: ≥50 years), sex, and dates of PrEP initiation and last pickup (categorized quarterly). Individuals who received PrEP in a previous quarter were eligible for a continuation visit in the new quarter. The primary outcome was PrEP continuation rate (i.e. the proportion of PrEP users who had a PrEP continuation visit), compared before (October 2022-June 2023) and after (July 2023 - March 2024) the intervention, using Chi-square.

Results: 33,529 PrEP users (Males: 59.1% [19,830/33,529], adults: 79.0% [26,492/33,529], adolescents: 16.6% [5,580/33,529]), were eligible for PrEP continuation, with 25.4% (8,531/33,529) continuation rate. PrEP continuation rate was higher after the intervention (35.5%, 4,822/13,593) compared to before (18.6%, 3,709/19,936) ($p < 0.001$); was higher among females compared to males before (20.4% vs 17.4%; $p < 0.001$) and after the intervention (36.6% vs 34.8%; $p = 0.042$) respectively; and was highest among the elderly before 29.9% (248/889) and after the intervention 47.2% (268/568).

Conclusions: The use of TOHIF improved the PrEP continuation rate in this setting. A systematic quality improvement approach to addressing barriers to continued PrEP access is effective and can be adopted by programs facing similar challenges.

TUPE083

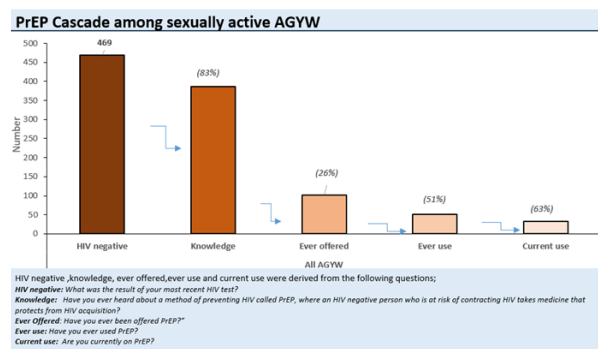
Pre-exposure prophylaxis cascade and factors associated with being offered PrEP among sexually active HIV negative adolescent girls and young women in Zimbabwe: a respondent driven sampling survey

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Background: Zimbabwe has rolled out oral pre-exposure prophylaxis (PrEP) as part of combination HIV prevention for adolescent girls and young women (AGYW). We describe the PrEP cascade and assess factors associated with being offered PrEP among eligible AGYW.

Methods: A cross-sectional respondent-driven sampling survey of AGYW, aged 15-24 was conducted in May-July 2023 in six urban/peri-urban Zimbabwean districts. Participants self-completed audio computer-assisted questionnaires on HIV risk and access to services. Logistic regression was used to assess factors associated with being offered PrEP, un-adjusted and adjusted (age, education, poverty, religion).



Results: Of 900 surveyed AGYW, 469 reported condomless sex in the past 3 months and were eligible for inclusion. Eight three percent (387/469) had heard about PrEP; of these 26% (102/387) had been offered and of these, 51% (52/102) had ever used it; 63% (33/52) reported continued use. Among those who never used PrEP, 71% (238/332) reported that they would take it if it were locally and freely



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available. The most cited reasons for not taking PrEP were low HIV risk perception (36%(121/332) and not knowing where to access it 31%(102/332). Factors associated with PrEP offer among those who had heard about it were having had a steady partner in the past 3 months (adjOR vs no steady partner: 0.39, 95%CI:0.16-0.98), ever consumed alcohol (adjOR vs never: 2.03, 95%CI:1.25-3.30), ever used recreational drugs in past 12 months (adjOR vs never: 2.30, 95%CI:1.35-3.94).

Conclusions: Although 80% of AGYW had heard about PrEP, PrEP use is very low. Interventions are required to motivate AGYW to take up PrEP (IEC materials, social media, and community campaigns, including parental involvement) and address access both through community provision and HCW training, and ensure adequate stock.

TUPE084

Preferences for HIV testing among partners of transgender women in Lima, Peru: a discrete choice experiment

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Background: Globally, there is increasing recognition that sexual partners of transgender women (PTW) should be a priority group for HIV prevention efforts given their significant vulnerability to HIV. Importantly, PTW are distinct from other priority populations (e.g., men who have sex with men), thus research is needed to inform accessible HIV prevention services that meet their needs.

Methods: From September-November 2023, we conducted a cross-sectional, web-based, discrete choice experiment (DCE) survey evaluating HIV testing service preferences among PTW in Lima, Peru. PTW were recruited via referral from transgender women living in downtown Lima, and were eligible for the DCE if they reported a negative or unknown HIV status. The DCE considered six attributes of HIV testing, each with 2-3 levels (Figure 1). Initial attributes/levels were selected based on findings from previous studies with PTW in Lima, then further refined through cognitive interviewing. Participants were presented with 12 choice tasks asking them to choose between two HIV testing service scenarios with different levels of each attribute. The DCE was administered using Sawtooth Discover. Preference data were analyzed with Hierarchical Bayesian models in Sawtooth.

Results: Among 292 PTW respondents, 284 (97%) were cis-gender men. Cost was the most important attribute (relative importance 40% [95% Confidence Interval: 38-42%]), followed by LGBTQ+ affiliation of the clinic (24% [22-25%]), clinic ownership (12% [11-13%]), service hours (10% [9-11%]), types of services offered (9% [8-10%]), and visit duration

(5% [5-6%]). When comparing levels within attributes, preferences for free HIV testing, known LGBTQ+ affiliation, and private clinic ownership were statistically significant.

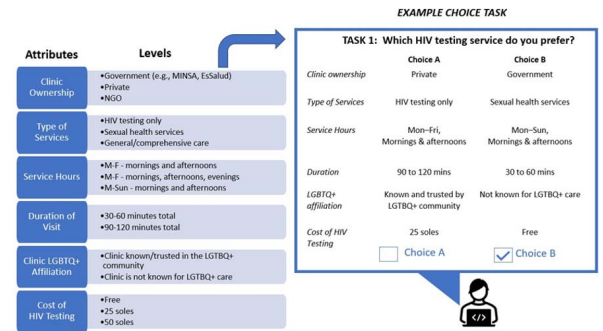


Figure 1. Connections between attributes, levels and choice tasks in this discrete choice survey.

Conclusions: Cost was the most critical factor for PTW when considering HIV testing. To best reach PTW in Lima, our findings indicate that HIV testing should be free and provided in clinics known and trusted by the LGBTQ+ community. Future testing services designed for PTW should consider these priorities.

TUPE085

Implementing EMR based opt-out universal HIV testing and comprehensive prevention services in federally qualified health centers in Alabama

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Background: Universal opt-out HIV testing has been a CDC recommended guideline since 2006 but is not systematically implemented in Alabama. Alabama ranks 11th highest in HIV acquisition rates in the US. Stigma challenges and cost barriers to implementing this guideline in the US prevail. To address the HIV burden in Alabama's community setting, we implemented an EMR based routine universal opt-out testing for HIV (EMR-ROUT-HIV) intervention in 9 or half of all (Federally Qualified Health Centers (FQHCs) in 2020. We also piloted a Comprehensive Prevention Services (CPS) program with 2 FQHC in 2023.

Methods: We implemented EMR-ROUT-HIV as a standard of care in 9 Federally Qualified Health Clinics (FQHCs) in 2020. All sites modified their EMR to trigger alerts for screening patients aged 15-65. Clinical and administrative champions were engaged and attended our CME trainings.

We used HRSA's UDS data ended December 2020 to compare testing rates of participating vs non-participating FQHC sites. A t-test was performed to confirm statistical significance. To compare testing rates for 12 months pre and post intervention periods for our participating sites, we utilized EMR-data submitted by them. We interpo-

lated missing baseline data for 6 sites using HRSA's UDS data. A paired t-test was utilized for this comparison. For CPS, we utilized a screener questionnaire to assess patient's risk at check in. We utilized testing data from 2023 for two FQHCs.

Results: The higher mean testing rate for our 9 EMR-ROUT-HIV intervention sites compared to the comparison sites were statistically significant ($p=0.0006$). The increase in percent of patients ever tested for HIV from their pre-intervention level were statistically significant ($p=.002$). There were 44 diagnosed positives and our linkage to care was 100%. For CPS, we tested 7041 individuals and detected 21 HIV positives. We determined that out of the tested population, 3113 individuals were eligible for CPS linkage and 2730 individuals were offered linkage. 670 had their first appointment for CPS scheduled. 82 attended this appointment or were linked.

Conclusions: This program demonstrated that EMR-ROUT-HIV overcomes structural constraints such as stigma and cost challenges in the US South while CPS is a viable strategy for HIV prevention.

TUPE086

Optimizing the delivery of PrEP choice through a multi-country quality improvement collaborative approach

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Background: The PEPFAR/USAID-supported CATALYST study is assessing the implementation of an enhanced service delivery package currently offering oral PrEP and PrEP ring to women in public health facilities in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe. A multi-country quality improvement collaborative (QIC) is nested in the CATALYST study to refine and contextualize the enhanced service delivery package to the diversity of participating sites.

To improve the quality of PrEP service delivery, PrEP outcomes, and client experience, the QIC iteratively assesses performance, introduces context-specific adaptations, and promotes learning across all sites.

Methods: Directed by a cross-country QIC faculty, key stakeholders in each country have adopted a QI charter outlining the aim, objectives, and measurement system of the QIC. Core objectives are increasing informed choice for PrEP, improving PrEP continuation, and fostering pos-

itive client experiences. Multidisciplinary QI teams from each CATALYST facility are trained in QI methods, and QI coaches support the teams to identify service delivery gaps and begin testing change ideas. Performance is measured through weekly and monthly run charts, and testing change ideas is documented in coaching reports. In-country learning sessions are held bi-annually to exchange experiences across sites, identify solutions to common challenges, and plan for subsequent action periods. Bi-annual QI briefs will serve as a data source for the CATALYST process evaluation.

Results: Stakeholder engagement, including with Ministry of Health and PrEP users, during the development of the QI charter was critical for buy-in and building motivation to implement the multi-country QIC. QI change ideas have focused mainly on redesigning client flow, improving access to PrEP through multiple clinic entry points, enhancing PrEP literacy through group health education prior to individual counseling, and creating appointment reminder systems to sustain engagement of PrEP clients. QI teams in the participating facilities have embraced the QIC as a tool for refining the service delivery package and improving PrEP services overall, but integrating QI refresher trainings into coaching visits is needed to help teams master QI methodology.

Conclusions: The multi-country QIC fosters collaboration, innovation, and shared learning. QI is a promising strategy for adapting and improving system performance to deliver multiple PrEP methods.

TUPE087

Peer-led digitally supported care for young people: electronic clinical management system supports a hub and spoke model of decentralised HIV prevention in rural South Africa

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Background: Freely available Anti-Retroviral Therapy (ART) based prevention delivery is limited by the structural and social barriers to facility-based care. Electronic clinical management systems have the potential to decentralise person-centred HIV prevention.

Methods: From June 2022 we have tested the effect of "Let's Talk" – A hub and spoke model of decentralised HIV prevention for adolescents and young adults (AYA) in northern KwaZulu-Natal (KZN) in a stepped-wedge trial. N=40 trained peer navigators (PN) use a real-time electronic clinical management tool (ECMT) on smartphones to support case-based care of AYA aged 15-30. The PNs assess health, social and development needs, rating their



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priorities (high, medium, low) and electronically communicating action plans with PN supervisors (PNS). PNS escalates priority (high) needs to a review committee. Together they review the action plans and provide immediate feedback to the PN through the ECMT.

Results: The area is 845 km² with mainly dirt roads and no public transport, with a population of approximately 15,335 15- 30-year-olds. June 2022–March 2024 (21 PN working months), PNs connected 19,903 times with 11,477 unique individuals, conducted 19,644 health assessments rating them as low (68,1%), medium (30,7%) or high risk (0,1%), 18,185 social need assessments (98,2% low, 0,5% medium, 0,1% high risk), 18, 077 Legal (98,8% low, 0,1% medium or high risk) and 18,172 educational assessments (98,5% low, 0,4% medium and 0,1% high risk). (Figure 1) 2,939 participants (1,710 – ciswomen) mobilised or referred by PNs visited mobile clinics, where 992 were initiated on PrEP/PEP, 82 on ART, 1,903 on contraception/emergency contraceptives, and 1,480 were treated for Sexually Transmitted Infections.

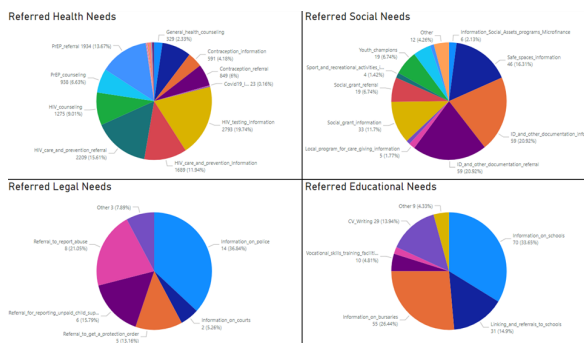


Figure 1.

Conclusions: An ECMT enabled the clinical and social care hub to monitor person-centred biosocial care provided by PN spokes in the community. This model provides real-time decentralised HIV prevention to AYA, including PrEP in poor rural settings.

TUPE088

Incident cases of HIV infection in a de-medicalized pre-exposure prophylaxis program in Mexico City

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Background: Since July 2021 to February 2024, 8,614 persons started oral Pre-exposure prophylaxis (PrEP) intake in a de-medicalized model of care, managed by counselors in three public clinics, one prison and five community centers, under the coordination and supervision of the Mexico City HIV Program. At the end of February 2024, 7,489 (87%) persons remained active in the program and 73 suspicious cases of HIV were detected in this population.

Methods: A retrospective, longitudinal and descriptive analysis was made, using data of the System of Preventive Interventions (SIP) and the System of the Specialized Laboratory of Condesa Clinic, to confirm new HIV infections in persons evaluated for PrEP, evaluate adherence and resistance to tenofovir/emtricitabine. Cases were categorized according to the evidence of PrEP intake, PrEP discontinuation, suboptimal adherence and adequate intake until the diagnosis.

Results: From the 73 persons with positive HIV test, 8 cases were false positive tests discarded by PCR or western blot, 50 confirmed cases correspond to baseline test, 2 to PrEP initiations in window period that were detected in the first follow up and 13 to incident HIV cases in PrEP users in the period of analysis. Evaluation of adherence showed that 7 cases (54%) suspended PrEP intake and were detected in the re-entry test, 3 (23%) had suboptimal intake and in 3 (23%) there was no documented adherence problems. Among all HIV positive cases, median viral load (VL) was 144,758 copies/ml and median CD4 count of 525 cells/mm³. VL was higher in persons that suspended PrEP (222,694 vs 24,491 p=0.00019) and no significant difference in CD4 count (474 vs 627 p=0.25). Consumption of crystal meth was documented in 5 cases (38%), 5 cases had confirmed latent syphilis and 2 Hepatitis C infection. HIV genotyping was performed only in 6 cases, showing susceptibility to tenofovir and emtricitabine. Seven persons were referred to other institutions and 6 started their treatment at Condesa Clinic with viral suppression after 3 months of treatment with bictegravir/3tc/TAF in all cases.

Conclusions: PrEP efficacy was 99.95% in people with good adherence. No cases of resistance to tenofovir/emtricitabine were observed in incident infections with prior PrEP intake.



TUPE089

Thetha Nami ngithethe nawe: early findings of cRCT of peer-navigators mobilisation into mobile integrated sexual health and HIV services on uptake of HIV oral pre-exposure prophylaxis in rural South Africa

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Background: Antiretroviral therapy (ART) based prevention has not translated into population-level impact in southern Africa due to sub-optimal coverage amongst youth with greatest need. We investigate the effectiveness of peer-led mobilisation into decentralised integrated HIV and sexual reproductive health (SRH) services amongst adolescents and young adults (AYA) in KwaZulu-Natal (KZN) on uptake of HIV pre-exposure prophylaxis (PrEP).

Methods: We conducted a cluster randomized stepped-wedge trial (SWT) in 40 clusters in a health a demographic site in rural KZN. Clusters were randomly allocated to receive the intervention in either period 1 (early) or period 2 (delayed). Intervention: Trained peer-navigators conducted tablet-based needs assessments with young men and women aged 15-30 years residing in their assigned cluster to tailor health promotion and psychosocial support; develop personalized action plans and referrals to nurse-led adolescent-friendly mobile clinics that visited each cluster regularly. The clinics provided SRH, HIV testing and status neutral HIV care or prevention (ART or PrEP). Standard of Care was PrEP delivered through primary health clinics. Here we report on PrEP demand in AYA following the 1st period of the SWT (NCT05405582).

Results: Between June 2022 and September 2023, peer-navigators reached n = 9584 / 13000 (74%) of 15-30 year-olds, including 5106 (53%) men with health promotion. Among 9511 with a needs assessment, peer-navigators identified 141 (1.5%) with social needs and 4139 (44%) with high or medium health needs, whom they referred to mobile clinics. Of those referred 2269 (55%) including 959 (42%) men attended the mobile clinics and 1149 (50%) were eligible for ART-based prevention: 179 (7.9%) were living with HIV - 68 of whom newly initiated ART- and 970 (43%) were offered PrEP with 763 starting PrEP compared to ~400 through eleven primary health clinics. Furthermore, 709 (54%) of women started contraception.

Conclusions: Peer navigators reached youth, including men, with unmet health and social needs and mobilised AYA with the highest need for ART based prevention. Community-based HIV/SRH care creates more demand

for PrEP than facility-based services and supports ART initiation among AYA. Social development and sexual well-being are integral to AYA resilience to HIV. Next steps are to add long-acting PrEP to biosocial care.

TUPE090

Optimizing uptake of pharmacy-delivered HIV prevention services for women during pregnancy

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Background: Pharmacy-delivered HIV prevention services could address facility-related barriers to reaching priority populations, including pregnant women who live in high HIV-burden settings. However, existing pharmacy services are not tailored to women's preferences during pregnancy.

We evaluated women's preferences for receiving HIV prevention services during pregnancy to identify service bundles that would maximize uptake and guide the types of services pharmacies can prioritize for implementation.

Methods: From June to November 2023, we conducted a discrete choice experiment with women of childbearing age recruited from maternal and child health clinics, pharmacies, and prior PrEP implementation studies. The survey assessed experiences with HIV prevention services, attitudes toward pharmacists, and perceived HIV risk. Hierarchical Bayes analysis estimated individual preference weights for each attribute level, and predicted choice probabilities were calculated to identify pharmacy-service bundles that maximized uptake—Kruskal-Wallis tests (and post hoc pairwise comparisons) evaluated differences in uptake across groups.

Results: Overall, 599 participants completed the survey; median age was 23 years (IQR: 18 - 27); 52% had been pregnant before; 87% and 35% had ever received HIV or STI testing when they were not pregnant, respectively; 60% reported that their partners had ever been tested for HIV; 15% had previously used PrEP. Perceived HIV risk was low (82%). The optimal pharmacy service (free comprehensive HIV prevention - Scenario 1) resulted in 49.7% uptake relative to a clinic-based scenario (50.3%). Introducing a 400 KSH fee (Scenario 2) decreased pharmacy



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uptake (42.1%). Uptake was higher among participants who agreed (vs. disagreed) that “pharmacists care about their health” (42% vs. 29%; $p < 0.0001$); participants who had received STI testing vs. not (44% vs. 39% $p = 0.01$), and those recruited from pharmacies vs. clinics (45% vs. 38%; $p = 0.02$).

Scenarios/ Attributes and Levels	Location (pharmacy with a private room/ pharmacy without a private room/ antenatal care clinic)	Travel time (15 minutes/30 minutes/60 minutes)	HIV test type (provider assisted/ blood self-test/ oral swab self-test)	STI testing (available/ not available)	Partner HIV testing (available/ not available)	PrEP pills (available/ not available)	Service Fee (free/400 Kenya Shillings/ 1000 Kenya Shillings)	Uptake (% probability)
Base case scenario	Clinic	30 minutes travel time	Provider-assisted HIV test	STI testing available	Partner HIV testing available	PrEP pills available	Free	50.3% relative to scenario 1 57.9% relative to scenario 2
Scenario 1	Pharmacy with a private room	15 minutes travel time	Provider-assisted HIV test	STI testing available	Partner HIV testing available	PrEP pills available	Free	49.7% uptake relative to the base case
Scenario 2	Pharmacy with a private room	15 minutes travel time	Provider-assisted HIV test	STI testing available	Partner HIV testing available	PrEP pills available	400 KSH	42.1% uptake relative to the base case

Conclusions: In this study, comprehensive HIV prevention services offered in pharmacies with private rooms might be a viable alternative to clinic-based service delivery for women during pregnancy. Uptake might be even higher among women with positive attitudes to pharmacists, prior STI testing experience, and regular pharmacy use.

TUPE091

Predictors of PEP-to-PrEP transition among clients accessing online PEP services in Kenya: findings from a pilot study

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Background: HIV post-exposure prophylaxis (PEP) has played a minor role in HIV prevention programs to date. We developed and pilot-tested a model of online PEP and pre-exposure prophylaxis (PrEP) delivery for HIV prevention in Kenya that encouraged the use of PEP as a bridge to PrEP and assessed characteristics associated with PEP-to-PrEP transition.

Methods: In collaboration with a Kenyan online pharmacy, MYDAWA, we developed a model of online PEP/PrEP delivery that utilized telemedicine, courier delivery, and HIV self-testing (HIVST). Eligible online PEP clients (≥ 18 years) reported exposure to HIV in the past 72 hours and were willing to pay associated fees for HIV testing (~\$2.00) and PEP delivery (~\$1.00).

We collected characteristics of online PEP clients at enrollment and assessed their transition to PrEP using pharmacy records. We used logistic regression models to evaluate the association between clients' characteristics and PEP-to-PrEP transition; characteristics with a p-value of < 0.1 in univariable models were included in a multivariable model and adjusted prevalence ratios (aPRs) were reported with 95% confidence intervals (CIs).

Results: Between October 2022 to December 2023, 1549 clients initiated online PEP, and 82 (5%) transitioned to PrEP. Among clients who initiated PEP, the majority were ≥ 25 years old (79%, 1224/1549), male (65%, 1006/1549), unmarried (88%, 1365/1549), and reported unprotected sex in the past 72 hours (71%, 1093/1549). Few clients identified as a member of a key population (2%, 26/1549) and reported any prior PrEP use (14%, 211/1549). In our analysis, being a member of a key population (aPR 5.23, 95% CI 1.85-13.32), any prior PrEP use (aPR 4.74, 95% CI 1.01-17.05), and having unprotected sex in the past 72 hours (aPR 1.89, 95% CI 1.07-3.54) were significantly associated with an increased likelihood of PEP-to-PrEP transition. Being married was significantly associated with a decreased likelihood of PEP-to-PrEP transition (aPR 0.08, 95% CI 0.004-0.37).

Conclusions: Transition to online PrEP services among eligible clients engaged in online PEP services in Kenya was low; prior PrEP use increased the likelihood of PrEP transition. Identification of effective implementation strategies to help more PEP clients with persistent HIV risk transition to PrEP services are needed.

TUPE092

Early insights from pre-exposure prophylaxis (PrEP) choice delivery in a community setting in Cape Town, South Africa

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Background: Increasing choice of HIV pre-exposure prophylaxis (PrEP) products bears potential to increase uptake, persistence, and HIV exposure coverage amongst those at risk of HIV acquisition. The ongoing PrEPared to Choose (PtC) study seeks to determine patterns of persistence on PrEP products when delivered within a choice framework to adolescents and young people (aged 15-29 years) and their intimate partners (any age) from a community-based mobile clinic site in Cape Town, South Africa.

Methods: This phase 3B clinical trial utilises a hybrid implementation design to compare persistence over 18 months among 1800 participants who self-select to initiate on injectable, oral, or vaginal ring PrEP products. PtC is delivered from a mobile clinic, staffed by adolescent-friendly nurses, HIV counsellors, and peer-navigators clinic. PrEP is provided within a sexual and reproductive health package that includes sexually transmitted dis-

ease testing and family planning. PrEP selection is guided by extensive PrEP choice counselling at each visit, with allowance for product switching.

Results: The first 205 participants (mean age 26.8 [15;63]) were enrolled between 13 February and 5 April 2024, of which 49.3% had prior PrEP use experience. After choice counselling, 151 (73.67%) initiated injectable PrEP, 52 (25.36%) initiated oral PrEP, and 2 (1.00%) initiated the vaginal ring. 128 (62.44%) identified as adolescent girls or young women, 72 (35.12%) as heterosexual men, and 5 (2.44%) as men who have sex with men.

For participants expected to return at month 1 (required for all products), injectable PrEP users have shown a higher rate of return (45/75 expected, 60%) compared to oral (3/19 expected, 16%) and ring users (0/2 expected, 0%). 98% (47/48) of those who returned continued on the same product and one participant switched from oral to injectable PrEP.

Conclusions: These findings provide early support for the delivery of different PrEP products, including injectable PrEP, from community-based settings. The rate of uptake among heterosexual men was greater than expected, potentially reflecting increased interest in injectable PrEP products. Early findings show substantially higher rates of return for injectable PrEP users compared to oral PrEP and vaginal ring users at month one.

TUPE093

Increasing preference of ShangRing device for voluntary medical male circumcision (VMMC) in Malawi, 2020-2023

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Background: Malawi adopted voluntary medical male circumcision (VMMC) for HIV prevention in 2012. In 2020, the Malawi VMMC program, supported by the United States President's Emergency Plan for AIDS Relief (PEPFAR), rolled out ShangRing (SR) device as an alternative option to the dorsal slit (DS) procedure. Currently, Malawi conducts the highest proportion of SR based circumcisions among all 15 PEPFAR supported VMMC countries. This analysis describes trends in uptake of the SR device in Malawi since its roll out in 2020.

Methods: Aggregate program data submitted on a quarterly basis by all PEPFAR Malawi VMMC implementing partners were analyzed. For each US government fiscal year (FY, October 1-September 30) data were stratified by quarter(Q), surgical method, and client age.

We conducted descriptive analyses to assess stratified annual trends in SR uptake from FY 2020 to FY 2023. Two sample Z-test of proportions were conducted to compare SR uptake between different age groups (15-24, 25-34, 35-44, 45+ years).

Results: A total of 461,446 VMMCs were conducted in PEPFAR supported sites between FY2020 and FY2023. The proportion of SR uptake increased from 0% in FY2020 Q1 to 62.4% in FY2023 Q4. The greatest quarterly increase in SR circumcisions was in FY2023, from 39.1% in Q1 to 58.8% in Q2. There have been more SR than DS circumcisions per quarter since FY2023 Q2. The highest proportion of SR circumcisions was in FY2023 Q3 at 66.4%. Cumulatively, the highest proportion of SR circumcisions was among men aged 35-44 years at 40.3% (CI: 39.5%,41.0%), significantly different from men aged 15-24 at 30.6% (CI:30.5%, 30.8%), and 25-34 at 37.5% (CI:37.2%,37.8%), and 45+ at 36.4% (CI:34.6%,38.2%). SR uptake proportions were significantly different across age groups except between 25-34 and 45+ age groups.

Conclusions: There is increase in preference for SR device across VMMC PEPFAR Malawi supported sites with the highest preference among older men. Anecdotally, reasons for SR preference included no injection for anesthesia, fewer clinic visits and appealing cosmetic outlook after healing. Promotion of SR has not been systematically different across age groups. Additional investigations are needed to understand the higher SR preference among older clients.



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TUPE094

Factors associated with PrEP retention and adherence among transgender and non-binary people in the San Francisco Bay Area: the STAY study

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Background: Few studies have evaluated real-world PrEP delivery for transgender and non-binary (TNB) people. We describe rates and correlates of retention and adherence in one of the first PrEP demonstration projects for TNB communities – the STAY Study.

Methods: The STAY Study enrolled HIV-negative trans women, trans men, and non-binary individuals across 5 community-based clinics in the San Francisco Bay Area (four gender-affirming primary care; one low-barrier PrEP-only clinic) and offered 48 weeks of PrEP with peer navigation and SMS support (2017-2020). Tenofovir-diphosphate (TFV-DP) levels in dried blood spots (DBS) collected at weeks 4, 12, 24, 36, and 48 were analyzed. Correlates of retention and adherence measured by protective TFV-DP levels (≥ 700 fmol/punch) were evaluated using multivariable logistic regression.

Results: Among 158 participants enrolled, median age was 37 years old; 27% were Latino/a/x, 24% White, 14% Black, 27% multi-race/other; 88% were trans women/women, 6% men/trans men, and 6% non-binary. At month 12, 60% were retained. Retention was associated with the PrEP-only clinic (AOR 6.05, 95% CI 2.18-16.77), age >35 years old (AOR 3.64, 95% CI 1.35-9.84), and having indicators of Post-Traumatic Stress Disorder (AOR 3.79, 95% CI 1.55-9.31). Latino/a/x participants (AOR 0.33, 95% CI 0.14-0.77) and those reporting condomless anal sex (AOR 0.36, 95% CI 0.20-0.67) had lower retention. Among those with DBS (75% of completed visits), the proportions with protective TFV-DP were 56%, 60%, 58%, 54%, and 64% at weeks 4, 12, 24, 36, and 48. In a multivariable model, having a visit with protective TFV-DP levels was associated with having a college education (AOR 5.04, 95% CI 1.70-14.95) and owning/renting (AOR 2.42, 95% CI 1.06-5.52), or living in an institution/hotel/single-room-occupancy (AOR 3.98, 95% CI 1.55-10.25), compared to experiencing homelessness/living in a shelter. Food insecurity (AOR 0.36, 95% CI 0.16-0.81) was associated with fewer visits with protective TFV-DP levels.

Conclusions: PrEP retention was higher among participants in the PrEP-only clinic, supporting the need for PrEP delivery models outside primary care for transgender and non-binary individuals. Food and housing insecurity were associated with lower PrEP adherence, highlighting the importance of addressing social determinants in PrEP delivery for trans and non-binary communities.

TUPE095

Incremental clinical personnel costs associated with integrating oral pre-exposure prophylaxis delivery in primary care family planning clinics in Kenya

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Background: In Sub-Saharan Africa (SSA), family planning (FP) clinics, highly accessible by sexually active women, offer opportunity to expand access to oral pre-exposure prophylaxis (PrEP) for HIV prevention. We assessed the incremental clinical personnel cost associated with PrEP integration in primary care FP clinics.

Methods: Between March 2021 and June 2023, we conducted a stepped-wedge cluster-randomized trial integrating oral PrEP provision in 12 FP clinics in Kisumu, Kenya. Trained ministry of health (MOH) nurses screened FP clients for PrEP eligibility and dispensed PrEP to eligible and interested clients. HIV testing was conducted by MOH HIV testing services (HTS) providers. Time-and-motion observations were conducted among five purposefully selected clinics.

Visits were categorized into initial or follow-up FP visits, and sub-categorized into no PrEP screening, screening, initiation, or follow-up visits with or without FP services. Staff time per visit was compared between FP visits with and without PrEP services. Average staff compensation was derived from government records and converted to 2024 US dollars (USD).

Results: Overall, 119 time-and-motion observations were included. Among initial FP visits, the average total time (minutes) spent by MOH providers was 15.1 (SD 8.2) with no screening (n=20), 22.1 (16.0) in screening (n=31), and 55 (23.0) in PrEP initiation visits (n=13). Among FP follow-up visits, the average total time (minutes) was 10.6 (SD 7.4) with no screening, 20 (16.9) in screening (n=24), 64 (17.1) in initiation (n=10), and 40 (17.8) in PrEP follow-up visits (n=7).

Additional clinical personnel compensation costs translated to 0.25-1.82 USD for initial and 0.24-2.42 USD for follow-up FP visits. Details are presented in Table 1.

FP visit type	PrEP visit type (n)	Nurse time (minute)	Nurse time difference (minute)	Nurse cost difference (USD)	HTS provider time (minute)	HTS provider time difference (minutes)	HTS cost difference (USD)
Initial	not screened (n=20)	15.1(8.2)	REF	REF	0(0)	REF	REF
	screening (n=31)	20.3(15.4)	5.2	0.28	1.7(5.2)	1.7	0.08
	Initiation (n=13)	42.8(15.2)	27.7	1.46	12.3(12.7)	12.3	0.36
Follow-up	not screened (n=14)	10.6(7.4)	REF	REF	0(0)	REF	REF
	screening (n=24)	18.1(14.3)	7.5	0.39	2.0(6.9)	2.0	0.06
	Initiation (n=10)	46.1(22.7)	35.5	1.87	18.5(13.7)	18.5	0.55
	Follow-up (n=7)	29.8(15)	19.3	1.01	10.4(9)	10.4	0.31

Conclusions: Integrating PrEP delivery within FP clinics incurs additional personnel costs. Incremental estimates align with previous findings in FP and maternal and child health settings in SSA. Costs need to be weighed against the benefits of offering integrated FP and PrEP services to women.

TUPE096

Enhancing access to HIV prevention services from the urgent care: a multifaceted intervention in a safety-net hospital in the Southern United States

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Background: Georgia has the highest rate of new diagnoses of HIV in the US. Pre-exposure prophylaxis (PrEP) is highly effective in preventing HIV but is underutilized in high-risk populations. Many people have limited healthcare engagement before HIV diagnosis, making emergency department (ED) and urgent care (UC) encounters crucial for HIV prevention.

A previous study found low PrEP referrals among people seeking sexual healthcare in ED/UC settings. We evaluated a UC-based intervention's impact on increasing referrals and linkage to comprehensive prevention services (CPS).

Methods: We describe a quality improvement (QI) project in our safety-net system UC in Atlanta, Georgia. The intervention, initiated on November 1st, 2023, included:

1. Integrating electronic medical record (EMR)-based display columns to identify eligible patients and quantify prevention need, and;
2. Placing a navigator to discuss HIV prevention options and facilitate CPS referral for eligible people. EMR data were abstracted for CPS-eligible people (HIV-negative and meeting predetermined criteria) seen in the UC between May 1st, 2023, and February 29th, 2024.

We defined CPS referral as an EMR referral order for PrEP and defined linkage as attending a PrEP-initiation visit. We compared pre- and post-intervention CPS referral and linkage rates using a mixed-effects model controlling for age, race, ethnicity, HIV risk score, and non-independence due to multiple visits.

Results: Of the 13,141 healthcare-encounters, 7,842 were CPS eligible. Of these, 92.5% were black, 4.4% Hispanic, and 70.2% female. Before the intervention, among 4,726 CPS eligible healthcare-encounters, 2.9% of people were referred and 1.6% linked to CPS. Post-intervention, among 3,116 healthcare encounters, 141 (4.5%) of people were referred and 88 (2.8%) linked to CPS. After controlling for confounders, the intervention significantly increased odds of referral and linkage (OR 1.88, 95% CI: 1.36 - 2.56 and OR 1.61, 95% CI: 1.26 - 2.07, respectively).

Conclusions: In our safety-net urgent care in Atlanta, Georgia, we implemented a multimodal EMR- and navigator- based intervention to engage eligible people in HIV prevention, which was associated with a significant increase in PrEP referral and linkage.

Future efforts will focus on increasing the total number of people assessed by the navigator and methods to enhance the impact of EMR-integrated tools.

WEPE075

HIV prevention service availability mapping to population at-risk in Uganda

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Background: Equitable access to health services is critical for closing gaps in HIV prevention and treatment. At-risk populations including adolescent girls and young women (AGYW) are prioritized for services including the DREAMS program that provides a combination of HIV prevention interventions to AGYW, coupled with extending services to their male partners such as voluntary medical male circumcision (VMMC), HIV testing and sexually transmitted infections screening. These service sites are selected based on HIV burden and AGYW population.

We mapped population HIV viral load (PVL) by district and overlaid facilities offering HIV prevention services in Uganda to assess alignment between geospatial access to HIV services and potential HIV exposure.

Methods: Estimates of PVL were obtained from a previously developed model for 13 African countries with data from Population-based HIV Impact Assessment surveys conducted 2015-2018. Using the estimates, we mapped spatial coordinates obtained from Uganda DREAMS database for PEPFAR-supported DREAMS service points and from DATIM for facilities reporting pre-exposure prophylaxis (PrEP) and VMMC for 2016-2023.



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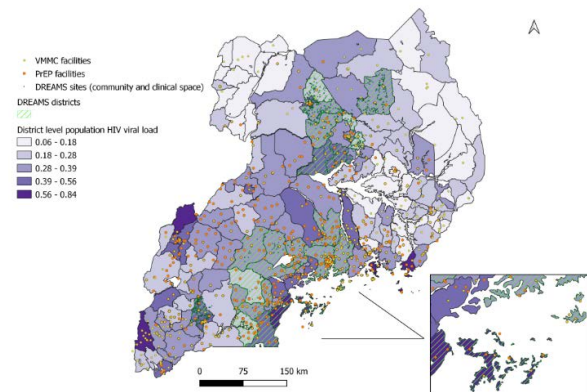
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Results: A total of 2,807 DREAMS service points, 362 PrEP facilities, 146 VMMC facilities, and 245 facilities providing both VMMC and PrEP were included. Districts with the highest estimated PVL were in the southern and western regions of Uganda. While overall service delivery access points were widely distributed throughout Uganda, spatial variability was observed when stratified by delivery type (Figure 1).

Overall, the district level distribution of PrEP facilities aligned positively with PVL. Districts in the western and southwestern region with high PVL did not have any DREAMS service points.



Conclusions: Service availability mapping of HIV prevention services with population level risk can help identify potential HIV inequities in service distribution. Further investigation of underserved areas with high PVL can help plan the expansion or re-alignment of HIV prevention services in Uganda.

WEPE076

Improving PMTCT outcomes in humanitarian settings through mother mentors: experience from Cameroon

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Background: Within the context of the Anglophone crisis in Cameroon, and its resultant decrease in access to HIV and PMTCT services due to the closure of 30% of health facilities (HFs), disruption of supply chain systems, and internal displacements of populations, a humanitarian approach was adapted to ensure access to PMTCT services.

Methods: The Project was implemented across 20 health districts in the Northwest and Southwest regions of Cameroon. The intervention was implemented from December 2021 to December 2023.

A retrospective evaluation of the Mother Mentor Strategy within the Global Fund NFM3 Humanitarian subgrant. Materials used were the project review where the project monthly reports, quarterly project reports, database of Mother mentor reports.

Results: 105 women living with HIV who had successfully gone through the PMTC were selected by the project team in collaboration with the Regional Technical Group for HIV and trained for 5 days to serve as Mother Mentors (M2Ms). Mother mentors conducted home visits, educational talks, referred and accompanied Pregnant women (PW) for ANC and other PMTCT services, treatment initiation, conduct active search for pregnant and breastfeeding women (PBW) living with HIV(LWHIV) Lost To Follow Up (LTFU) and link them back to care, ensure early infant diagnosis for HIV exposed infants (HEI), ensure viral load testing for PBW LWHIV. M2Ms reached 4225 PBW through home visits and made a total of 8125 follow-up phone calls to PBW. 1627 PWs were identified in the community by M2Ms and referred to the HF and of these 1068 (65.6%) were received at health facilities.

A total of 764 HEIs benefited from Early Infant Diagnosis (EID) and linked to HFs and 649 (84.9%) were successfully placed and retained on prophylaxis treatment. 193 PBW LWHIV with an unsuppressed viral load were initiated on Enhanced Adherence Counselling by M2M. 829 PBW LTFU from ART were brought back to care.

Conclusions: In conflict settings, maintaining access to PMTC services for PBW and ensuring EID is challenging. The use of M2Ms for peer-to-peer coaching in favor of PMTC services could make it possible for women LWHIV to lead PMTCT activities in such context with significant positive outcomes.

WEPE077

Assessing HIV prevention efficacy in Nasarawa State, Nigeria: insights from Recency Testing Data

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Background: In response to Nigeria's considerable HIV/AIDS burden, the adoption of recency assays stands out as a critical element in HIV management. Recency Testing identifies recent HIV infections, plays a pivotal role in estimating HIV incidence and surveillance. Targeting individuals with newly acquired infections offers a valuable tool for directing prevention efforts. Utilizing recency testing beyond mere diagnosis, it serves as a strategic asset in

analyzing local HIV patterns, guiding prevention strategies, and assessing program impact on the national HIV epidemic.

Despite the availability of national data, Nasarawa State lacks specific insights into recent HIV infections. This research aims to bridge this gap by analyzing recency testing data to discern recent infection incidence trends. Through this analysis, actionable insights can refine prevention strategies, ensuring they align with Nasarawa State's distinct epidemiological, cultural, economic, and social contexts. Such efforts are crucial for effectively combating HIV/AIDS and improving public health outcomes in the state.

Methods: Data on recent HIV infections were collected between November 2020 and August 2023 from 9 distinct SDAs, at both healthcare facilities and community-based settings at 3 LGAs of the State. Data extraction was done from Recency Testing worksheets and registers. In total, 1,216 HIV-positive individuals underwent recency testing. A baseline viral load test was administered, subsequently, a Recent Infection Testing Algorithm (RITA) test was conducted, followed by a confirmatory viral load test to validate the recency of the infection.

Results: In 3 years of data collection, 1,216 individuals aged 15-49 underwent Asante recency testing for HIV. Results identified 39 (3%) as RITA-Recent. Of these, 18 (46%) - (12 women and 6 men) confirmed positive in subsequent tests and 2 were key population members. All 18 had viral loads $\geq 1,000$ copies/mL, highlighting recent infections and the critical need for focused prevention efforts.

Conclusions: Nasarawa State's HIV prevalence stands at 1.4% per the 2018 NAHS report, contrasting with the 3% indicated by recent RITA-Recent detections. This discrepancy highlights the critical need for refined, data-driven prevention strategies. Integrating recency testing into HIV management is essential for an effective response, ensuring interventions are well-designed to combat the HIV epidemic's evolving landscape in Nigeria.

WEPE078

Provision of Pre-Exposure Prophylaxis utilizing a community model to reach adolescent boys and young men in Western Kenya

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Background: Adolescents and young persons account for 41% of new HIV infections. However, reaching this population, particularly boys and young men, remains a major challenge within health facilities. Therefore, innovative strategies are required if epidemic control is to be achieved, including the provision of pre-exposure prophylaxis (PrEP) at the community level.

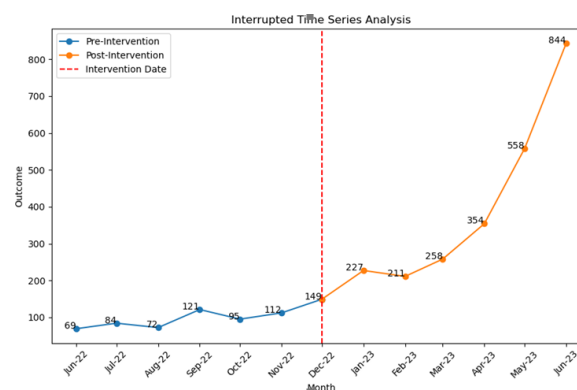
Methods: We utilized routinely collected de-identified aggregated programmatic electronic data from 4 supported counties of AMPATH Uzima to compare the uptake

of PrEP among adolescent boys and young men (ABYM) before and after the roll-out of a community PrEP model from July 2022 to June 2023. Before January 2023, initiation and refills of PrEP were done only within health facilities. However, from January 2023, the program targeted gold mine quarries, motor vehicle garages, long-distance truck drivers' stopover points, motorbike riders' shades, and public transport pick-up points to reach ABYM. At the community, ABYM were provided with HIV testing, PrEP provision and referral for other prevention services.

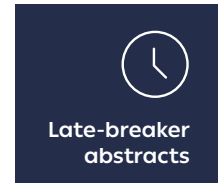
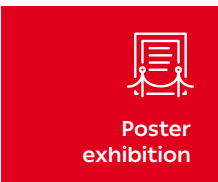
We conducted an interrupted time series analysis to determine the impact of community PrEP uptake among the ABYM.

Results: During the community PrEP pre-intervention period (July 2022 and December 2022), there was a low PrEP uptake among ABYM, with a monthly average of 26.67 (standard deviation (sd) = 10.42) new PrEP initiations. However, with the implementation of community PrEP activities targeted at ABYM, there was a significant improvement between January 2023 and June 2023, with a monthly mean initiation of 109.17 (sd=76.20) new PrEP clients.

On conducting an interrupted time series analysis, the post-intervention number of ABYM initiating on PrEP significantly increased by 48.93 clients every month (95% confidence interval 27.72 - 70.15, p-value <0.001).



Conclusions: Community approaches increase PrEP uptake among ABYMs who rarely visit health facilities. Interventions designed to meet this population's demands in convenient settings play a critical part in enhancing PrEP uptake.





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WEPE079

PrEP-Pro: a multi-component intervention to train and support family medicine providers to promote PrEP for adolescent girls and young women in the Deep South

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Background: Black adolescent girls and young women (AGYW) experience high HIV incidence in the U.S. South. We used a community-engaged approach and Intervention Mapping (IM) to adapt PrEP-Pro, an intervention to support Family Medicine (FM) physicians to provide/prescribe PrEP to Black AGYW.

Methods: Draft intervention content included PrEP educational curricula, CDC's sexual history tool, and a PrEP Champion training program. Using IM techniques (Program Design and Production), two community advisory boards (CABs) of physicians and AGYW adapted intervention content during meetings over 10 months (Figure). Two focus group discussions with physicians adapted training materials. We pre-tested PrEP-Pro at two sites over three months and assessed acceptability, appropriateness and feasibility (5-point scales, maximum=5).

Results: The physician CAB advised multiple training strategies:

- 1) Locally-informed sexual history videos of diverse provider-client interactions;
- 2) Local HIV epidemiology review;
- 3) Badge cards to guide PrEP prescribing and eliciting sexual histories;
- 4) Didactic, case-based content;
- 5) Web-based content.

Informed by the AGYW CAB, we developed:

- 6) a paper sexual history screener, and;
- 7) clinic posters emphasizing confidentiality and previewing adolescent-provider sexual health conversations. (Figure)

Focus groups recommended more graphics and case-based content.

Acceptability (mean=4.16 [SD=1.36]), appropriateness (4.16 [1.36]) and feasibility (4.19 [1.37]) were high (n=8 PrEP-Pro participants). Six participant interviews informed adaptations including fostering a community of practice, increased case-based learning, and badge card content modifications.

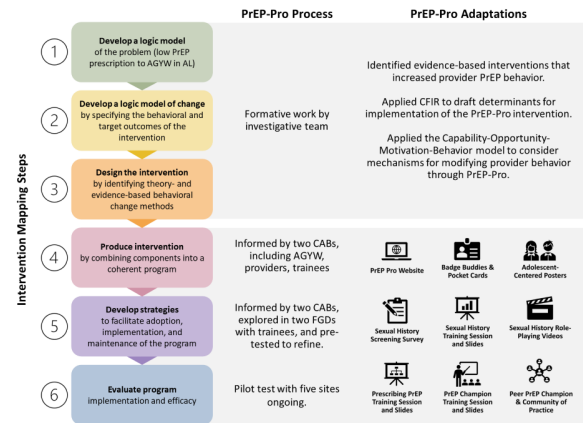


Figure.

Conclusions: This multi-component, theory-driven implementation study exemplifies scientific initiatives necessary to improve equitable access to PrEP in resource-limited, Ending the HIV Epidemic priority states among key populations; observed implementation determinants will inform a future trial.

WEPE080

Feasibility of assessing Prevention Effective Use (PEU) utilizing a phone-based, self-reporting system: early CATALYST study findings

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Background: PrEP reduces HIV acquisition when temporally dosed in alignment with potential exposure, referred to as prevention effective use (PEU). However, efforts to assess PEU are nascent because continuous daily measurement of both dosing and exposure is challenging. We developed a phone-based, daily, self-reporting system to evaluate PEU, within CATALYST, a PEPFAR/US-AID-supported study currently offering choice of oral and ring PrEP to women. In this analysis, we assess feasibility of the system.

Methods: A subset of CATALYST participants received three questions daily via cellphone, over no more than two six-week periods: PrEP method used prior day, sex prior day, and whether used condom during sex. Escalating incentives were issued to encourage responsiveness. Participants also completed a survey about their impressions of the system. We analyzed survey findings and completeness of response data, using descriptive statistics, to evaluate feasibility. Regression analysis was conducted to assess associations between response rates and factors including age, education, income, sex-worker status, alcohol use, and facility location.

Results: Data were analyzed for 309 participants across Kenya and South Africa, 58.9% using oral PrEP and 41.1% using ring PrEP. The mean observation period was 57 days (SD: 24 days), with a median of 42 days (IQR: 26-72 days) of complete responses. About 50% of oral and ring users responded nearly daily (Figure 1). The proportions responding with "refused" or "do not remember" were <1%. There were no statistically significant predictors of low (20%), medium (50%), or high (80%) response rates. Almost all participants (95%) reported the system was easy to use.

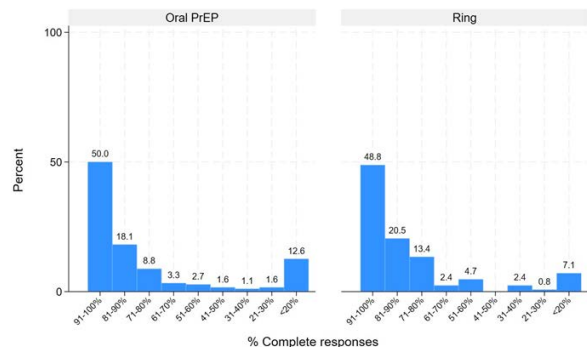


Figure 1: Response Rates.

Conclusions: It is feasible to collect PEU data using a phone-based, self-reporting system, given high response rates and reported ease of use among users of either PrEP product. Additional validity assessments for self-reported PEU will further examine the method's utility, and advance user-aligned PrEP programming.

WEPE081

Adopting client-centered adaptations to maintain HIV prevention services among at-risk LGBTQI+ persons following passage of Uganda's Anti-Homosexuality Act (AHA) 2023

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Background: Uganda's Anti-Homosexuality Act 2023 (AHA)—signed into law on May 26 and largely upheld by the Constitutional Court April 3, 2024—mandates up to life imprisonment or death penalty for individuals convicted of promoting or engaging in "homosexual behavior." AHA exacerbates already well-documented increased HIV acquisition risk among LGBTQI+ persons.

USAID worked with key population (KP)-led civil society organizations (CSOs), the Ministry of Health (MOH), and Uganda AIDS Commission (UAC) to develop a multi-prong AHA adaptation package to ensure HIV service continuity: 1) Enhanced physical and data security at KP drop-in cen-

ters (DICs); 2) KP-led and community-based differentiated service delivery approaches; and 3) Rapid legal and social support response for LGBTQI+ clients facing arrest, eviction, and assault. Uganda formed a national multisectoral Rapid Response Team—with Global Fund support, and with representatives from government, donors, and communities—to ensure continuous engagement and monitoring, in complement with additional independent USAID and CSO-led monitoring platforms.

Methods: We analyzed HIV service delivery data reported in an online secure KP tracker data system and corresponding financial expenditure data during March-December 2023. We also routinely engaged KP-led CSOs to triangulate data with firsthand reports via KP CSO meetings, phone calls, and community-led monitoring consultations.

Results: There was a 60% decrease in HIV prevention service uptake among KPs at PEPFAR-supported community DICs from May 6-June 24, 2023. Service uptake thereafter rebounded to pre-AHA levels beginning in late June 2023 onward. DIC security incidents rapidly increased and then reduced by 94% between April 2023 (following initial passage of the bill) through February 2024. USAID-supported emergency activities responded to 2,323 incidents from June 2023-February 2024 (evictions-42%, threats/discrimination-24%, assault-17%, and arrests-3%). AHA-specific adaptations came at increased cost: USAID partners doubled planned KP budgets to accommodate pivots (July-September 2023).

Conclusions: Working closely with KP communities, Government, and CSOs to co-create HIV adaptations, combined with increased funding for adaptations and emergency response support, helped ensure continuity of HIV prevention service uptake among LGBTQI+ in the first six months following AHA.

These findings may inform stakeholders in Uganda's HIV and AIDS program and those in the other countries considering similar laws.



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WEPE082

Increased uptake of services for adolescents and young adults through community-based integrated Sexual Reproductive Health and HIV Services: a cluster-randomized stepped-wedge trial, KwaZulu Natal, South Africa

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Background: KwaZulu-Natal (KZN) has high HIV, sexually transmitted infections (STI), and teenage pregnancy rates. Adolescents and young adults (AYA) face barriers accessing facility-based primary health care. We describe AYA uptake of services through accessible youth-friendly, mobile sexual reproductive health (SRH) and HIV services in northern KZN.

Methods: From 06 June 2022 to 05 March 2024, we conducted a cluster randomized stepped-wedge trial (SWT) in 40 communities in rural KZN (*ClinicalTrials.gov Identifier – NCT05405582*). Communities were randomly allocated to receive the early or delayed roll-out of the intervention: trained peer-navigators mobilised AYA into nurse-led mobile clinics that visited each community regularly and provided SRH, HIV testing, and status-neutral HIV care or prevention (ART or PrEP). Here we report on the pattern of services received in the mobile clinics during the first period of the SWT (early intervention).

Results: From 06 June 2022 to 05 March 2024, 2904/13,000 (22% of AYA population) attended the mobile clinics. The median age was 22 years (interquartile range 18–26), 35% (n=1019) were aged 20–24, and 58% (n=1686) were female. About 98% (n=2847) received point-of-care HIV testing, with 10% (n=260) being found to be living with HIV of which 4% (n=106) were newly diagnosed and started on ART. About 40% (n=1157) of those who were HIV-negative started PrEP. About 65% (1088/1686) of females received contraception and 84% (1000/1218) of men were circumcised. About 5% (55/1254) of women tested positive for pregnancy at baseline. Among 663 (56%) who were offered a PAP smear, 5% (n=33) accepted it and 5% (1/21) had an abnormal result. Of 1980 that tested for gonorrhoea, chlamydia, or trichomonas sexually transmitted infections (STIs), 29% (n=564) tested positive for any curable STI, and 36% (416/1159) were women. The most common STI detected was chlamydia 24% (n=465) and was higher among women (28% [327/1159]).

Conclusions: Community-based mobile youth-friendly integrated SRH and HIV services reached AYA, including young men, with high unmet sexual health and HIV care and prevention needs in this rural community demon-

strating that these services have the potential to augment South African Department of Health services, to support access for AYA in rural communities.

WEPE083

Patterns of PrEP use among women in the context of choice: early results from CATALYST, an implementation study offering oral PrEP and PrEP ring across five African countries

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Background: Biomedical HIV prevention options are expanding. However, PrEP use patterns in the context of choice remain unknown. The PEPFAR/USAID-supported CATALYST study aims to understand how different products are used among women offered PrEP choice.

Methods: CATALYST is initially offering choice between oral PrEP and PrEP ring to women attending public health sites across Lesotho, Kenya, South Africa, Uganda, and Zimbabwe.

We analyzed cohort questionnaire data and clinic records (May–December 2023) using descriptive statistics to assess method initiation (within 14 days of product receipt), one-month refill, and total PrEP volume dispensed; logistic regression to assess factors associated with one-month refill; and survival analysis to assess time until first interruption in PrEP use/supply (PrEP supply exhausted without refill within 30 days or until PrEP stopped).

Results: Of 1,078 PrEP-naïve participants enrolled for ≥2 months, 97.0% of those reached reported initiating PrEP within 14 days (n=748/771), 96.2% for oral and 99.1% for ring. Refill return at one month was 33.9% for oral and 50.7% for ring. Ring initiators had higher odds of refill compared to oral PrEP initiators (aOR=2.09, 95% CI: 1.56–2.80, p<0.001). Women aged 15–24 years had lower odds of refill compared to older women (aOR=0.62, 95% CI: 0.46–0.82, p=0.001).

Of participants with ≥1 refill visit, 44/499 (8.8%) switched methods at least once, with 19/323 (5.9%) switching from oral to ring and 25/176 (14.2%) from ring to oral (p=0.002). Fifty percent of oral PrEP initiators versus 38% of ring initiators had interruption by day 72. Among those who returned for their one-month refill, subsequent risk of interruption was similar across methods (HR=0.85, CI: 0.52–

1.43, $p=0.55$). Since study start, twice the volume of oral PrEP (1773 months' supply) has been dispensed compared to ring (831 months' supply).

Conclusions: PrEP use varies by product in the context of choice, with initial refill return higher for ring. Adolescent girls and young women, regardless of method chosen, had lower odds of initial PrEP refill, suggesting more efforts are needed to support this group. Early product switching is occurring in <10% of PrEP initiators. Longer-term follow-up will better inform use patterns.

WEPE085

Access to HIV PrEP in Europe and the Americas: findings from a survey using geospatial dating applications

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Background: Access to HIV Pre-exposure Prophylaxis (PrEP) is crucial to meet 2030 UNAIDS goals. Identifying groups with unmet demand and access barriers globally can inform advocacy and policy making.

Methods: We conducted a secondary analysis of a survey of gay men, bisexual men, other men who have sex with men, trans and gender diverse people using geospatial dating applications. WHO launched this survey in May 2023 in 23 countries to identify behavioural adaptations due to the mpox outbreak. Multivariate regression modelling was used to estimate adjusted prevalence ratios (aPR) with 95% confidence intervals (95%CI) associated with using PrEP, and factors associated with considering starting PrEP soon among those not using PrEP.

Models were adjusted for age group, gender identity, sexual orientation, history of sex work and world region: Western Europe (Belgium, France, Germany, Ireland, Italy, Netherlands, Portugal, Spain, Switzerland, UK), Northern America (US, Canada), Latin America (Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Mexico, Peru), and Eastern Europe and Western Balkans (EEWB - Poland, Serbia).

Results: Among 11,708 HIV-negative participants, 34.8% ($n=4,076$) reported currently taking PrEP. Of those not taking PrEP, 30.1% (2,295/7,632) considered starting it soon. PrEP use varied widely by region, and was highest in Western Europe (40.0%) and North America (56.4%) and lowest in Latin America (19.3%) and EEWB (18.6%, $p<0.001$). Considering future PrEP use was highest in Latin America (37.6%) and EEWB (30.9%, $p<0.001$).

In adjusted regression models, those in Latin America (aPR=0.54, 95%CI=0.50-0.58), in EEWB (aPR=0.51, 95%CI=0.41-0.63), aged 18-25 years (aPR=0.52, 95%CI=0.46-0.59), aged 55+ years (aPR=0.83, 95%CI=0.77-0.89), or not

identifying as gay were less likely to be using PrEP compared to their counterparts. Participants in Latin America (aPR=1.39, 95%CI=1.29-1.50), aged 18-25 years (aPR=1.22, 95%CI=1.11-1.34), or who had never done sex work (aPR=1.18, 95%CI=1.05-1.32), were more likely to consider starting PrEP soon, whereas those aged 55+ years (aPR=0.75, 95%CI=0.66-0.84) were less likely to consider starting it.

Conclusions: Differences in PrEP use and consideration were present across regions and age groups. Unmet demand in Latin America and EEWB, and for younger people, is evidenced by lower use and increased consideration; programmatic scale-up is needed to meet this demand.

WEPE086

Early lessons from FASTPrEP: Greater access options increased PrEP persistence in young people accessing community based sexual and reproductive services in Cape Town, South Africa

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Background: Oral PrEP is effective in all populations, but non-persistence has undermined effective use in some. FASTPrEP is a community-wide implementation study in Cape Town, South Africa designed to evaluate whether greater PrEP access via differentiated service delivery may enhance persistence among diverse young people (15-29 years) offered comprehensive sexual health services.

Methods: FastPrEP introduced multiple PrEP service delivery access points in a phased approach between August 2022-November 2023. These included 4 mobile clinics and 12 fixed public health facilities for PrEP initiation and outlets for PrEP maintenance in the form of school access ($n=12$), and a community-wide courier service. Young people could choose where they would like to access PrEP and switch to different maintenance outlet as needed.

Four participant cohorts were defined based on their PrEP initiation date and grouped according to the four-month intervals (Cohort 1: August-November 2022; Cohort 2: December 2022-March 2023; Cohort 3: April 2023-July 2023; Cohort 4: August-November 2023) of the phased PrEP delivery platform ramp-up.

A Kaplan-Meier survival analysis was used to estimate PrEP persistence (defined as ongoing PrEP beyond the month 1 visit) at each follow-up visit (1- 4 months after PrEP initiation). The log-rank test was used to compare PrEP persistence between each of these cohorts.

Results: Of the 2648 people (2276 mobile clinic and 372 government health facilities) who initiated PrEP and attended their month 1 PrEP refill visit, the median age was 23 (IQR 19-27) years and 1625 (61.4%) were young women. PrEP was initiated by 370(14.0%), 424(16.0%), 947(35.8%),



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and 907(34.3%) people between cohorts 1 to 4, respectively. PrEP persistence at 3 months was 49.9% (95% CI: 44.5%-55.1%), 48.1% (95% CI:42.6%-53.3%), 59.7% (95% CI:56.3%-62.9%) and 62.5% (95% CI:59.1%-65.6%) for cohorts 1-4, respectively.

The median persistence time for early cohorts (1 and 2) was 3 months extending to 4 months in later cohorts (3 and 4) ($p=0.02$).

Conclusions: This preliminary evaluation of the FASTPrEP project indicated that early oral PrEP persistence (beyond month 1) increased among young people accessing community and facility-based PrEP when PrEP access and distribution outlets increased.

WEPE087

Missed opportunities for HIV prevention interventions during the Mpox outbreak in Mexico City. A cascade of prevention approach

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Background: The Mpox epidemic in 2022 and 2023 uncovered the need to offer HIV prevention services to people diagnosed with Mpox who had substantial risk of HIV. From May 2022 to December 2023, 1,019 cases of Mpox were confirmed in 2 Mexico City clinics dedicated to HIV prevention and treatment. One third of cases occurred in people with no known HIV infection, who should have been tested for HIV and linked to pre-exposure prophylaxis (PrEP).

We propose and construct a prevention cascade with the objective to evaluate the effectiveness of the Mexico City HIV Preventive Program in Mpox cases.

Methods: A PrEP cascade approach was elaborated considering Mpox cases as the first pillar (Focus population), people who had a baseline HIV test performed as the second pillar (Coverage) and those who were linked to prevention services at the end of isolation as the third pillar (linkage).

Population was segregated according to HIV risk and PrEP usage. Missed opportunities were defined as an HIV incident case in the focus population through PrEP.

Results: 299 cases of Mpox without HIV infection were considered as the focus population. Testing coverage was 99.1%, 1 case was not tested and 8 new cases of HIV (2.7%) were diagnosed. Among the 290 HIV-negative cases, 102 (35%) were on PrEP, and 188 (65%) were not. By March 31st 2024, 204 (69%) had at least one subsequent HIV test and PrEP coverage rose to 78%. Retention rate was higher in people with substantial risk (69% vs 42%), persons in PrEP (98% vs 55%) and with history of chemsex (88% vs 68%).

4 new cases of HIV were detected in target population without PrEP, one of them was thought to be in window period at the moment of Mpox diagnosis and was confirmed at the end of isolation.

Conclusions: We documented three cases of missed opportunities for HIV prevention and a suboptimal proportion of high-risk population linked to PrEP. The cascade of prevention of HIV in Mpox cases served as a tool to evaluate the performance of preventive services in these large outpatient care facilities in Mexico City to establish improvement actions.

WEPE088

A PrEP demonstration study to Herald PrEP Scale Up at the National Level: the experience of ImPrEP in Peru

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Background: Demonstration studies of health interventions can, when implemented in partnership with the national health sector, play important roles in the subsequent national scale-up of those interventions. This may be particularly relevant in complex interventions such as offering daily oral HIV pre-exposure prophylaxis for key populations. ImPrEP was a demonstration study of daily oral PrEP implementation in public facilities in Brazil, Mexico and Peru, led by Fiocruz.

Herein we examine the experience of the ImPrEP demonstration study in Peru, implemented by Universidad Cayetano Heredia (CISSS/UPCH) in collaboration with the National HIV/STI/VH Prevention and Control Program (PCVIH) at the Ministry of Health (MoH), to prepare for the implementation of a national PrEP delivery strategy.

Methods: The processes concerning ImPrEP planning and implementation in Peru were analyzed, including the CISSS/UPCH team interactions with the PCVIH/MoH and the HIV/STI Reference Centers during ImPrEP. We then documented the steps taken by the PCVIH/MoH to implement a country-wide PrEP delivery strategy. Herein we discuss our findings and include feedback from PCVIH officials and other stakeholders.

Results: Since its inception, the PCVIH/MoH committed to supporting the demonstration study in multiple public facilities, which required a MoU and special arrangements for training, staffing and logistics. CISSS/UPCH implemented the study in 10 sites (5 cities, 2018-2021); and enrolled/followed nearly 2000 men who have sex with men and transwomen. Meetings with PCVIH/MoH were

held 3-4 times/year, and progress reports with accomplishments, emerging issues and solutions were delivered to them biannually. After study closure (December 2021), CISSS/UPCH offered support for PrEP implementation, but the COVID emergency delayed immediate action. In June 2023, a country-level public MoH PrEP program for key populations was approved. The ImPrEP experience facilitated immediate implementation and quick inclusion of several new sites per month. CISSS/UPCH has continued to support community dissemination.

Conclusions: ImPrEP expresses the potential achievements of a valuable, transparent collaboration between academia and government that created demand and advocated for PrEP, allowed for the development of various PrEP processes, and provided other forms of support, leading to the quick implementation of the national PrEP strategy in Peru.

WEPE089

Pattern of oral pre-exposure prophylaxis use and self-reported reasons for discontinuation among key population in Nepal

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Background: Nepal has made progress towards HIV epidemic control, but an estimated 680 new infections in 2021 suggests outstanding gaps to access prevention services. Nepal introduced daily oral HIV pre-exposure prophylaxis (PrEP) in August 2020 to prevent HIV among key and priority populations, but continuation rate following initiation have been low.

This study explores the reasons of PrEP discontinuation among individuals initiating PrEP with support from PEP-FAR/USAID supported Meeting Targets and Maintaining Epidemic Control (EpiC) Project.

Methods: The study team analyzed routine program database information to quantify discontinuation and self-reported reasons of discontinuation collected during outreach or phone follow up over a year-long period among a cohort of individuals initiating PrEP in March 2021 and followed till 2022. Reported reasons of discontinuation were classified into thematic categories to facilitate descriptive statistics.

Results: Among 986 individuals who initiated PrEP (41% MSM, 39% FSW, 19% transgender people and 1% priority populations), only 28 (3%) continued to one-year follow up while 347(35 %) had on and off use in the following year. Among 958 (97%) who experienced discontinuation, 653 (68%), 159 (17%), and 88 (9%) did so within the first, three and six months of initiation, respectively, and 453 (47%) subsequently reported a primary reason for discontinuation. The most reported reasons for discontinuation were reductions in risk behavior (39%), barrier to access

due to mobility, COVID-19-related restrictions (34%) and individual/social reasons like PrEP denial, forgetting appointments, and social stigma (19%) and side effects (6%). The proportion of discontinuation was highest among FSW (50%), followed by transgender (41%) and MSM (35%). Among 29 individuals who discontinued and reported being in sero-discordant relationships, 38% cited viral load suppression of their partner as a reason.

Conclusions: Reductions in risk behavior were the most reported discontinuation causes, but most individuals who provided feedback cited other barriers to access without indications of reduced HIV infection risks.

Taken alongside of the fact that most who discontinued did not return for clinical visits or could not be reached for follow up, the provision of mobile, community-based, and online PrEP access strategies may play important roles in sustaining PrEP access among those who may benefit.

WEPE090

Considerations for implementing PrEP choice (oral PrEP and PrEP Ring) through Community Based Service Delivery: early findings from the DREAMS PrEP choice study

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Background: Long-acting PrEP methods have the potential to further reduce HIV acquisition and increase uptake among adolescent girls and young women (AGYW) by offering alternative HIV prevention options. The monthly Dapivirine Vaginal Ring (PrEP ring) approved for use in South Africa was offered alongside oral PrEP in a USAID funded DREAMS community-based PrEP programme in Johannesburg, South Africa. We describe implementation considerations for delivering PrEP choice across 36 community sites.

Methods: The DREAMS PrEP Choice study is an implementation science study delivering PrEP choice to women 18 years and older at community-based sites (safe spaces, education and training institutions) through mobile clinics or pop-up gazebos. We extracted data from the routine patient management system (REDCap) and a focus group discussion with nurse practitioners. Quantitative data was presented descriptively whilst qualitative data was analyzed using content and thematic analysis.

Results: Between October 2023 and March 2024, 589 participants were enrolled and offered PrEP choice, with 73% being 18-24 years old. Participants accessed services at community sites (50%) and institutions of education and training (44%). The majority (71%) of participants chose oral PrEP with 28% choosing PrEP ring, 1% no method. The majority of participants accessed services through



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mobile truck (n=322, 55%) vs pop-up gazebo (n=267, 45%). Most participants who chose a ring (28%) preferred a nurse to insert it on site (n=96, 59%). On average offering choice of an additional PrEP product took 7 minutes longer than where beneficiaries were only offered one method. Providers reported that delivery of PrEP Ring in a community-based setting is feasible, particularly with adequate training and mentorship in the early stages of introduction.

However, consistent access to running water to conduct urine pregnancy testing to rule out pregnancy among ring users as per national guidelines was a barrier.

Conclusions: As one of the first community-based programs offering PrEP choice, our study found that PrEP choice is feasible, and participants are willing to use PrEP ring.

However, a few implementation considerations need to be noted when offering PrEP ring, understanding where the demand is, service delivery conditions like access to toilets, ensuring privacy and time required to offer informed choice.

WEPE091

Early PrEP discontinuation amongst adolescents accessing services through a DREAMS community-based programme

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Background: Despite South Africa having the largest oral Pre-Exposure Prophylaxis (PrEP) programme in the world, PrEP continuation remains a challenge, with less than 50% of PrEP users known to come back at month 1.

This study examines factors associated with early oral PrEP discontinuation among AYP, who have the highest national HIV incidence, who were provided with PrEP through mobile health services in 14 districts across seven provinces in South Africa.

Methods: We analysed longitudinal secondary socio-demographic, vulnerability, clinical, contraception, STI management and laboratory data from clinical records of 105,234 beneficiaries who initiated PrEP between October 2022 and September 2023, from a USAID funded HIV and Violence Prevention programme (DREAMS) in South Africa. Using STATA version 18, we used mixed effects logistic regression to determine factors associated with early PrEP discontinuation, defined as returning for a PrEP prescription pick up after 30 days of the scheduled pick-up date.

Results: The median age at oral PrEP initiation was 19 years (IQR: 17-21). Eighty-nine percent of PrEP users were females; the highest proportion of clients receiving PrEP came from the large metropolitan cities (Johannesburg: 14% and Cape Town: 11%). Fifty-eight percent of females (63,082/ 107,936) and 55% (7,391/13,400) of males reported

early PrEP discontinuation. Having sex under the influence of alcohol in the past year among both females and males showed higher odds of early PrEP discontinuation (aOR = 1.19, 95% CI:1.09-1.30, and aOR=1.90, 95% CI:1.41-2.57, respectively).

For both females and males, an STI diagnosis[4] (ever) (aOR=0.86, 95% CI:0.77-0.96, and aOR=0.50, 95% CI:0.31-0.79, respectively); and condomless sex at last sex act (aOR=0.78, 95% CI:0.74-0.82, and aOR=0.68, 95% CI:0.55-0.84, respectively) had lower odds of early PrEP discontinuation. Using injectable contraceptives among females (aOR=0.91, 95% CI:0.86-0.96) or pill (aOR=0.83, 95% CI:0.74-0.93) showed lower odds of discontinuing PrEP early.

Conclusions: Our study demonstrates an urgent need for strategies to expand PrEP choice among AYP to include methods which may yield better continuation outcomes. This should be done through strengthened SRH (STI management and contraceptive) service delivery, alcohol cessation initiatives and client centred counselling focusing on risk perception messaging which supports clients to improve their PrEP use.

WEPE092

Uptake and observed persistence in an urban remote PrEP follow-up program for predominately Black and Latino sexual minority clients in Miami, Florida

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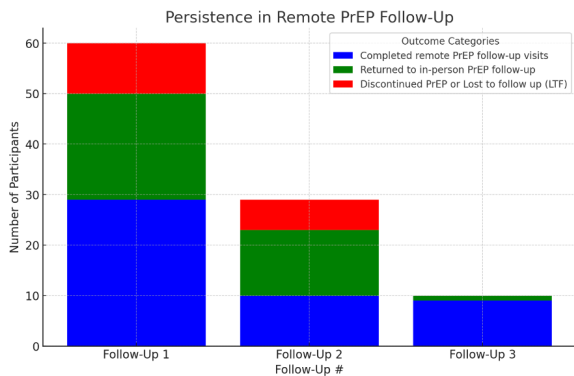
Background: Barriers to pre-exposure prophylaxis (PrEP) care and persistence include structural-functional limitations that may potentially be addressed by remote PrEP follow-up. We assessed uptake and persistence in PrEP care among those offered remote PrEP follow-up.

Methods: From February 2022 to December 2023, 225 PrEP clients were approached, 161 screened and offered remote follow-up, and 60 elected to enroll in remote follow-up. Enrolled clients were offered three quarterly remote visits with planned in-person return for the 12-month visit. Remote visits involved specimen self-collection (mail-in kit), remote provider check-in, and electronic PrEP prescription. All services were offered at no cost.

Descriptive statistics were used to summarize participant characteristics. Chi-square, Fisher's Exact, and t-tests were employed to compare those who completed all planned remote PrEP visits to those who did not.

Results: Most screened clients (101/161; 62.7%) chose in-person over remote care. Clients choosing remote care predominately identified as white-Hispanic (73.3%), Black (13.3%), and male (98%); 63.3% were born outside the U.S. Completion rates for the first, second, and third remote visits were 29/60, 10/60, and 9/60, respectively. Factors associated with completing all 3 visits included increased age ($P<0.01$) and having more in-person PrEP visits prior

to enrollment ($P < 0.01$). Of initially remote clients, 44/60 returned to in-person care; 16/60 were lost to follow-up (Figure). Difficulty with specimen self-collection and mailing were the most common reasons for discontinuation.



Conclusions: Remote PrEP follow-up may be an acceptable and convenient alternative for some BLSGM, particularly older individuals well-established in PrEP care. However, more clients chose in-person visits over the remote program, and of those electing remote follow-up most returned to in-person care prior to program end. Additional modifications may be needed to broaden the appeal and sustainability of remote PrEP follow-up.

WEPE093

Scaling pre-exposure prophylaxis (PrEP) through Global Fund grants: a comparative analysis of prioritized strategies and innovations in Kenya, Mozambique, Nigeria, Uganda, and Zambia

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Background: Kenya, Mozambique, Nigeria, South Africa, Uganda, and Zambia collectively accounted for over 60% of PrEP initiations in 2022, but saw >400,000 new HIV acquisitions that same year, highlighting persistent unmet need for prevention. With an increased focus on prevention in the Global Fund (GF)'s strategy and additional funding for PrEP in these six countries through the Children's Investment Fund Foundation (CIFF)'s innovative Matching Fund, the 2024-2026 GF implementation period offers a critical opportunity to expand PrEP coverage, generate evidence, and measure impact of PrEP delivery at scale through Ministry-owned programming.

Methods: GF grants fund three-year implementation periods, driven by collaborative planning and country dialogues, engaging communities, government, private sector, donors, and implementers. This process culminates in submission of prioritized interventions in funding requests. Through the CIFF-GF Matching Fund partnership, six selected countries were eligible to receive an additional \$25 million to be focused on PrEP.

This analysis compared prioritized PrEP interventions in five Matching Fund countries that submitted funding requests in 2023 (South Africa will submit in 2024) to identify themes and approaches to monitor during implementation.

Results: Across all five countries, increased allocation of funding towards PrEP was incentivized through access to supplementary finance through the Matching Fund. Prioritized activities to increase PrEP scale included expanding provider training and development or revision of national PrEP strategies and guidelines.

All five also included activities to support introduction of novel PrEP modalities – long-acting injectable cabotegravir, the dapivirine vaginal ring, and/or event-driven PrEP. Introduction activities varied from direct procurement, piloting, and provider capacitation to introduction plan development and health system preparation.

All five prioritized expansion of differentiated service delivery, with varying strategies and models.

For example, Uganda and Kenya prioritized pharmacy PrEP delivery. Nigeria and Mozambique also referenced pharmacy models, with a focus on pharmacy-based testing, which could support linkages to PrEP. Zambia prioritized youth-friendly PrEP services and integrated sexual health clinics.

Conclusions: All five countries included ambitious PrEP scale-up plans, expanding innovative delivery models and PrEP options. Throughout GF implementation, effective monitoring, including community-led, alongside targeted technical assistance will be crucial for tracking the impact of these strategies and driving course correction.





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WEPE094

Willingness to pay for HIV pre-exposure prophylaxis among men who have sex with men and transgender women in 11 low-and-middle income countries in Asia: implications for access to long-acting Cabotegravir

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Background: In Asia, a significant proportion of men who have sex with men (MSM) and transgender women (TGW) are not accessing PrEP despite an indicated demand and need. New products such as long-acting Cabotegravir (CAB-LA) may help to address unmet PrEP need where affordable.

We assessed willingness to pay (WTP) for PrEP among MSM and TGW and compared it to two CAB-LA market price benchmarks:

- 1) known access pricing for Africa and
- 2) an estimated price for Asia.

Methods: We conducted an online cross-sectional survey among HIV-negative MSM and TGW aged ≥ 18 years, in 11 low-and-middle income countries in Asia in May-November 2022. Participants were asked about PrEP use history, preferences for different PrEP products (including CAB-LA) WTP for PrEP. Participants were dichotomized as WTP at least 30USD or per 200USD per CAB-LA injection or not. We estimated the percentage increase of WTP from lowering the price per injection from 200USD to 30USD.

Results: Among 10,689 MSM and 1,260 TGW, 3,521 (29.5%) were not willing to pay anything for PrEP. Among 3,944 PrEP-naïve participants who wanted PrEP 28.0% reported it was too expensive. Among those who discontinued PrEP (n=934), 16.6% stopped due to cost. Of all participants (n=11,949), the potential cost of CAB-LA was a significant concern (n=3,724, 31.2%). Of the 7,681 MSM and 747 TGW willing to pay for PrEP, 24.7% MSM and 13.9% TGW were willing to pay at least 30USD per injection and 1.9% MSM and 0.5% TGW were willing to pay 200USD. Countries with the largest overall WTP were China (63.5% WTP at 30USD and 5.7% WTP at 200USD), Malaysia (24.2% WTP at 30USD and 1.0% at 200USD), Thailand (26.4% WTP at 30USD and 3.4% at 200USD) and Vietnam (22.6% WTP at 30USD and 0.6% WTP at 200USD).

Conclusions: Price really matters when it comes to MSM and TGW reporting WTP where at the current access price for CAB-LA in Africa (30USD/injection) nearly a quarter would be WTP while at 200USD per injection, fewer than

2% were WTP. Current CAB-LA pricing for Asia presents significant inequity; efforts must be made to reduce the price and ensure equitable access.

Testing: Technology, coverage, viral load, point of care and CD4 count

TUPE097

Importance of extramural HIV and syphilis prevention devices among key populations in Córdoba Argentina

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Background: Extramural prevention devices are established to expand the offer of HIV and syphilis diagnosis in various contexts:

- 1) general population (GP: musical shows, youth meetings and social activities in the suburb),
- 2) permanent stand (PS: afternoon devices in public spaces in the center),
- 3) key populations (KP: coordinated with NGOs of cis and trans sex workers and LGTTTBQ+ social events); and,
- 4) pregnant people and their partners (PP: during the distribution of trousseau).

Access is provided to quality information, prevention measures and rapid diagnostic tests (RDTs); promoting healthy practices in sexual relationships and facilitating inclusion in the health system.

The objective of this work was to analyze the results obtained for RDT during 2021-2023 according to the different devices' context, to establish the importance of the different strategies established.

Methods: Counseling and RDT for HIV and syphilis were carried out, according to current national algorithms, law and international recommendations. Confirmatory tests were offered to people who tested positive; follow-up for treatment or other interventions were carried out through telemedicine. Using the Chi-Square test, the significance of the differences found in PS, PP, KP in comparison with GP was evaluated.

Results: As shown in Table, a total of 17,318 people underwent RDT in 723 activities. 1,237 tested positive for syphilis (7.1%), and 197 tested positive for HIV (1.1%). Positivity for

HIV and syphilis found in the activities involving KP were significantly higher than those obtained for PG (HIV: 2.0% vs 0.7%; $p < 0.00001$; syphilis: 12.4% vs 6.0%; $p < 0.00001$). Positivity for HIV found in PS was significantly higher than that obtained for PG (HIV: 1.2% vs 0.7%; $p = 0.036$).

TYPE OF ACTIVITY	ACTIVITIES (n)	RDT (n)	SYPHILIS + (n)	SYPHILIS + (%)	HIV + (n)	HIV + (%)
GP	214	5,835	350	6.0	42	0.7
PS	352	9,303	630	6.8	113	1.2
PP	15	119	2	1.7	1	0.8
KP	142	2,061	255	12.4	41	2.0
TOTAL	723	17,318	1,237	7.1	197	1.1

Conclusions: The accessibility and acceptance of the prevention devices in KP and PS are fundamental for HIV diagnosis. Activities carried out among KP should be central, due the higher positivity observed for both HIV and syphilis with respect to the general population. Implementation of HIV self testing in KP is soon to be initiated.

TUPE098

Virological non-suppression among socio-economically disadvantaged children and adolescents receiving ART at two peri-urban HIV clinics in Kampala, Uganda: a mixed methods cross-sectional study

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Background: Despite advancements in ART accessibility over the past decade, there is a growing concern of sub-optimal treatment outcomes among children and adolescents living with HIV (CALHIV) in sub-Saharan Africa. Even with the HIV services offered to CALHIV, many psychosocial and economic issues remain inadequately addressed by ART programs.

We assessed psychosocial, poverty-related challenges, and virological non-suppression among CALHIV receiving ART at two peri-urban HIV clinics in Kampala, Uganda.

Methods: We conducted a mixed-methods cross-sectional study at Mbuya and Kinawataka HIV clinics in Kampala between January and December 2023 among socio-economically disadvantaged CALHIV aged 1-19 years who had been on ART for at least 6 months. Data on socio-demographics, clinical, and psychosocial-economic characteristics were collected.

The primary outcome was virological non-suppression defined as viral load ≥ 200 copies/mL. Multivariable Poisson regression analysis with robust variance was used to identify factors associated with virological non-suppression. Eligible and consenting adolescents and caregivers of children with virological non-suppression were engaged in in-depth discussions using interview guides to

understand the challenges they face during care. Qualitative data were analysed using a thematic content approach.

Results: We assessed 192 CALHIV, mean age was 13.2 years (SD=4.3), over half (55%) were female and 10% were non-suppressed. Nearly all (99%) initiated ART at WHO stage I. Median duration on ART was 9.1 (IQR= 5.7-10.6) years and median CD4+ T-cell count at baseline was 635 cells/mm³ (IQR= 344-1042). The majority (97%) were on first-line ART regimen and >95% adhered to their treatment. Most (82%) CALHIV initiated ART at the clinic. Most (69.8%) CALHIV were on Facility-Based Group Model (FBGM) of care followed by Facility-based Individual Model (FBIM) at (27.6%).

At adjusted analysis, CALHIV on the FBIM were at a lower risk of non-suppression (aRR=0.83; 95% CI: 0.72-0.96). Qualitative findings indicated that most of the CALHIV faced financial constraints, particularly food security and transportation challenges. Additionally, they encountered HIV-related stigma and discrimination, leading to difficulties in disclosing their HIV status.

Conclusions: Given the significant burden of virological non-suppression among CALHIV and the identified psychosocial and economic barriers to treatment success, tailored strategies are needed to enhance viral suppression and achieve the 95-95-95 targets.

WEPE095

"I fear STIs more than HIV": qualitative findings from a randomized trial of integrated PrEP and STI services for transgender women in Uganda

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Background: Tenofovir alafenamide fumarate (TAF) is potentially more efficacious and safer than tenofovir disoproxil fumarate (TDF) for HIV pre-exposure prophylaxis (PrEP) but is understudied in sub-Saharan Africa. To address this gap, we conducted qualitative interviews with transgender women (TGW) in Uganda to explore their experiences with TAF-based PrEP and urine tenofovir testing with drug-level feedback.

Methods: The Tandika PrEP study was a randomized trial that evaluated same-day TAF initiation, the impact of drug-level feedback on PrEP adherence, and integrated PrEP and sexually transmitted infection (STI) services for HIV-negative TGW (NCT04491422). Participants were fol-



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lowed quarterly for 12 months. Scheduled clinic visits included PrEP refills and testing for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in urine.

We conducted a qualitative sub-study with 30 TGW (April 2022-February 2023). TGW interviews explored perspectives on and experiences of:

1. Same-day initiation of TAF PrEP,
2. Urine testing for TFV levels and receiving drug-level feedback, and;
3. Self-collection of samples for STI testing. Qualitative data were analyzed using an inductive content analytic approach.

Results: The median age was 20 years (interquartile range 19–22), and most (70%) engaged in sex work. Integrated PrEP/STI services were valued by this sample of TGW because the convenience of urine testing motivated adherence and allowed for tenofovir and STI detection.

1. Preferred TAF characteristics: TAF-based PrEP was easy to take and not readily identifiable as an HIV-related medication, resulting in less stigma than the better-known tenofovir disoproxil fumarate (TDF). Weight gain associated with TAF use was viewed positively by TGW as a symbol of health and prosperity in African settings.
2. Adherence motivation: PrEP adherence was motivated by a desire not to disappoint healthcare workers; TGW reciprocated adherence support and drug-level feedback by taking PrEP.
3. Facilitating adherence and STI care: Urine testing enhanced STI detection and treatment. Utilization of urine for tenofovir and STI testing motivated the uptake of HIV/STI care, emphasizing the importance of integrated PrEP/STI services.

Conclusions: TAF-based PrEP with real-time adherence monitoring was highly valued by this sample of TGW from Uganda. Integrating PrEP and STI services into differentiated delivery models could increase prevention uptake in this vulnerable population.

WEPE096

Simple and rapid detection of HIV integrase inhibitors bicitegravir, cabotegravir and dolutegravir in blood across clinical benchmark concentrations by lateral flow assay

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Background: Second-generation HIV-1 integrase strand transfer inhibitors (INSTIs), bicitegravir (BIC), cabotegravir (CAB), and dolutegravir (DTG), are leading components of highly potent antiretroviral therapy and long-acting chemoprevention. Rapid detection of relevant concentrations of INSTIs would be useful for: point-of-care (POC) assessment of long-acting PrEP concentrations at clinic

visits or self-monitoring between dosing visits; diagnostic testing settings to assess possible interference with test results; and adherence assessments in clinical studies and surveillance. Here we report a low-complexity lateral flow assay (LFA) that detects BIC, CAB, and DTG in blood and evaluate its performance in discriminating drug concentrations across thresholds for efficacy.

Methods: A competitive LFA specific to DTG, BIC, and CAB was developed with a commercial manufacturer using a highly sensitive and specific monoclonal antibody created at the CDC. The LFA was designed to visually detect relevant INSTI concentrations in 30 µL blood without the need to alleviate protein binding. The evaluation of LFA performance was conducted on fresh whole blood samples spiked with 0, 0.5, 0.75, 1.0, and 1.3 µg/mL of CAB, BIC, or DTG, corresponding to a range of negative, below benchmark levels, borderline target protective levels, and trough therapeutic or protective concentrations achieved for the inhibitors.

Results: The principle of the assay is that two different concentration-dependent test lines diminish with increasing inhibitor concentration in that an absence of both test lines indicates optimal INSTI concentrations. In evaluating the three inhibitors we found increased sensitivity of DTG detection over that for BIC/CAB such that a separate running procedure involving a single dilution was established for DTG testing.

The concentration-dependent disappearance of the test lines allowed for visually discerning INSTI concentrations below (two lines), bordering (one line), and within benchmark protective concentrations in blood. Test results are read in 20 minutes.

Conclusions: The LFA successfully provided rapid detection of clinically relevant INSTI concentrations. The visual results permit assessments of INSTI pharmacokinetics that may inform optimal long-acting dosing intervals for individuals, indicate treatment adherence, and provide confidence that protective levels are present. The ability to use unprocessed whole blood supports simple testing of INSTI concentrations by laboratories, POC clinics, and self-testers.

WEPE097

Exploring disparities in HIV early detection among key populations in Tajikistan

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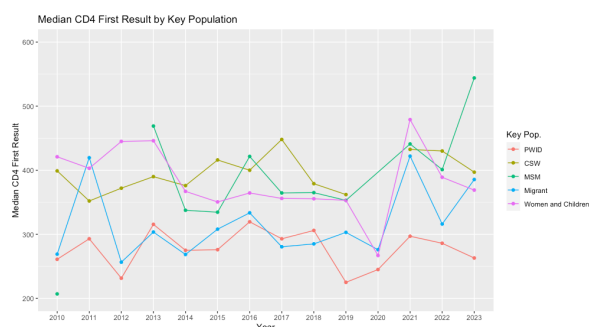
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Background: Key populations in Tajikistan including persons who inject drugs (PWID); commercial sex workers (CSW); men who have sex with men (MSM); Tajik migrants returning from employment outside Tajikistan; and women and children face a notably heightened risk of HIV infection and transmission to others. Early detection of HIV utilizing CD4 count testing (CD4 counts ≥ 350 cells/ μ L) is crucial for enhancing antiretroviral therapy (ART) outcomes.

Methods: We analyzed cross-sectional national HIV data of 9,880 newly detected cases in Tajikistan (2010 to 2023). CD4 first result median was calculated for each year disaggregated by key population.

Results:

Significant disparities were evident among various key populations. Over the time period, CSW, MSM, and women and children consistently exhibited early HIV detection compared to PWID and migrants who consistently exhibited late detection. Women and children were adversely affected in 2020 progressing to late detection for the only time in the period. PWID were adversely affected after COVID-19 as the only key population below the 350 cells/ μ L threshold in 2023. MSM experienced accelerated early detection to nearly 550 cells/ μ L in 2023. Migrants experienced their earliest detection of the time period in 2021 (above 400 cells/ μ L).



Conclusions: Our findings indicate a discrepancy among different key populations with respect to early detection. MSM were consistently detected early with the largest improvement among all key populations during COVID-19. However, PWID faced late detection throughout the entire time period, while migrants experienced improvement to a stage of early detection post-COVID-19. The pandemic

may have accelerated best practices to improve early detection. Further access to CD4 count testing is necessary to determine the stage of progression of HIV and tailor interventions to specific key populations detected at later stages.

Behavioural and social science research

TUPE100

Higher levels of pre-exposure prophylaxis (PrEP) stigma are associated with lower PrEP adherence among adolescent girls and young women in Siaya County, Kenya

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Background: Despite high HIV incidence among adolescent girls and young women (AGYW) in sub-Saharan Africa, rates of effective PrEP use have been low. Qualitative studies suggest stigma is a barrier to PrEP adherence in this population, but there are limited quantitative data on how stigma impacts PrEP adherence. This study sought to test whether PrEP stigma is associated with PrEP adherence among AGYW in Siaya County, Kenya.

Methods: From December 2021–May 2022 we recruited AGYW aged 16–24 who had received a PrEP prescription or refill ≤ 6 months ago. Study staff administered questionnaires and collected hair samples to test for tenofovir, a biomarker of PrEP adherence, at enrollment and Month 3. Stigma was measured with the 17-item Young Women's PrEP Stigma Scale, which we previously developed and validated in this population. Associations between PrEP stigma (total score and anticipated, perceived, experienced, and internalized stigma subscales) and higher PrEP adherence (hair tenofovir >0.021 ng/mg; >2 doses/week) were tested using mixed-effects robust Poisson regression models with a random effect for participant, adjusted for potential confounders.

Results: We enrolled 250 AGYW and 89% completed Month 3. Median age was 22 years, 42% had completed secondary school, and 48% were married. Mean scores were highest for perceived and anticipated stigma (Table 1). On average, participants with 1-point higher total PrEP stigma scores were 39% less likely to have higher PrEP adherence ($p=0.01$; Table 1). Results were similar for perceived and experienced stigma scores, while anticipated and internalized stigma scores were not associated with PrEP adherence.



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Stigma type	Mean (Standard Deviation)	Adjusted Risk Ratio ^c	95% Confidence Interval	P
Total PrEP stigma (range 1-5) ^a	2.3 (0.6)	0.61	0.42, 0.90	0.01
Perceived stigma (range 1-5) ^a	3.1 (1.1)	0.72	0.58, 0.89	0.003
Anticipated stigma (range 1-5) ^a	2.8 (0.9)	0.92	0.74, 1.15	0.48
Experienced stigma (range 1-4) ^b	1.4 (0.7)			
score 1.1–1.5 (vs. <1.1)		0.71	0.37, 1.38	0.32
score >1.5 (vs. <1.1)		0.51	0.28, 0.94	0.03
Internalized stigma (range 1-5) ^b	2.0 (0.6)			
score >2 (vs. ≤2)		1.14	0.74, 1.77	0.55

n=249 participants with 470 visits

^aAnalyzed as a continuous variable; ^bAnalyzed as a categorical variable due to highly skewed distribution; ^cAdjusted for age, education, earning income, DREAMS participation, months since starting PrEP, and any self-reported HIV risk factors.

Table 1: PrEP stigma scores and associations with higher PrEP adherence (hair tenofovir concentration >0.021 ng/mg)

Conclusions: Higher PrEP stigma was a strong predictor of low PrEP adherence among Kenyan AGYW. Stigma reduction interventions, especially those focused on perceived and experienced stigma, could support effective PrEP use in this population.

TUPE101

Empowering voices: leveraging social influencers to champion pre-exposure prophylaxis (PrEP) among young Black and Latino men who have sex with men

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Background: Young Black and Latino men who have sex with men (YBLMSM) are disproportionately diagnosed with HIV in the US and underutilize PrEP, in part due to stigma and medical mistrust.

This study aimed to identify trusted messengers to promote PrEP and test content strategies that would reach this underserved population.

Methods: We piloted a video-based social media intervention aimed at YBLMSM. Steps included focus groups to identify trusted messengers and shape content; collaborating with social media influencers to co-create 8 full-length and 28 promotional videos that shared their experiences with PrEP to promote PrEP awareness, knowledge, and uptake; surveys to assess videos' appeal for

PrEP motivation; and establishing a dedicated website for additional content and PrEP information. Influencers disseminated the promotional videos on Instagram with website links and fostered PrEP discussions with followers. We monitored engagement metrics on Instagram and the website and conducted thematic analysis on Instagram comments about the promotional videos for audience insights. This analysis focuses on findings from the thematic analysis of engagement with social influencers.

Results: Of 166 Instagram comments, 40 discussed social influencers. Two interrelated themes emerged:

Advocacy, reflecting credibility and pride in the messenger, and appreciation of influencers' genuine dedication and altruism (*All the people who died for love are proud that this is even possible, thank u for advocating; I am sooooo excited for this movement; Thank you for your commitment to our community, thank you for doing the work! I love you; Honestly it's ridiculous how so many medical professionals don't know of it in THIS day and age. Thank you for spreading awareness*); and,

Relatability, reflecting representation, appeal, shared identities, trust, and connection with social influencers (*Thank you for being a part of this! I feel like I don't see queer Asians represented in PrEP commercials; Absolutely stunning! I love your look; Beautifully put and continue to be an inspiration!; Love to hear you speak to your experience*).

Conclusions: We demonstrated that social media influencers are trusted, relatable messengers to YBLMSM about the value of PrEP. As community role models, credible influencers can bridge the gap between PrEP awareness and uptake.

TUPE102

Young women's use of existing contraceptive and HIV prevention products and preferences for future multipurpose prevention technologies (MPTs) in Kampala and Nairobi: a respondent driven sampling (RDS) survey

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Background: Adolescent girls and young women (AGYW) in Sub-Saharan Africa are faced with sexual and reproductive health (SRH) challenges, including the need for contraception, HIV, and other sexually transmitted infections (STIs) prevention services.

We aimed to assess preference for future multipurpose prevention technologies (MPTs) for HIV, STIs and contraception, among AGYW in Kampala and Nairobi.

Methods: In November 2022, using respondent driven sampling (RDS), we surveyed women aged 15-24-years who had sex in the last 12-months. Twenty-four initial seeds recruited 322 women. We assessed their use of contraception and HIV prevention, and their preferences for MPT products i.e. type, duration, administration, and preferred delivery point. Data were adjusted for RDS and summarized as means, standard deviation (SD), and frequency distributions.

Results: 322 AGYW were surveyed over 11 waves; mean age was 21years (SD 2.43), 89.5% reported using contraceptives in the last 12-months; 25.2% injectable, 11.4% contraceptive pill, 19.8% emergency pill, 13.7% implant, 1% intrauterine device (IUD), and 18.4% used condoms. 62.4% reported using HIV prevention products in the last 12-months; predominantly male condoms (53.5%), with 6.5% using oral pre-exposure prophylaxis, 2.5% using post-exposure prophylaxis and one unnamed injection.

When asked about future single or multiple indication products, 69.9% preferred MPTs, with 40.6% preferring dual protection against HIV and pregnancy, 23.8% against HIV and STIs, and 5.5% against STIs and pregnancy. Participant's preferred MPT administration routes were oral (49.6%) and injectable (40.2%), with limited interest in implants, vaginal inserts, or skin patches (10.2%). 85% of women preferred long-acting products, with 19.9% choosing 1-monthly, 18.8% 3-monthly, 10.2% 6-monthly and 36.1% at least annually. Most AGYW would prefer to access MPTs at fixed clinics, located inside (48.8%) or outside (32.1%) their communities compared to 5.2% at mobile clinics; 13.9% preferred access at pharmacies.

Conclusions: The study revealed a strong preference among AGYW for MPTs that provide long-term protection against both HIV and pregnancy, delivered orally or by injection, available at fixed clinic settings. Understanding these preferences is critical for designing products that are not only effective but also acceptable and accessible to the women who need them most, ultimately facilitating better health outcomes and broader usage.

TUPE103

Stress-responsive biomarkers and HIV incidence among adolescent girls and young women in rural South Africa: an HPTN 068 analysis

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Background: Adolescent girls and young women (AGYW) experience the highest risk of HIV acquisition on the African continent. Previous research has demonstrated that stressors, such as violence and economic strain, can activate the biological stress response leading to adverse health outcomes. Biological stress has also been associated with HIV progression and pathogenesis but not with HIV incidence.

We therefore hypothesized that elevated stress-responsive biomarkers would be associated with incident HIV among AGYW through changes in immune function and viral infection.

Methods: We conducted a case-cohort study nested within the HIV Prevention Trials Network (HPTN) 068 study among AGYW in rural South Africa. Cases were AGYW who tested HIV-positive during the eight-year follow-up. Controls were unmatched and randomly selected from the HIV-negative population at enrollment. Stored biospecimens from cases and controls were tested for stress-responsive biomarkers at enrollment (2011-2012), including dried blood spots for C-reactive protein (CRP), herpes simplex virus type-1 (HSV-1) antibody titers, and cytomegalovirus (CMV) antibody titers. Biomarkers were operationalized ordinally (CMV and HSV-1: 0=seronegative, 1=low antibodies, 2=medium, 3=high; CRP: tertiles). Cox proportional hazards models estimated the association between each biomarker at enrollment and time to incident HIV.

Results: Among the 949 AGYW in the case-cohort study, there were 175 incident cases during the follow-up period (18.4%). Compared to the lowest CRP levels, medium and high CRP levels were associated with incident HIV (HR: 1.45, 95% CI: 0.95, 2.21; HR: 1.50, 95% CI: 0.98, 2.30, respectively). The relative hazard of incident HIV was also higher among AGYW who were CMV seropositive vs. seronegative (low antibodies HR: 2.18, 95% CI: 1.2, 3.87; medium HR: 2.25, 95% CI: 1.28, 3.95; high HR: 1.78, 95% CI: 0.99, 3.21). Those



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with the highest HSV-1 antibody levels experienced an increased hazard of HIV compared to HSV-1 seronegative AGYW (HR: 1.58, 95% CI: 1.03,2.44).

Conclusions: Stressful life events, which have been associated with herpesvirus infection and reactivation, may increase AGYW's susceptibility to HIV acquisition and impair immune function. HIV prevention interventions should therefore aim to reduce biological stress, possibly by intervening on commonly experienced psychosocial stressors and mental wellbeing.

TUPE104

Reaching young girl who sells sex can potentially improve national achievement: lesson learned from HIV prevention program in 55 districts in Eastern Indonesia

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Background: Despite their vulnerability, there were limited data on young girl who sell sex in Indonesia. Current program targets adult female sex worker (FSW), however during implementation, they also come across young girl who sell sex.

This study aims to analyze data of young girl who sell sex in 55 districts in Eastern Indonesia in 2023.

Methods: The study analysed regular 2023 programmatic data from HIV prevention program for FSW in Eastern Indonesia. Monthly data were collected and reported by outreach workers from 55 districts in Kalimantan, East Java, Sulawesi, Bali, West Nusa Tenggara, East Nusa Tenggara, Maluku, Papua and West Papua. Data collected consist of date of birth, HIV tests, HIV tests result, Initiation of ARV and 3 months retention of ARV. Descriptive analysis was conducted then comparison been made between age groups.

Results: Through 2023, 27% (13,670) of all FSW reached were young girl aged 15-24 years old and 15% were aged < 20 years old. 28% tested in health services, 29% through mobile HIV testing and 26% referred to do confirmatory test after reactive in HIV screening using oral fluid test. Yes to test proportion was higher in younger age group: <20 y.o 62%, age 20-24 y.o 59% and ≥ 25 y.o 54%. 146 HIV cases (22%) were young girl with positivity rate was increase in older group, 1.7%, 1.8%, 2.5% respectively. On the contrary younger age group has higher yes to treat proportion: 73%, 51% and 48%, respectively. Additionally, Young girl has slightly higher proportion in 3-month ARV retention, 38% (aged 15-24 y.o) and 37% (aged ≥ 25 y.o).

Conclusions: With contribution of quarter of HIV cases among FSW, Young girl who sells sex has the highest yes to test, yes to treat and ARV retention proportion compare to adult FSW. By focusing in this age group, Indonesia can potentially improve national achievement of global

HIV target 95-95-95. Indonesian government needs to pay more attention to these vulnerable young groups, ensuring they can receive proper support and access to sexual and reproductive health information and services tailored based on their specific needs.

TUPE105

Drug use risk profiles and associations with depression among Latino MSM in a U.S.-Mexico cross-border region: a latent profile analysis

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Background: Drug use and poor mental health are associated with HIV risk among men who have sex with men (MSM). However, specific drug use profiles and their association with depression among Latino MSM in a United States-Mexico cross-border region remain understudied. We characterized distinct drug use risk profiles among a sample of Latino MSM in San Diego and examined their associations with depression symptoms.

Methods: We employed latent profile analysis (LPA) to characterize drug use risk of baseline data collected from a longitudinal social network study involving 410 Latino MSM living in San Diego, California, between June 2021 and April 2024. Substance use risk was measured with the The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) and depression was measured using the Center for Epidemiologic Studies Depression Scale Revised-10 (CESD-10). Participants were recruited using both in-reach and out-reach approaches, leveraging our study's community partners.

Associations between drug use risk profiles and depression symptoms were examined using linear regression, adjusting for sociodemographic characteristics.

Results: Most participants were under 35 years of age (68.7%), identified their race as 'other' (57.1%), held a Bachelor's degree or higher (53.3%), were born in the U.S. (59.9%), and earned <\$50,000 per year (56.6%). 36.7% of the sample scored ≥10 on the CESD-10, the cutoff indicative of clinical depression. We identified five distinct drug use profiles: no/low drug risk (59.0%), club drug experimenters (27.6%), high club drug risk (5.6%), sleep pill/sedative risk (4.4%), and meth use risk (3.4%). Participants in the sleep

pill/sedative risk (β (95% CI)=4.05(1.52, 6.59); $p=0.002$), meth use risk (β (95% CI)=3.80(0.95, 6.65); $p=0.009$), and club drug experimenter (β (95% CI)=1.27(0.08, 2.46); $p=0.037$) profiles exhibited greater depression symptoms compared to those in the no/low drug risk profile.

Conclusions: Our study identified distinct drug use risk profiles among Latino MSM in San Diego, highlighting associations between specific drug use patterns and elevated depression symptoms.

Notably, sleep pill/sedative, meth use, and club drug experimentation risk were associated with increased depression symptoms, suggesting that Latino MSM may benefit from tailored interventions to enhance mental health outcomes and mitigate HIV risk associated with drug use risk.

TUPE106

Beliefs about toxic interactions between alcohol and PrEP predict use among

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Background: Numerous studies across a variety of populations and settings have shown that among people living with HIV the belief that there toxic interactions between alcohol and ART is common and directly associated with ART nonadherence.

However there has been little research on how these beliefs may impact PrEP use, particularly among key populations such as young MSM where HIV incidence is high and hazardous drinking is relatively common.

Methods: Data were collected as part of the RADAR (n=1,161) longitudinal study of young MSM (mean age = 23). The analytic sample consisted of 506 HIV-negative participants who completed the PrEP-related alcohol interactive toxicity belief items. Hazardous drinking was measured using the well-validated Alcohol Use Disorders Identification Test (AUDIT). Informed by work by Kalichman and Eaton on measuring alcohol-antiretroviral treatment interactive toxicity beliefs we developed a novel 5-item measure assessing individuals' perception of the hazardous effects of mixing alcohol and PrEP ($\alpha = .94$; range: 1-4). PrEP use was assessed by self-report.

Results: 78% percent of participants (n=394) were classified as low risk for alcohol use disorders, 18% (n=91) as moderate, and 4% (n=21) as high risk. 23% (n=118) reported taking PrEP in the past 6 months. Percent agreement with the PrEP-related alcohol toxicity beliefs items stratified by AUDIT score is reported in Table 1.

Higher AUDIT scores were associated with lower toxicity beliefs ($\rho=-0.34$; $p<.0001$). Regression modeling predicting PrEP use found a significant main effect for both AUDIT score (OR=1.17, 95% CI: 1.01-1.34) and toxicity beliefs (OR=0.64, 95% CI: 0.42-0.97) and a significant interaction (OR=0.90, 95% CI: 0.84-0.97; Figure 1 for simple slopes). The

magnitude of rate of change was greatest for participants with the highest toxicity beliefs and lowest for participants with the lowest toxicity beliefs.

Conclusions: Beliefs about toxic interactions between alcohol and PrEP medications were common and significantly association with PrEP use. Given high rates of drinking and the frequency of these beliefs, interventions should be developed to dispel the myth of toxic interactions through medical and social media channels, while acknowledging the case that this is not true for all medications.

TUPE107

Social determinants on HIV in Mexican MSM attending a community center

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Background: Gay and bisexual men in Mexico are part of the key populations with a high prevalence of HIV. Understanding the role of social determinants of health beyond sexual behavior as risk factors for new transmission can help us design local interventions. The objective was to identify the social determinants related to HIV acquisition among gay and bisexual men who were users of the HIV quick test at a community center.

Methods: A cross-sectional study of 2665 men who underwent an HIV test between October 2019 and May 2022. We gathered survey data on Sexual Behavior, other STDs, Social Security, sex workers, Chemsex, partners and relationships, residence, and migration. We then performed a univariate analysis to compare the HIV-negative and HIV-positive populations and identified statistically significant variables for a logistic regression model.

Results: Of the 2665 participants, we identify an HIV incidence of 9% and a syphilis incidence of 10.6% the sample was composed of 87% of gay man and 13% of bisexual man, 15% reported use of substances during sex, with 33% of the sample migrated to Guadalajara, with an average of 7 years living there. 5% of them were sex workers.

The logistic regression revealed that self-report of a high perception risk for HIV (OR= 3.4 P= .0001 CI 95% 2.1-5.7) and having a new diagnosis of Syphilis (OR=4.4 P=.0001 CI 95%=2.6-7.3) were identify as risk factors, while having a stable sexual partner (>6 months) (OR=.5 P=.004 CI95%=.3-.8), having less sexual partners (<5 partners) (OR=.5 P=.04 CI95%=.3-.96) and higher-level education (> High school) (OR=.5 P=.013 CI95%=.3-.8) were found to be protective factors.

Conclusions: Other STD detection services and self-identification of risk are crucial social determinants for the prevention of new HIV diagnosis in community-based settings. There is a need to enhance the services offered and



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increase awareness about this within local communities. The presence of protective factors indicates that structural determinants of sexual relations and education are related, but it is not clear how they specifically contribute to HIV prevention. These findings also suggest that community centers alone may not be sufficient to reach the most vulnerable individuals.

TUPE108

Perceived advantages and disadvantages of PrEP choice by young sexual and gender minority (SGM) in Brazil - a qualitative study

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Background: Efficacy of long-acting injectable cabotegravir (CAB-LA) for HIV PrEP is well known from clinical trials. Nevertheless, research is needed to guide effective strategies for its implementation in real world settings. There is a lack of available data on user perceptions regarding PrEP options. We aimed to assess the perceived advantages and disadvantages of different PrEP options by young sexual and gender minorities (SGM) in Brazil.

Methods: ImPrEP CAB-Brasil is an implementation study of same-day delivery of injectable CAB-LA PrEP for young SGM (18-30 years) in oral PrEP public health clinics in six Brazilian cities. Participants can choose between oral or injectable PrEP. A subset of participants was invited to participate in a qualitative study after PrEP choice. Interviews were recorded and transcribed. Conventional content analysis was used for coding categories based on inductive reasoning process.

Results: Thirty-seven interviews were analyzed (32 cis-gender men who have sex with men, three transgender women, two nonbinary persons; mean age 24 years; 62% Black/Pardo; 32% with secondary education). Perceived advantages of injectable PrEP choice:

- 1) convenience to take once every two months;
- 2) fewer side effects;
- 3) privacy and reduced stigma by family members and others;
- 4) greater confidence, security and protection, without the task of using oral medication.

Disadvantages:

- 1) fear of needles and injections;
- 2) pain at the injection site;
- 3) concern with long duration of appointment disrupting daily routine, especially work;
- 4) suspicion of unknown long-term effects or developing drug resistance.

Advantages of oral PrEP:

- 1) less returns for appointments (every three months);
- 2) easiness in taking medicines anywhere;

- 3) no injections;
- 4) option to stop use if desired or needed.

Disadvantages:

- 1) remembering daily use;
- 2) gastrointestinal and nausea side effects;
- 3) fear of judgment of family members and distrust of partners with disclosure of daily pill.

Conclusions: Thematic descriptions of perceived advantages and disadvantages of each PrEP choice among young SGM from Brazil demonstrated the importance of accurate understanding of PrEP information by users, including perception of clinical, biological and social benefits. Our data may be used to inform health policymakers to develop strategies to support PrEP uptake and adherence.

TUPE109

Exploring relationship dynamics: the impact of disclosure and partner influence on oral and injectable PrEP adherence among users and their intimate partners - HPTN 084 qualitative findings

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Background: Daily oral PrEP and long-acting injectable PrEP are proven to prevent HIV when used as indicated. Their use within intimate relationships may create complex dynamics in communication, trust, and gender roles, potentially influencing adherence. We explored the perspectives, experiences, and relationship dynamics between female users of oral and injectable PrEP and their male partners (MPs).

Methods: This qualitative sub-study was conducted in Malawi, South Africa, Uganda and Zimbabwe from 2021 to 2023. We interviewed 17 purposively selected women (ages 18-37) taking oral or injectable PrEP and 20 intimate MPs (ages 23-39) during the unblinded portion of HPTN 084. One couple was interviewed together, and the remaining interviews were conducted individually. Interviews explored relationship dynamics, disclosure, and partner influence on adherence. Interviews were recorded, transcribed, and translated. Data were coded and organized into matrices and memos to identify and visualize themes.

Results: Female participants were primarily motivated to take PrEP because of concerns about contracting HIV from their MPs. Most participants disclosed trial participation to their MPs after joining, and oral PrEP (but not injectable) use due to challenges with discrete use. Upon disclosure, MPs often reacted with worry, fear, and suspi-

cion, some expressing concerns that the participant was HIV-positive: "I thought she was sick with HIV." Concerns about participant promiscuity and immediate and long-term side effects (particularly during pregnancy) were prevalent among MPs. Some MPs accepted their partner's decision to participate/use PrEP, and suggested HIV testing together.

Although several MPs initially wanted their partners to stop study participation and/or PrEP use, a turning point came after visiting the study site and consulting health-care providers. This experience led to an understanding of the trial/PrEP and many decided to provide instrumental (e.g., pill-taking or injection visit reminders) and emotional support (e.g., encouragement). Several MPs who initially opposed PrEP use later requested and/or used their partner's pills for personal benefit.

Conclusions: This study shows the central role that intimate partners play in influencing trial participation and PrEP use. The findings suggest a need for supportive communication strategies that reach beyond participants to partners and community to dispel myths, alleviate fears, and ensure optimal support.

TUPE110

Spatiotemporal heterogeneity of online HIV Self-testing sales and its potential driving factors in China, 2015-2020: a retrospective nationwide study

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Background: Since UNAIDS introduced HIV self-testing in 2014, its application has been widely adopted globally. Developed in China around 2015, HIV self-testing (HIVST) has seen the online purchase of testing kits via e-commerce platforms emerge as the most significant distribution method. This approach offers numerous benefits, including user-friendliness, speed, and enhanced privacy protection.

Understanding the spatiotemporal heterogeneity of online HIVST purchasing behavior and its potential driving factors in China will help promote the HIV self-testing strategy.

Methods: The online retail data of HIVST kits from two largest e-commerce platforms in China from 2015 to 2020 were collected for this study. The Bayesian spatiotemporal hierarchical model (BSTHM) was used to investigate the spatiotemporal characteristics, to identify the hot and faster spots of online purchased HIVST kits. Furthermore, the BSTHM was used to identify potential driving factors associated with the online purchase, including

college students per 10,000 persons, GDP per capita, net per person, phone per person, population density, road density and HIV screening cases per 100,000 persons.

Results: From 2015 to 2020, the sales of online HIVST kits experienced a dramatic surge, escalating from 837,061 to an astonishing 7,827,411 kits annually, cumulating in a total of 23,987,155 kits sold, with annual peak sales in December. Four economically superior regions in China, the Pearl River Delta, Yangtze River Delta, Beijing and Tianjin areas, and the Shandong Peninsula showed the comparatively higher spatial preference for online purchased HIVST kits. The 38 hot and faster spots were mainly located in north-eastern China (28.9%, 11/38), the Pearl River Delta (26.3%, 10/38) and Beijing and Tianjin areas (15.8%, 6/38).

The college students per 10,000 persons, GDP per capita, net per person, population density and the HIV screening cases per 100,000 persons were identified as the driving factors that were positively associated with the online purchase rate of HIVST kits.

Conclusions: Our study illuminates the spatiotemporal dynamics and driving factors behind online HIVST kit purchases across mainland China, offering pivotal insights for crafting detailed HIVST guidelines. We pinpointed regions with significant demand, guiding policymakers in resource reallocation and HIV care continuum optimization, particularly in identified critical 'hot and faster' areas.

TUPE111

"What will they think when they see me swallowing pills": perceived stigma and non-adherence to pre-exposure prophylaxis among people at high risk of HIV in East and Southern Africa

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Background: Oral pre-exposure prophylaxis (PrEP) is highly effective in preventing HIV transmission when taken as prescribed. However, non-adherence persists, partly due to the perceived stigma associated with HIV/AIDS. We explored the experience of taking daily PrEP and how perceived stigma influenced PrEP adherence among individuals aged 18-40 years participating in the PrEPVacc phase IIb HIV vaccine at four sites in South Africa, Tanzania, and Uganda. Participants enrolled in the trial included female



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sex workers, bar workers, fisher folk, and members from the general population, and oral PrEP (Truvada and Descovy) was provided in the trial for the first 6 months, with subsequent encouragement to obtain non-study PrEP (generic Truvada) from public facilities thereafter.

Methods: Qualitative data were collected at all sites between October 2021 to September 2023. In-depth interviews were done with 105 (81% females) participants at months 2, 6 and 12, and 121 (77.7% females) took part in 15 focus group discussions.

Participants were purposively selected based on age, gender, PrEP arm, and adherence behaviours according to self-report and urine tenofovir test results. Areas of investigation were experiences of using PrEP, disclosure, adherence, and perceptions of taking PrEP during and after the trial. Thematic content analysis was used to analyze the data.

Results: Participants expressed fears about being stigmatized if seen taking PrEP. They did not like the PrEP packaging because it was the same packaging used for antiretroviral treatment (ART), raising suspicion that they were living with HIV or engaged in behaviors associated with HIV, such as promiscuity. The fear also extended to obtaining PrEP from local providers, some of whom doubled as ART providers, for fear of being labeled 'HIV positive' and being discriminated against in their communities.

Conclusions: Perceived stigma persists among people at high risk of HIV affecting PrEP use. Community sensitization, provision of correct information about PrEP, and fostering an environment of acceptance and support at all layers of society will improve PrEP adherence and contribute to the reduction of HIV transmission among vulnerable populations.

TUPE112

Breaking new ground: exploring volunteer acceptance of sampling techniques in IAVI-G003

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Background: Public engagement in Experimental Medicine Vaccine Trials (EMVTs) in Africa faces challenges, notably unfamiliarity with non-conventional sampling techniques such as fine needle aspiration (FNA), large blood draws (LBD), and leukapheresis.

Our study, within the IAVI G003 trial, a Phase 1 study evaluating the safety and immunogenicity of the eOD-GT8 60mer mRNA vaccine (mRNA-1644), sought to explore participants' perceptions of non-conventional sampling techniques in Rwanda and South Africa. Recognising the inherent discomfort associated with these techniques, our aim was to understand how these perceptions influenced

participants' attitudes towards and experiences within the trial, ultimately informing strategies to improve engagement and experiences in early-phase research.

Methods: Utilising Sekhon et al.'s Theoretical Framework of Acceptability (TFA), our study examined the acceptability of FNA, LBD, and leukapheresis across three phases: prospectively (after the first LBD and before FNA and leukapheresis), concurrently (during trial participation), and retrospectively (after trial completion). We conducted in-depth interviews (IDIs) with 18 IAVI G003 participants, analysing the transcribed data thematically with NVivo 12 to extract insights into their cognitive and emotional responses to these techniques.

Results: Acceptability varied among the sampling techniques, with common initial fears and misconceptions. For LBD, concerns were initially about the volume of blood drawn and potential health impacts, but these were mitigated as participants gained experience with procedures.

FNA elicited fears about pain and needle insertion, particularly given the sensitive nature of the armpit area; however, post-procedure, many experiences were less daunting than anticipated.

Leukapheresis, with its use of machinery and being a lengthier procedure, generated significant anxiety about potential health repercussions and discomfort relating to loss of white blood cells.

Yet, with proper information and support, volunteers' apprehensions diminished over time. Across all techniques, a lack of understanding about the purposes of these procedures was noted, although participants had better clarity regarding FNA and its rationale.

Conclusions: The study highlights the necessity for increased clinical trial literacy, particularly concerning non-conventional sampling techniques within research communities in Africa.

Our work underscores the importance of developing tailored interventions and communication strategies to better manage participant expectations and experiences in trials involving non-conventional sampling techniques.



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Methods: HLA-DR+/CD38+ co-expression on CD4+ and CD8+ T cells was measured by flow cytometry in 252 HIV-uninfected female sex workers (FSWs) from Kenya who provided blood samples at up to three study visits from 2019-2021. Inflammatory cytokine concentrations were measured in plasma samples in a subset of participants (n=200) by multiplex immune assay. Sociodemographic factors were compared between participants who indicated past 6 month GBV exposure, mental health issues, and/or alcohol/substance use in a behavioural questionnaire.

The effect of these factors on T cell activation was estimated using a prospective mixed effects model, and the association of these factors with log-transformed plasma cytokine concentrations was estimated cross-sectionally in a multivariate linear regression model.

Results: Past 6 month emotional, physical, and sexual violence was associated with decreased plasma IL-13 ($\beta=-0.17$, $p=0.02$), decreased IL-1 β ($\beta=-0.29$, $p=0.03$), and increased IFN- γ ($\beta=0.24$, $p=0.01$), respectively. Daily alcohol use was associated with decreased IL-12 concentrations ($\beta=-0.36$, $p<0.01$). Daily tobacco use was associated with decreased HLA-DR+/CD38+ co-expression on CD4+ T cells ($\beta=-0.57$, $p<0.01$) and increased IL-12 ($\beta=0.26$, $p=0.03$) and IL-8 ($\beta=0.24$, $p=0.03$) levels. Depression, anxiety, post-traumatic stress disorder (PTSD), and daily cannabis use were not significantly associated with differences in immune parameters.

Conclusions: Past 6 month GBV exposure, daily alcohol use, and daily tobacco use were associated with broad immune dysregulation of blood T cell function. Alongside the complex behavioural pathways that link GBV and alcohol/substance use to HIV risk, these findings suggest that women who experience these factors may also exhibit impaired immunoregulation that may affect HIV infection outcomes.

WEPE100

Drought, flooding, and interlinked HIV vulnerabilities experienced by refugee youth in a humanitarian setting in Uganda

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Background: Climate change is associated with increased extreme weather events (EWE) such as drought and flooding, which in turn elevate HIV vulnerabilities through complex, understudied pathways. Refugee settlements worldwide face increased exposure to EWE. Little is known, however, of EWE and HIV vulnerabilities among

refugee youth in Uganda, Africa's largest refugee hosting nation. We explored experiences of climate change, EWE, and HIV vulnerabilities among refugee youth aged 16-24 in Bidi Bidi refugee settlement, Uganda.

Methods: This community-based qualitative study recruited a purposive sample of refugee youth (n=32) in Bidi Bidi that experienced water, food, housing, and/or sanitation insecurity. We conducted walk-along interviews, whereby youth guided an interviewer to a place that reflected experiences of climate change-related impacts. We conducted n=12 key informant (KI) in-depth interviews, with multi-disciplinary service providers working in HIV, refugee wellbeing, food security, and climate change in Bidi Bidi. We conducted thematic analysis informed by an ecosocial theoretical lens to examine social and environmental factors shaping wellbeing.

Results: Participants (N=44) included youth (n=32; mean age: 20.0, standard deviation [SD]: 2.4; 50% men, 50% women) and KI (n=12; mean age: 37.0, SD: 5.8; 75% men, 25% women). Narratives described how impacts of drought and flooding exacerbate social vulnerabilities and inequities, including food insecurity, which itself elevates HIV vulnerabilities. Drought experiences included: environmental-level (firewood insecurity; destroyed crops); community-level (sexual violence risks fetching water); household-level (exacerbated household stress and/or alcohol use coping that increase intimate partner violence [IPV] and early/child marriage); and interpersonal-level (transactional sex; reduced sexual agency) impacts that in turn increase adolescent pregnancy and HIV risks. Flooding experiences included: environmental-level (infrastructural damage to roads that reduced food access/distribution; destroyed crops); community level (damage to shops/market stalls); and household-level (damaged housing) impacts. Food insecurity increased mental health challenges (stress, substance use), violence (IPV, community-level), and transactional sex.

Conclusions: Flooding and drought result in environmental, community, and household-level impacts among refugee youth that exacerbate resource insecurities (food, water, firewood), social inequities (gender-based violence), and ultimately elevate HIV vulnerabilities through increased transactional sex, sexual violence, and reduced sexual agency. Climate-informed HIV prevention strategies can attend to intersecting climate crises and conflict among refugee youth.

WEPE101

The relationship between stress and sexual behaviors among adolescent girls and young women in rural South Africa: an HPTN 068 analysis

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Background: Adolescence is a vulnerable developmental stage, during which chronic stress can result in a more extreme, sustained biological response and lead to adverse health outcomes, including impaired executive function. Such impaired decision-making can consequently increase the risk of behaviors that are predictive of HIV, such as substance use and condomless sex. However, limited research has examined the relationship between biological stress and sexual behavior among adolescent girls and young women (AGYW) in high-HIV incidence areas. We therefore hypothesized that elevated measures related to biological stress would be associated with engagement in sexual behaviors that are predictive of HIV, such as age-disparate partnerships.

Methods: We used data from a case-cohort study that was nested within the HIV Prevention Trials Network (HPTN) 068 study and occurred over nine years in rural South Africa. Stress-responsive biomarkers were tested retrospectively from enrollment (2011-2012) and included dried blood spots for C-reactive protein (CRP), herpes simplex virus type-1 (HSV-1) antibody titers, and cytomegalovirus (CMV) antibody titers. Biomarkers were ordinal operationalized (CMV and HSV-1: 0=seronegative, 1=low antibodies, 2=medium, 3=high; CRP: tertiles). To estimate the longitudinal associations between each biomarker and each sexual behavior (transactional sex, age-disparate partnerships ≥ 5 years), multiple partners, and unprotected sex), we used log-binomial regression models with GEE.

Results: At enrollment, 25.5% (n=228/897) of the sample had ever had sex, 7.1% (n=63/897) had >1 partner, 8% (n=71/897) had unprotected sex in the past 3 months, and 3.2% (n=27/897) reported transactional sex. Compared to low CRP levels, medium (RR: 1.31, 95% CI: 1.03,1.66) and high CRP levels (RR: 1.32, 95% CI: 1.04,1.68) were associated with

having an older partner. Medium (RR: 1.30, 95% CI: 1.05,1.59) and high CRP levels (RR: 1.33, 95% CI: 1.08,1.64) were associated with unprotected sex.

Conclusions: CRP is a measure of systemic inflammation due to stress or other biologic processes. Stressful life events may lead to changes in executive function, which may in turn impact sexual behaviors commonly associated with HIV acquisition.

Additional research is needed to understand the mechanism for this relationship and to identify areas of intervention.

WEPE102

Application of machine learning algorithms to investigate the relationship between social vulnerabilities and psychological distress among transgender women in São Paulo, Brazil: an intersectional analysis

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Background: Suboptimal mental health outcomes among transgender women (TGW) are well documented. Less is known regarding differentiated mental health outcomes among TGW with intersectionally marginalized social identities/positions. Using machine learning algorithms, we investigated interactions of socioeconomic positions and lived experiences generated by systems of oppression (racism, classism, transphobia) and their relationship to psychological distress among TGW in São Paulo, Brazil.

Methods: We leveraged baseline data from a randomized controlled trial (ClinicalTrials.gov: NCT04114955) evaluating peer-led interventions to address intersectional stigma and improve HIV testing and PrEP uptake among TGW in São Paulo (2020-2024; N=392).

Eligible participants were: ≥ 18 years old; São Paulo residents; assigned 'male' sex at birth and identified as female/transgender; and HIV-negative at enrollment. Participants completed interviewer-administered questionnaires providing demographic, sexual behavior, and psychosocial information.

Psychological distress (prior month) was measured using the Kessler Psychological Distress Scale (K10). Covariates captured social vulnerabilities due to classism (age, unstable housing, low income, education, unemployment, recent sex work), racism (race/ethnicity), and discrimination (recent incarceration, anticipated intersectional stigma, gender-based violence). Conditional inference trees (CIT) and random forests (CRF) identified subgroups with



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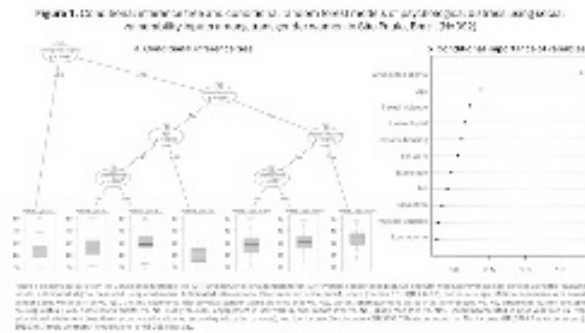
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highest mean K10 scores. CIT/CRF offer non-parametric approaches to detect subgroup differences while handling highly collinear variables. CIT applied Monte-Carlo approximated p-values; minimum node size was n=20. CRF used cross-validation procedures over 100 iterations to determine covariates most predictive of psychological distress.

Results: One-quarter of TGW were Black; median age was 32 (IQR 25-40). Median K10 score was 28 (IQR 22-34), suggesting high psychological distress. Analyses identified seven subgroups (median K10=20-34). The strongest differentiating covariates for psychological distress were anticipated stigma, age, sexual violence, unemployment, and unstable housing.



Conclusions: Variability in psychological distress among TGW in São Paulo may be explained partially by intersectionally marginalized social positions. Targeted strategies that mitigate systems of oppression may address the mental health needs of the most socially vulnerable.

WEPE103

Acceptability of an integrated model of mental health and PrEP service delivery for South African adolescent girls: qualitative results from a pilot hybrid effectiveness-implementation randomized trial

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Background: Adolescent girls and young women (AGYW) at elevated HIV risk frequently have symptoms of common mental disorders (CMD; e.g., depression, anxiety), which are associated with lower PrEP adherence. We conducted a pilot trial of a CMD intervention ("Youth Friendship Bench SA") adapted for PrEP delivery to improve CMD symptoms and PrEP adherence among South African AGYW. We qualitatively explored participants' experiences with integrated CMD and PrEP services.

Methods: The study was conducted in Johannesburg in 2023, with 116 AGYW (18-25 years) who were using PrEP and had CMD symptoms based on the Self-Reporting Questionnaire-20 item. Participants were randomized to standard-of-care ([SOC]=CMD screening, referral for further care as needed) or SOC *plus* Youth Friendship Bench SA (five individual problem-solving counseling sessions, one group session) and followed for 12 weeks. Intervention procedures were conducted alongside PrEP counseling. In-depth interviews with 30 participants, sampled by arm, assessed acceptability of CMD services integrated with PrEP delivery. Transcripts were analyzed using a rapid qualitative analysis approach.

Results: Most participants had not previously received CMD screening ("no one ever asked me how I'm feeling"). Screening, implemented regularly in the study, was seen as a beneficial intervention in itself; however, few AGYW sought further care following referral. Barriers to referral uptake included stigma, beliefs that referrals were for "serious mental issues", concerns around healthcare worker confidentiality, and inability to make time for additional appointments. The Youth Friendship Bench SA was highly acceptable as being "not formal" and "felt like talking to a friend". Problem-solving in the intervention empowered AGYW to address mental health and PrEP challenges ("My favorite part was when I came up with the ideas"). AGYW viewed integrated, same-day CMD and PrEP services as critical for person-centered PrEP delivery: "I won't be given pills and go home...I get to talk about what is happening in my life".

Conclusions: AGYW infrequently received CMD services prior to participation, despite South African guidelines on CMD screening and referrals. Youth Friendship Bench SA, integrated with PrEP, was acceptable, addressed unmet mental health needs, and could improve AGYW's CMD and PrEP adherence.

WEPE104

PrEP method choice in the context of gender-based violence: early observations from the CATALYST study in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe

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Background: Gender-based violence (GBV) remains common in sub-Saharan Africa, with lifetime estimates of GBV ranging from 21% to 49%. GBV affects people's ability to prevent HIV, including effective use of PrEP. However, new PrEP methods present an opportunity for people experi-

riencing GBV to prevent HIV safely and effectively. Early findings from the PEPFAR/USAID-supported CATALYST study, which currently offers PrEP ring and oral PrEP, provide insights into GBV experiences of PrEP users and how they navigate product choice.

Methods: CATALYST provides PrEP choice for women at public health sites in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe. We analyzed CATALYST participant baseline and follow-up data from May-December 2023 using descriptive statistics and explored associations using logistic regression.

Using quantitative reports, we described non-study related GBV and partner-related social harms (SH) – negative experiences in participant intimate partner relationships associated with study participation ranging from non-violent discord to GBV.

Results: At data cutoff, 2,678 participants had enrolled in CATALYST. Of 2,549 participants responding to baseline GBV questions, 900 (35.3%, country range = 9.0-60.2%) reported ever experiencing GBV. Participants reporting GBV were more likely to choose the PrEP ring (aOR:1.2; 95% CI: 1.0-1.4) or no method (aOR:1.8; 95% CI: 1.2-2.8) upon enrollment, compared to oral PrEP.

Among 1000 participants who responded to GBV questions during follow-up, GBV since the last visit was reported 122 times by 113 (11.3%, country range = 3.5-20.2%) participants.

In comparison, partner-related SH were infrequent, with 20 incidents reported by 19 (0.7%) participants, eight involving physical harm. Most (12/19; 63%) participants who experienced SH were sex workers, people who inject drugs, or people younger than 25 years.

All partner-related SH involved PrEP use, with participants opting to continue PrEP after about half (11/20; 55%) of the incidents.

Conclusions: Early results indicate that GBV is common among CATALYST participants and that experience may influence a participant's product choice. However, partner-related SH remains relatively infrequent, with many participants continuing PrEP use afterward.

CATALYST continues to explore these connections to support GBV survivors, including members of marginalized groups, in PrEP choice and use.

WEPE105

The effectiveness digital communications to help with PrEP adherence for transgender women, gay, bisexual and other men who have sex with men: a systematic review and meta-analysis

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Background: Daily oral PrEP can reduce HIV acquisition; however, its effectiveness is contingent on proper adherence, which poses a challenge for many individuals. Effective public health strategies are needed to promote and sustain PrEP adherence. Digital communication interventions, such as SMS reminders and mobile applications, have been effective at increasing adherence to other medications, including antiretroviral treatment for people living with HIV.

The purpose of this systematic review and meta-analysis was to evaluate the effectiveness of digital communication interventions to improve daily oral PrEP adherence among key populations.

Methods: We searched four electronic databases (PubMed, Embase, Web of Science, PsychInfo) and clinical trial registries for randomized controlled trials published between 2012 and 2023. Studies eligible for inclusion compared digital communication interventions to standard of care with a PrEP adherence outcome - e.g. tenofovir-diphosphate (TFV-DP) blood level concentration, self-reporting, electronic monitoring. We used random effects meta-analysis to estimate pooled risk ratios for the effect of digital communication interventions on adequate PrEP adherence (TFV-DP levels ≥ 700 fmol/punch) at 12- and 24-weeks post-intervention.

Results: Out of the 913 studies reviewed, seven met the inclusion criteria. Of these seven studies, one included cisgender women only, six included gay, bisexual, and other men who have sex with men (GBM), and of those studies, three included transgender women. Studies focussed on SMS texting interventions (n=3), mobile applications (n=3) and mobile game (n=1). Due to variations in outcome measurement and timing, for the meta-analysis, five studies were included in the 12-week pooled risk ratio and four studies were included in the 24-week pooled risk ratio. Those five studies involved GBM and transgender women. At week 12 (n=769), digital communications interventions had a small but significant effect on PrEP adherence (RR=1.10, 95% CI: 1.02-1.14) while they had no effect at week 24 (n=377, RR=1.20, 95% CI: 0.75-1.93).

Conclusions: The results of this meta-analysis indicate a limited impact on PrEP adherence among the studied populations in the initial phases of implementing digital interventions. However, the results indicate a need for sustained and perhaps varied intervention strategies to help with proper long-term PrEP adherence.



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WEPE106

Digital encounters: unveiling the risks of HIV among adolescent app users

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Background: Online dating applications have become a prevalent method for young people and adolescents to find casual sexual partners. However, there is limited knowledge about the potential risks of HIV transmission associated with these digital platforms. This study seeks to examine the way in which dating apps and online platforms contribute to the risk of HIV transmission among adolescents and young adults aged 15 to 19 and 20 to 24 years, respectively, in Delhi, Mumbai, and Chennai.

Methods: The research involved conducting 21 focus group discussions, 26 in-depth interviews, and 6 key informant interviews, which were audio-recorded, transcribed followed by application of a coding system to the transcriptions. Data analysis was performed quantitatively using Dedoose software.

Results: The accessibility and broad-reach of online platforms have opened up new avenues for adolescents (boys & girls) and young adults to connect in ways not possible through traditional, offline methods. The ability to browse anonymously, along with the promise of privacy and confidentiality, has facilitated increased encounters with potential sexual partners, leading to rise in casual sexual activities. Users often seek out strangers online for casual hookups, pursuing variety of sexual experiences with multiple partners. Unfortunately, a significant number lacked knowledge about HIV, its transmission routes, and sexually transmitted infections (STIs) following sexual activity with casual partners and even uninformed about the protective benefits of using condoms against HIV and STIs. Moreover, various factors like the influence of pornographic content, encounters with non-consensual pornography, engaging in unprotected sex without awareness of the partner's HIV status, and reacting to communications from unknown contact contribute substantially. Inspirations from films, deceptive identities, and unreliable profile information also play a part in initiating casual sexual relationships, thus elevating the risk of HIV transmission but also expose individuals to STIs, sexual violence, and rape.

Conclusions: The research identified prevalence of unsafe sexual practices among dating app adolescent users with notable risk of engaging in unprotected sex. This highlights the urgent need for further research into sex education and digital vulnerabilities faced by adolescents and young adults, aiming to enhance their understanding of sexual health protection.

WEPE107

The characteristics of young people (aged 15-30 years) who use oral PrEP in Thetha Nami ngithethe nawe, a cluster randomised trial of HIV prevention in rural KwaZulu-Natal, South Africa

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Background: Despite the widespread availability of oral PrEP, uptake remains suboptimal among adolescents and young adults (AYA) aged 15-30 years in rural South Africa. Understanding the characteristics of AYA who initiate PrEP and return for refills is essential to generate evidence to guide methods to improve uptake and retention.

As part of a process evaluation of a cluster randomised trial of peer-led social mobilisation into decentralised, integrated HIV and sexual and reproductive health services, we used a mixed methods approach to explore the characteristics of AYA who initiated PrEP and returned for refills.

Methods: Between July-December 2023, we triangulated intervention process data including clinic data collected at a community-based mobile health facility and in-depth interview data collected from a purposive sample of 33 AYAs using a semi-structured guide. Clinic data included participant demographic details, the date of each visit, and services used. Qualitative data was transcribed, translated from IsiZulu into English, and analysed thematically.

Results: Among 1243 participants eligible for PrEP, 864 (70%) initiated; 442 (51%) were male; median (IQR) age was 22 (19-25) years. More females (45%) than males (34%) returned for a PrEP refill. Among 523 who discontinued PrEP use after 30 days; majority (75%) were lost to follow-up, 16% pill burden, 9% other reasons. Qualitative interviews revealed that both male and female AYA initiating and continuing PrEP had mistrust of their partner's sexual behaviour, a desire to protect them from infection, a desire to maintain a negative HIV status, and fear of taking lifetime ARVs. Most reported having support for PrEP use from family, friends, and sexual partners. Participants described concerns that PrEP does not protect against acquiring STIs through condomless sex and (for young women) becoming pregnant without contraceptive use. Some expressed pill fatigue, preferring injectable PrEP due to its single-dose regimen, while others discontinued PrEP because of side effects, work travel, and missed clinic dates.

Conclusions: Despite the availability of oral PrEP, retention among AYAs remains low. Expanding the range of PrEP choices (oral, injectable, ring) is important to optimize HIV prevention strategies for AYA. Engaging the support of families and partners is critical to PrEP continuation.

WEPE108

Provider perceptions of offering PrEP choice: a quantitative assessment of early experiences in Eswatini

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Background: HIV prevention strategies across sub-Saharan Africa are rapidly shifting toward the introduction of multiple methods of PrEP. The expansion of options provides opportunities for individuals, collaborating with their health care providers (HCP), to select the method that will work best for them.

HCP are critical to the successful delivery of PrEP choice counseling, yet little is known regarding HCP acceptability of the service.

Methods: Between May and September 2023, eight health facilities in Eswatini began offering the PrEP ring alongside oral PrEP as part of the Eswatini PrEP Ring Study, implemented through the PEPFAR/USAID-supported MO-SAIC project.

During the first two months offering PrEP choice, up to three PrEP service providers per facility were selected at random to complete a structured questionnaire. Survey domains included HCP knowledge, acceptability, appropriateness, and feasibility of PrEP choice service delivery. Data were analyzed descriptively.

Results: All responding HCP (n=16) believed that counseling adolescent girls and young women (AGYW) on sexual and reproductive health was part of their job and that information on PrEP should be included in HIV prevention education for AGYW. Three-quarters felt they had received sufficient training and information to offer oral PrEP, and 56% to offer the PrEP ring.

Nearly all respondents (94%) liked to offer PrEP choice counseling to clients, believed offering PrEP choice to clients seemed like a good match to their needs, and thought it was possible to offer the service at their site. Providers were concerned about the PrEP ring's efficacy (94%) and clients' ability/willingness to insert and remove it on their own (63%).

Ninety-four percent of HCP were concerned about clients' ability to return on time for resupply for both oral PrEP and the PrEP ring, with 81% worried about clients' ability to follow a daily oral PrEP schedule.

Conclusions: Overall, HCPs were accepting of PrEP choice counseling and anticipated that it would be feasible in their facilities.

In addition to training, on-site mentoring may improve providers' confidence in their ability to provide the ring and support effective use. Countries should consider enhanced provider support as they introduce more PrEP options.

WEPE109

The Vuka+ Digital Health App to optimize South African women's HIV pre-exposure prophylaxis adherence: month 1 preliminary outcomes from a randomized controlled trial

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Background: Effective medication adherence support tools are needed for adolescent girls and young women (AGYW) to benefit from Pre-Exposure Prophylaxis (PrEP). Working with AGYW, we co-designed the Vuka+ PrEP adherence app, then tested Vuka+ in a randomized controlled trial in Cape Town, South Africa. Here we present preliminary month 1 results.

Methods: PrEP-eligible AGYW, age 15 to 24 years old, reporting no PrEP use in the past 6 months, were randomized 1:1 to Standard of Care (SOC) or Intervention. SOC included pregnancy and HIV/STI testing and counseling and PrEP counseling.

Intervention arm received SOC and the Vuka+ app (medication tracking, reminders, educational resources, social support, health questions forum).

Participants received Truvada as oral PrEP; completed surveys at baseline and months 1, 3 and 6; and completed SureQuick™ (detects absence of tenofovir in urine) at months 1 and 6. Stata was used to calculate frequencies and differences in proportion adherent by self-report and urine biomarker, stratified by arm.

Results: 330 participants were enrolled from February to September 2023. Month 1 survey retention was 91.8% (303/330). At baseline, average age was 20 years, 22.7% were in school, 34.9% had recent food insecurity, 60.0% worried about getting HIV, 87.9% had a regular partner and 14.9% always used condoms.

At month 1, the percent of time PrEP was taken as prescribed in the past four weeks was higher among Intervention (median %=81.0; n=151) than SOC (median %=64.5; n=152) participants (z=1.99, p=.047). In addition, 89.4% (135/151) of Intervention vs. 80.3% of SOC (122/152) participants (X²(1)=4.92, p=.03) self-reported taking ≥ 4 PrEP doses in the past 7 days. For biomarker, 30.5% (46/151) of Intervention vs. 27.6% (42/152) of SOC participants (X²(1)=0.30,



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$p=.59$) had no detectable tenofovir in urine. Most Intervention participants were satisfied with Vuka+ (86.1%) and agreed the app helped them take PrEP (88.1%).

Conclusions: Early results show high acceptability and significantly higher self-reported past-week and past-month adherence in Vuka+. Although SureQuick does not differentiate between 1 or more pills taken prior to clinic visit, no significant difference was found on adherence based on tenofovir in urine. Analyses of 3- and 6-month adherence using dried blood spot testing are underway.

WEPE110

Reductions in mental distress among young trans women participating in a peer-based HIV prevention and care engagement intervention in Rio de Janeiro, Brazil

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Background: Young trans women (YTW) at elevated risk of or living with HIV face a high burden of mental distress due to stigma, which negatively affects care and prevention engagement. We examined changes in mental distress over time for YTW participants in a HIV status-neutral peer-led systems navigation intervention to improve HIV care and prevention engagement called Brilhar e Transcender or BeT.

Methods: Data are from the baseline and final assessment for BeT, which was conducted with YTW (18-24 years of age) in Rio de Janeiro, Brazil (February-July/2022). Participants answered structured surveys that assessed experiences of anti-trans violence and measured symptoms of anxiety and depression in the last 2 weeks (Patient Health Questionnaire-4) along with suicidal ideation and suicide attempts in the last month. Chi-squared analyses were conducted to verify associations between indicators of mental distress with anti-trans physical and verbal violence and healthcare avoidance and to assess changes in mental distress over time.

Results: Among 164 participants (74% 20-24 years, 66% Black/Pardo), 142 (87%) were HIV-negative and 22 (13%) living with HIV. Overall, there was high mental distress at baseline as 32% of YTW screened positive for depression and 44% for anxiety.

More than half (60%) expressed recent suicidal ideation and 28% reported recently attempting suicide. Physical and verbal violence related to gender identity were significantly associated with suicidal ideation and/or attempt ($p = 0.05$, $p = 0.005$, respectively) among Brazilian YTW. Anti-trans physical violence was also significantly associated with symptoms of anxiety ($p = 0.03$) and depression ($p = 0.04$).

At the final BeT follow-up assessment only 12% of youth reported depression symptoms, 10% reported anxiety, 9.5% reported suicidal ideation and 3.4% reported a suicide attempt.

Conclusions: BeT participants exhibited a remarkable reduction in mental distress from baseline to the final follow-up assessment, likely due to behavioral health and peer support services provided as part of the intervention. Given the central role of mental health on HIV care and prevention engagement outcomes for youth and trans women, HIV interventions for YTW may be most effective when mental health and anti-trans stigma are addressed.

WEPE111

Shaping tomorrow: exploring perceptions on AGYW involvement in HIV vaccine and bnAb trials in the Multisite Adolescent Girls and Young Women (MAGY) study

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Background: Inclusion of Adolescent Girls and Young Women (AGYW) in trial designs is vital towards supporting product development that is tailored to the end users' needs. Engagement of AGYW is crucial to ensure that both HIV vaccine and broadly neutralising antibodies (bnAb) product development programmes are tailored to be effective and available for this vulnerable population.

This study aimed to explore the perceptions of AGYW, their parents/guardians, and community members on participation in future HIV vaccine and bnAb trials by understanding their perspectives on trial inclusion, and identifying concerns, motivations, and factors affecting decisions on participation.

Methods: Conducted in South Africa, Uganda and Zambia, the study encompassed qualitative methods, including 80 in-depth interviews (IDIs) and 20 focus group discussions (FGDs) with AGYW aged 15-24 years, their parents/guardians, and community members. Thematic analysis was employed to analyse the data, utilising NVivo software for organising and identifying key themes.

Results: The study revealed broad support for the inclusion of AGYW in HIV vaccine and bnAb trials, driven by the potential for health benefits and need for access to health services offered to study participants as part of the standard of care. Parents/guardians expressed their support, conditioned on the provision of health education and addressing misconceptions about side effects and infertility. AGYW were motivated by the prospect of

accessing free health services, HIV prevention education, and the empowerment derived from research participation. However, AGYW and parent/guardian concerns about sampling techniques such as safety including potential infertility, especially around mucosal and immune cell sample collections, were noted.

Conclusions: This study illustrates the importance of comprehensive engagement and education of AGYW, parents/guardians and other community members in facilitating AGYW participation in HIV vaccine and bnAb trials as well as the need for clear communication and addressing fears related to study procedures. Addressing misconceptions, providing comprehensive health education, and transparent communication about research procedures are crucial for enhancing trial participation among AGYW.

This study's insights into AGYW and parent/guardian perspectives can inform the design and implementation of future HIV vaccine and bnAb trials, ensuring they are culturally sensitive and adolescent-centric, thereby maximizing participation and retention.

WEPE112

Demographic differences in long-acting injectable PrEP use in two large samples of young sexual minority men and gender minorities in the U.S.

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Background: Pre-exposure prophylaxis (PrEP) is highly effective at preventing HIV acquisition, but nonadherence and discontinuation continue to compromise effectiveness. Further, some individuals never initiate PrEP due to concerns related to daily pill-taking (e.g., perceived burden, disclosure worries). Long-acting injectable PrEP (LAI-PrEP; approved in the U.S. in 2021) may help to overcome these barriers related to initiation, adherence, and persistence, because given in clinic settings and daily pill-taking is eliminated. Research on uptake of LAI-PrEP, and demographic differences in its use, is limited.

Methods: We drew from two large samples of young sexual minority men (YSMM) and gender minorities (GM) at risk for HIV to examine rates of LAI-PrEP use and demographic differences in use. Sample 1 was baseline data from >1300 YSMM from across the U.S. enrolled in an effectiveness trial of an eHealth HIV prevention program. Sample 2 was a longitudinal cohort of YSMM in Chicago (N>1200). Among PrEP users in each sample, we examined differences in rates of LAI-PrEP use (relative to daily oral PrEP) by age, race/ethnicity, education, sexual orientation, gender identity, and geography (sample 1 only).

Results: 52.2% of Sample 1 (i.e., cross-sectional, national) participants were PrEP-users; of these, only 4.8% were using LAI-PrEP. In this national sample, the proportion of LAI-PrEP users was significantly higher in California, Illinois, and New York compared to other states.

Further, GM participants were more likely to be LAI-PrEP users than cisgender participants. In Sample 2 (i.e., longitudinal cohort), 40% were PrEP users at most recent visit, of which 10.7% were using LAI-PrEP.

Only 5 participants had switched from daily oral to LAI-PrEP longitudinally – i.e., most LAI-PrEP users were PrEP-naïve. Further, the proportion of LAI-PrEP users was significantly higher among Black (compared to White) and less highly educated participants.

Conclusions: LAI-PrEP use remains low among YSMM and GM but is somewhat higher in more highly-resourced states. Few had switched from daily oral to LAI-PrEP, but LAI-PrEP users were from more marginalized groups, (i.e., Black, GM, and less highly-educated). Finding point to gaps in LAI-PrEP uptake in the U.S., as well as its potential to reach underserved groups at risk for HIV.

WEPE113

Differences in Condomless Anal Sex and substance use between young men who have sex with men using and not using PrEP from Buenos Aires, Argentina

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Background: Higher frequency of condomless anal sex (CAS) was found among gay, bisexual and other men who have sex with men (GBMSM) who use pre-exposure prophylaxis (PrEP), increasing exposure to other sexually transmitted infections (STIs). Substance use in a sexual context may play a significant role.

This study compared CAS and substance use between young GBMSM who use and who do not use PrEP in Buenos Aires, Argentina.

Methods: Among 143 cisgender young GBMSM between 16 and 30 years old, 88 (61.5%) were using PrEP and 55 (38.5%) were not. Between April-September, 2022, a survey designed ad hoc was administered at the HIV testing service of an NGO. Information on sociodemographic variables, sexual behaviour (receptive and insertive CAS in the last month), substance use (in a sexual context in the last three months, and type of substance), problems related to substance use and possible dependence (DAST-10), and alcohol use (AUDIT) was gathered. Chi-square tests, odds ratios (OR) and confidence intervals (CI), for categorical variables, and independent samples t-tests, for continuous variables, were run.

Results: Median age was 22 years (IQR=23-28), 38.5% were migrants, 7.7% reported engagement in sex work. PrEP use was associated with being migrant (p=.03) and with engagement in sex work (p=.006). Young GBMSM using PrEP were more likely than those not using PrEP to engage in receptive (OR=4.40; 95%CI=2.14-9.05) and insertive (OR=4.32; 95%CI=2.10-8.90) CAS in the last month, and to report substance use in a sexual context in the last three



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Delivery technologies: Novel approaches, formulation and multi-purpose

TUPE114

Using an online reservation system to improve uptake of HIV prevention and treatment services: a case study of Lerlouwer in Senegal

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Background: Senegal has a concentrated HIV epidemic within key populations and an environment marked by punitive laws, stigma, and discrimination. To address these issues, the USAID/PEPFAR-funded EpiC project launched Lerlouwer, a web-based tool to assess HIV risk, book service appointments, and report service satisfaction for key populations.

Methods: We analyzed results from October 1, 2023, through February 29, 2024, to compare HIV case finding between Lerlouwer and the overall program at US-AID-supported sites, disaggregated by demographics. Clients are sent a satisfaction survey via SMS post appointment, and we analyzed results to determine factors influencing service use. New Lerlouwer users are encouraged to take an online risk assessment and results were analyzed to explore previous HIV testing experience.

Results: There were 3,084 bookings and 2,971 arrivals among people aged 15 years+ (90.5% arrival rate). Most users (n=2,155) were people living with HIV (PLHIV) booking HIV treatment and viral load services. Among non-PLHIV users, HIV testing and PrEP were the most common services.

Of the 199 HIV testing services provided, 51 people were positive. Case finding among people using Lerlouwer was 25.6% while the overall program HIV case finding of 10.4%. A quarter (39/157) of respondents to satisfaction surveys indicated that confidentiality of health data was a driving force for accessing care and 80% indicated they would return for services.

Of the 116 clients who completed risk assessments, 52 (45%) had never taken an HIV test and 86% of these self-identified as MSM.

Population	Reservations (#)	Arrivals (#)	Arrival rate (%)	HIV case finding [% (HIV+/Total tested)]
MSM	433	399	92%	27% (37/139)
FSW	37	27	73%	33% (4/12)
TG	30	24	80%	12% (2/17)
All other KP (PWID, SW clients)	3	1	50%	0% (0/1)
Gen pop	367	355	97%	25% (7/28)
Unknown	8	8	100%	33% (1/3)

Table 1: Lerlouwer reservations (all services), arrival rate (all services), and HIV case finding by non-PLHIV accessing HIV testing services.

Conclusions: The higher case finding among Lerlouwer users highlights how virtual approaches can engage higher risk clients, complementing traditional programming. Lerlouwer can serve as an entry point for higher risk, non-PLHIV populations, particularly MSM.

However, more efforts to collect risk assessment data are needed for more representative data to better describe demographics and previous testing experience among users.

TUPE115

Learning from the past: tracking progress and streamlining coordination to accelerate successful introduction of the Dual Prevention Pill

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Background: Introduction of oral pre-exposure prophylaxis (PrEP) was characterized by small, fragmented demonstration projects and poor coordination. Delayed approvals and scale-up underscored the need for a coordination mechanism and plan to accelerate rollout of future PrEP products.

The Dual Prevention Pill (DPP), a multi-purpose prevention technology (MPT) co-formulating oral PrEP and oral contraception, could reach markets by 2025. DPP rollout planning requires enhanced coordination to bridge HIV and family planning (FP) systems and programs.

Methods: The DPP Consortium, established in 2019 to facilitate rapid, coordinated rollout of the DPP, developed the DPP Market Preparation and Introduction Strategy in 2021 based on BioPIC's adaptable framework for PrEP introduction.

We analyzed key results from the strategy's pre-regulatory approval period (through 2025) against current timelines to assess progress toward DPP introduction.

Progress was calculated based on status of results (completed, on track, off track) across five domains: regulatory approvals and policies; introduction planning and health systems capacity; evidence generation and implementation research; market research and demand generation; and procurement and financing.

Results: The DPP Consortium has realized 57% of 23 total key results towards preparing for DPP introduction, with 26% completed; 48% on track; and 26% off track.

Market research and demand generation shows the greatest progress achieved (65%), followed by evidence generation and implementation research (63%); regulatory approvals and policies (55%); introduction planning and health systems capacity (50%); and procurement and financing (50%).



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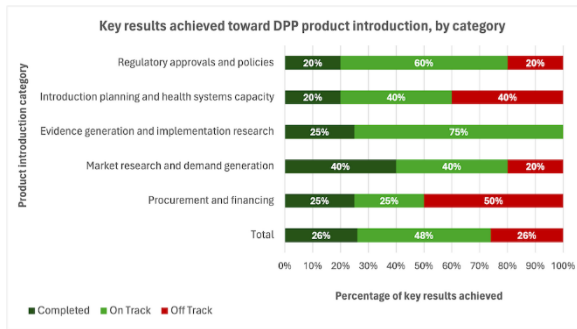
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Conclusions: With two years to complete 43% of key results, tracking implementation of the DPP Market Preparation and Introduction Strategy identifies where to focus efforts to achieve a 2025 launch, leveraging lessons from PrEP introduction. Given added complexity for procurement, financing, and health systems, which cut across HIV and FP systems, greater investments in these areas will ensure successful preparation for the DPP and preempt challenges experienced with oral PrEP rollout.

TUPE116

Safety, pharmacokinetics, and degradation of ultra-long-acting injectable, biodegradable, and removable in-situ forming implant with cabotegravir for HIV prevention

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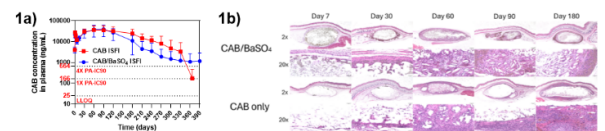
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Background: The effectiveness of pre-exposure prophylaxis (PrEP) in HIV prevention is significantly limited by poor adherence and the consequent risk of antiretroviral resistance. To address these challenges, we developed an ultra-long-acting (ULA) injectable in-situ forming implant (ISFI) with Cabotegravir (CAB) and barium sulfate (BaSO₄), a contrast agent, for improved adherence and traceability.

Methods: A time-to-completion pharmacokinetics (PK) study and a long-term (180-day) safety study were conducted in female BALB/c mice (n=6/timepoint) with CAB and CAB/BaSO₄ ISFI formulations administered via sub-

cutaneous (SC) injection (50 mL). Plasma samples were collected longitudinally to quantify drug, TNF- α , and IL-6 levels over ≥ 180 days. At 7-,30-,60-,90-, and 180-days post-administration, implants and surrounding SC tissue were excised to assess local inflammation with histology. An in-vitro degradation study was conducted where depots were collected at 3-,30-,60-,90-,120-, and 180-days post-injection (30 mg) into release medium (0.01M PBS with 2% solutol, pH 7.4, 37°C) to quantify polymer degradation (GPC), analyze implant microstructure (scanning-electron-microscopy, SEM), and determine elemental composition over time (SEM with energy dispersive X-ray, SEM-EDX).

Results: CAB plasma levels exceeded the 4X PA-IC90 threshold for 390 days, indicating sustained release. Mild/moderate systemic inflammation was observed through TNF- α and IL-6 levels. Histological evaluation showed minimal to marked foreign body responses and mild to moderate fibrosis by day 180. After 180 days in-vitro, CAB/BaSO₄ depots showed ~34% degradation, with SEM and SEM-EDX analyses confirming the presence of CAB and/or BaSO₄ in the ISFIs.



1a) In-vivo CAB plasma levels remain above the 4X PA-IC90 threshold for 390 days, eliciting zero-order release kinetics. **1b)** By day 180, excised implants and surrounding tissue showed minimal to marked foreign body and mild to moderate fibrosis response, based on blind scores by a certified pathologist (0-none to 5-severe).

Conclusions: Our study demonstrates the ability of CAB and CAB/BaSO₄ ISFIs to sustain plasma CAB levels well above the known benchmark for PrEP. CAB/BaSO₄ ISFI showed sustained zero-order plasma levels over 390 days (last time point analyzed, ongoing) with low-to-moderate systemic and local inflammation. The polymer degradation rate and retention of the implant's structural integrity highlight the feasibility of using these ISFIs for extended PrEP delivery beyond six months.

TUPE117

Rectal douche behavior and acceptability of rectal douche for HIV prevention in a sample of young MSM from ATN 163

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Background: On-demand rectal tenofovir (TFV) douche for HIV prevention via receptive anal intercourse (RAI) would fill a critical gap in PrEP product availability, yet little is known about young men's douching practices.

As part of ATN 163, we examined young men who have sex with men's (YMSMs) douching practices and how those relate to acceptability of rectal douche for HIV prevention.

Methods: We surveyed 278 young men who reported sex with men (age range: 18-24) about douching behavior and for potential enrollment in a Phase I trial at a single site between January and August 2022. Of the 278 surveyed, 135 completed phone screening to participate in the biomedical trial and 36 completed an in-depth interview (IDI). We used an explanatory mixed method design to understand douching practices and acceptability of rectal TFV douche for HIV prevention.

Results: 191 participants (69%) reported douching, with most douching before RAI (96%, N=184). A small proportion of participants reported douching after RAI (17%, N=32). Common reasons for douching included: to feel clean (N= 174, 95%) and partner request (N=54, 29%). Most reported douching 30 minutes to 1 hour (57%) or 1 to 2 hours (24%) prior to RAI.

Among the 36 who completed an IDI, 28 (77%) described benefits of douching including how effective it was in "thorough" cleaning and "preventing accidents" (68%), "convenient" and "easy to use" (32%) and feel more confident during sex (18%); and dislikes of douching including "time consuming" and "inconvenient" (46%), and "uncomfortable" (36%). Most participants (N=32, 89%) shared in their interviews that they would recommend a rectal TFV douche for HIV prevention if effective.

Conclusions: Rectal douching is common and acceptable among YMSM; to be an effective behaviorally congruent method, more work is needed to develop its use including optimizing administration techniques.

TUPE118

Advancing HIV prevention through virtual platforms: project NETREACH

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Background: In the last decade, India has experienced massive growth in internet users. As of Feb 2023, there were 692 million internet users in India. Internet access has not left the key populations untouched. Increasingly, MSM, FSW, MSWs, TGs, IDU and men and women with high-risk behaviours are also using internet-based communication technologies to socialise and seek sexual and romantic partners. The changing nature of social and sexual networks among KPs warrants that the HIV program looks beyond the traditional models of service delivery. Investments in the virtual intervention will help strengthen HIV prevention efforts, including access to HIV testing among Key Populations (high-risk groups and at-risk adolescents and youth, men and women with high-risk behaviours) through virtual platforms that these groups access.

Methods: Project NETREACH, implemented over two years, engages MSM, FSW, MSWs, TGs, IDUs, and individuals with high-risk behaviours through virtual outreach activities. Virtual Navigators establish rapport, provide HIV-related information, and encourage self-assessment of HIV risk using the web portal. The program facilitates online appointment booking for HIV-related services with government and private healthcare providers. An extensive online media campaign dispels myths and promotes healthy sexual practices.

Results:

A. Successful Outreach Strategies: Over five million individuals reached out through social media campaigns, and Virtual Navigators engaged 248,153 profiles.

B. HIV Testing Impact: 18,611 key and at-risk populations tested, revealing a 3.8% HIV positivity rate and a 7% syphilis positivity rate nationwide.

C. Collaborative Partnerships: Positive collaboration with the State AIDS Control Society (SACS) and tailored strategies for diverse target populations contributed to success.

D. Innovative Approaches: Adoption of self-testing and collaboration with private healthcare providers for community-friendly services proved effective.

Conclusions: The findings from Project underscore the potential of virtual platforms in augmenting HIV prevention efforts. Collaborative engagement with SACS and ongoing community consultations are crucial for sustained success. The program's focus on AI for dynamic risk assessment and exploring strategies for PrEP, PEP, Hep B, and Hep C indicates a forward-thinking approach. It aims to train SACS and targeted intervention (TI) officials for sustainable virtual outreach, ensuring the longevity and impact of the program in advancing HIV prevention, treatment, and care.



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TUPE119

End-user preferences for long-acting HIV prevention products during pregnancy and lactation in Kenya

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Background: Oral HIV pre-exposure prophylaxis (PrEP) has demonstrated safety and efficacy during pregnancy and lactation. However, uptake and persistence have been challenging due to disclosure, stigma, and the burden of using other tablets during pregnancy or post-partum. Long-acting (LA) HIV prevention products have the potential to address some of the challenges but data on product-specific preferences and reasons among pregnant and lactating women is limited.

Methods: We conducted a cross-sectional study to assess preferences and acceptability of long-acting PrEP modalities either under development or already established (monthly and weekly oral tablet, vaginal ring, injectable PrEP, implantable PrEP).

We completed quantitative surveys in four healthcare facilities in central and western Kenya. Participants' eligibility included; pregnant/lactating, HIV uninfected, ≥ 15 years of age, and accessing ANC/MCH services at enrollment. A multivariate logistic model was used to assess usability, effectiveness, and discreteness. Quantitative analyses were conducted using R statistical software.

Results: The median age of women was 25 years IQR [19.3-31.0]. The majority were married (61%, 263/434), and had completed high school (51%, 222/434), with no condom use in the past 3 months (80%, 348/434). Injectable PrEP and Implant were the most preferred formulations with (57%, 251/434) and (40%, 175/434) respectively.

Vaginal ring had the least preferences across both sites (4.8%, 21/434). Women who reported ease of use as their preference reason had 7.30-fold higher odds of preferring injectable PrEP than those who didn't (aOR = 7.30, 95% CI: [3.38-16.60]).

Among those who reported discreteness as their preference reason had 3.55-fold higher odds of preferring injectable (aOR = 3.55, 95% CI [1.54-9.35]), and 1.63 odds of preferring weekly oral tablets (aOR = 1.63, 95% CI [1.05-2.55]).

Among those who reported effectiveness had 4.70-fold higher odds of preferring monthly oral pill (aOR = 4.70, 95% CI [2.17-11.48]) and 2.65-fold higher odds of preferring injectable PrEP (aOR = 2.65, 95% CI [1.10-7.02]).

Conclusions: Pregnant and lactating women had a higher preference for longer-acting formulations due to perceived ease of use, discreteness, and perceived effectiveness in HIV prevention, which holds promise for optimizing the use of LA products during pregnancy and lactation.

ceived ease of use, discreteness, and perceived effectiveness in HIV prevention, which holds promise for optimizing the use of LA products during pregnancy and lactation.

WEPE115

Reshaping USAID's HIV microbicide research and development program for greater collaboration and impact

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Background: Historically, the USAID Microbicide Program has supported research and development (R&D) of HIV prevention products for women primarily through Global North product developers via separate awards with stand-alone objectives. Accelerating R&D requires many partners with different capabilities working together. We describe USAID's approach to reshape microbicide product development (PD) for greater impact.

Methods: A two-phase approach was used to redesign USAID's Microbicide R&D Program. First, an internal assessment of current and past R&D projects was performed. Second, 38 key informants were interviewed to identify strengths and gaps in the USAID's approach.

Results: Awarding separate projects focused on a specific product candidate led to a siloed approach with inadequate ability to generalize findings across products.

Also, preclinical/early clinical activities were conducted primarily in the Global North with suboptimal input from local end-users, health care providers and communities. Additionally, historical approaches made PD course correction challenging. Respondents cited USAID's leadership in convening stakeholders, and commitment to developing a broad range of products. Key gaps included a need for standardized stage-gating criteria to justify continued investment; improved visibility into funding decisions; and, greater incorporation of end-user inputs into research activities.

As a result, USAID awarded the MATRIX Project, co-led by Global North and South researchers, in a consortium with expertise in PD, clinical trials, participatory research, and business case development. The MATRIX governance structure promotes coordination and collaboration while ensuring that stage-gating objectively monitors R&D progress for agile decision-making.

To date, engagement of end-users, providers, communities and male partners have provided developers with critical insights on acceptable product attributes. Through the MATRIX stage-gating process three products have advanced from preclinical to first-in-human clinical testing.

Additionally, five products not meeting benchmarks and milestones are being replaced with more promising ones. Finally, product developers worked with business case experts within the consortium to determine product market potential.

Conclusions: At its culmination, the MATRIX project will have successfully utilized its supportive structures to optimize product success, thereby advancing the most impactful products down the development pathway which will eventually expand the HIV prevention toolbox.

WEPE116

"I prefer the implant ... it does the work without my assistance": CAPRISA 018 trial participant perspectives on sub-dermal HIV prevention implants

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Background: The ongoing high HIV incidence rates together with low uptake, and high discontinuation rates, of daily, oral pre-exposure prophylaxis (PrEP) in young women is an impetus for the development of longer-acting PrEP agents for eastern and southern Africa (ESA). The acceptability of an annual tenofovir alafenamide (TAF) implant was assessed post-trial exit in participants previously enrolled in the CAPRISA 018 Phase 1 implant safety trial in South Africa.

Methods: In-depth interviews with 29/36 consenting participants and focus group discussions with 18/36 participants [all Black, African, women, with median age 26 (21.5–29.5) years] were conducted in Durban, South Africa in 2023. Interviews and discussions were recorded and transcribed, and thematic analysis undertaken, with NVivo software used for data coding.

Results: The implant insertion procedures were considered acceptable by 90% of interview participants (26/29), with comments such as "I didn't feel any pain. I didn't have any problems" reflecting this.

The majority (27/29) also reported that the immediate post-insertion invisibility of the implant was a strong acceptability trait. However, local implant site reactions (ISRs) and skin discolouration that developed over time caused some discomfort and concerns about drawing attention to the implant.

The implant removal experience was considered less acceptable than the insertion and lived experience of the implant, with 48% (14/29) of women recalling complications, distress or pain during the removal process.

While 17% (5/29) were concerned about their own scarring post implant removal, 83% (24/29) found mild scarring acceptable.

Despite these experiences with the removals and scarring, 89% (16/18) of FGD participants confirmed that they would be willing to undergo another implant removal if the implant proved to be effective in preventing HIV. 61% (11/18) of women indicated that they would choose an efficacious HIV PrEP implant over other PrEP options as they preferred its potential for discrete use, long-acting nature, reduced clinic visits and zero pill burden.

Conclusions: These acceptability data from the novel long-acting HIV PrEP implant provide valuable participant-centred insights. Despite concerns about ISRs leading to low tolerability, and complicated removal processes; there was good acceptability among women, indicating that the motivation for using PrEP implants is complex.

WEPE117

Potential facilitators, barriers, and mitigation measures for delivering six-monthly injectable PrEP at private pharmacies in Kenya: a qualitative study

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Background: Ongoing Phase 3 clinical trials are evaluating a six-monthly injectable form of HIV PrEP called Lenacapavir. If Lenacapavir is approved for use, countries will need to decide where to make it available for maximal impact. In Kenya, private pharmacies are emerging as an acceptable and feasible venue for differentiated delivery of oral PrEP. To understand the potential facilitators and barriers to delivering Lenacapavir at private pharmacies, we conducted qualitative formative research.

Methods: From July to September 2023, we purposively sampled and interviewed pharmacy providers, PrEP users, and key stakeholders from policy-making, regulatory, and professional organizations in Central and Western Kenya. Interviews were conducted using a semi-structured guide-informed by the Updated Consolidated Framework for Implementation Research (CFIR)—which solicited participants' perspectives on factors that might help or hinder the delivery of Lenacapavir in private pharmacies



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and potential mitigation measures for addressing barriers. Drawing on principles of rapid qualitative analysis, we analyzed transcripts thematically and organized findings by CFIR constructs.

Results: We interviewed 16 pharmacy providers, 24 PrEP users, and 9 key stakeholders. Median age of PrEP users was 26 years (IQR: 28-23). About half (8/14) of pharmacy providers had prior experience delivering oral PrEP. Participants anticipated that the long interval between Lenacapavir injections would make delivering it at pharmacies cost-effective (CFIR: Innovation cost), in part, because clients would have less frequent visits, which would keep workload manageable for providers (CFIR: Innovation Recipients; Compatibility). Participants also anticipated that pharmacies' long operating hours and privacy would facilitate Lenacapavir delivery via this venue (CFIR: Relative Advantage).

Anticipated barriers included lack of pharmacy staff able to legally administer injections (CFIR: Capability; Policies & Laws) and resource constraints (CFIR: Local Conditions). Recommended mitigation measures included training pharmacy providers or partnering with clinicians, and enacting policies to authorize and regulate pharmacies to deliver PrEP injections (CFIR: Tailoring Strategies).

Conclusions: The pharmacy providers, PrEP users, and key stakeholders interviewed in this study were supportive of the concept of pharmacy-based Lenacapavir delivery but pinpointed several areas that merit additional consideration and research.

WEPE118

Acceptability of the 3-month dapivirine ring versus the 1-month dapivirine vaginal ring: qualitative findings from a crossover bioavailability trial among 18-45-year-old women in Bloemfontein, South Africa

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Background: The 1-month (25mg) dapivirine vaginal ring (DVR) is being introduced throughout sub-Saharan Africa. The 3-month (100mg) DVR in development may increase adherence, potentially increasing effectiveness and reducing costs (4 vs 12 rings annually). We evaluated the acceptability of the 3-month DVR in a bioavailability study (IPM-054).

Methods: We randomized 124 women to the sequence of using three 1-month (Ring A) rings and one 3-month (Ring B) ring for 3m each, with a 28d washout between treatments. Both rings have the same external and cross-sectional diameters, are made of the same elastomer, and have similar properties (e.g., hardness, compression force). We interviewed a subset of participants after study exit, balanced by sequence (AB vs BA), stratified by age.

Interviews were conducted in English using a semi-structured guide, transcribed, and analyzed using a rapid analysis framework.

Results: Of 31 participants interviewed (mean age, 29 years; range 21-44), 16 did not feel the rings in situ, whereas 15 said they felt it during toileting, menstruation or sex, with no overall differences between the 1- and 3-month rings. 17 participants preferred the 3-month ring, primarily due to the convenience of only needing to change it once every 3 months. 13 participants preferred the 1-month ring, some reporting increased vaginal wetness or increased discomfort during sex with the 3-month ring. 2 participants had no preference.

A few women experienced involuntary expulsions, during bathing or sex, or removed the ring to reposition it. Most participants thought that women would be willing to switch to the 3-month DVR if the 1-month ring was no longer available, as long as it was proven safe and caused no side effects. Some thought different women will prefer the 1-month vs 3-month ring. Only 1 participant said she would not use either ring in the future because her partner did not like it.

Conclusions: There is a market for both 1- and 3-month DVRs, but if only the 3-month ring were available, most women would be willing to switch. Creating a longer-acting, more cost-effective DVR will expand women's access to multiple HIV prevention modalities and will likely increase women's coverage, overall.

Ethics in HIV prevention research

TUPE120

Navigating ethical considerations in HIV prevention research: insights and challenges

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Background: Ethical considerations are paramount in HIV prevention research to ensure the protection of participants' rights, dignity, and well-being. As the field continues to advance, it is imperative to critically examine ethical frameworks and practices to address emerging challenges and complexities.

This abstract explores key ethical dimensions in HIV prevention research, highlighting ethical principles, dilemmas, and evolving approaches to safeguarding participants' interests.

Methods: Drawing on a review of literature, case studies, and expert insights, this abstract provides a comprehensive analysis of ethical issues in HIV prevention research. Ethical principles, such as autonomy, benefi-

cence, non-maleficence, and justice, are examined within the context of diverse research methodologies, including clinical trials, behavioral studies, and implementation science projects.

Results: Ethical considerations in HIV prevention research encompass a wide range of domains, including informed consent processes, confidentiality and privacy protections, community engagement, and equitable access to interventions. Challenges arise in balancing individual autonomy with collective interests, ensuring meaningful community involvement, and addressing power differentials within research partnerships.

Additionally, advancing biomedical interventions, such as pre-exposure prophylaxis (PrEP) and HIV vaccines, raises unique ethical dilemmas related to risk perception, access disparities, and the potential for social harm.

Conclusions: As HIV prevention research evolves, ethical frameworks must adapt to address emerging challenges and uphold ethical standards. Collaborative approaches involving researchers, community stakeholders, policy-makers, and ethicists are essential for navigating complex ethical dilemmas and promoting responsible conduct in research. By integrating ethical considerations into study design, implementation, and dissemination, HIV prevention research can uphold principles of justice, respect, and beneficence while advancing scientific knowledge and improving public health outcomes.

This abstract calls for continued dialogue, reflection, and action to ensure that ethical principles remain at the forefront of HIV prevention research efforts.

Other STIs

TUPE121

Improving access to HIV and STI management among female sex workers through clustering – lessons from FSW clusters in Ondo State, Nigeria

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Background: Sexually transmitted infections (STIs) continue to be a major public health concern worldwide, with female sex workers (FSWs) being a highly vulnerable population. FSWs face a disproportionately high risk of contracting STIs, including HIV, due to various factors such as unprotected sex, multiple partners, and limited access to healthcare services necessitating innovative approaches to improve access to STI management.

This study explores the impact of cluster formation as a community-based approach to enhance access to STI management and improve STI prevention, testing, and treatment outcomes among FSWs in Ondo State.

Methods: A total of 300 FSWs were recruited. 150 FSWs formed the intervention group (cluster formation) while 150 FSWs served as the control group (standard care). The intervention group were clustered with relevant stakeholders, these include Brothel owners/Managers, Health Workers, Security personnel, Chair ladies, CBOs and Brothel based peer educators responsible for providing referral/linkages for FSWs based on need, peer education on STI prevention, and coordinating access to STI testing and treatment services. Pre and Post intervention data collection was done through a structured questionnaire to assess changes in STI testing rates, treatment adherence, and knowledge about STI prevention.

Results: Results revealed a significant improvement in STI testing rates (from 40% to 75% and 41% for intervention and control groups respectively), treatment adherence (Among FSWs in the intervention group who received a positive STI diagnosis, 85% completed the full course of treatment, compared with 35% of FSWs in the control group), and significant improvement in knowledge by the intervention compared to the control group. The differences in testing rates, treatment adherence, and knowledge between the two groups were statistically significant ($p = 0.005$).

Conclusions: Cluster formation has a significant positive impact on improving access to STI management services among FSWs in Ondo State. The intervention group demonstrated higher rates of STI testing, improved treatment adherence, and increased knowledge about STI prevention compared to the control group. These findings emphasize the potential of community-based interventions in addressing the unique healthcare needs of vulnerable populations, such as FSWs.

TUPE122

STI testing and diagnoses among sexually active gay, bisexual, and other sexual minority men (SMM) in China: missed opportunities for dual STI/HIV testing

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Background: There is increasing concern about sexually transmitted infections (STIs) among gay, bisexual, and other sexual minority men (SMM) in China, as the prevalence of STIs among SMM is consistently greater than in the general population. However, little is known about STI testing behaviors and diagnoses among this at-risk population.



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This analysis sought to examine the prevalence of recent STI testing and diagnoses and to identify opportunities to improve integrated STI/HIV services in China.

Methods: An online survey was conducted among SMM users of a gay geosocial networking application in late 2020. For this analysis, we included SMM who reported having anal sex in the past months and without a prior HIV diagnosis (n=956). We log-binomial regression to identify correlates of recent STI testing and we used McNemar's test to compare recent STI vs. HIV testing to determine the missing opportunities of dual STI/HIV testing.

Results: Only 44.7% of sexually active SMM reported recent STI testing, of whom 87 (20.3%) reported being diagnosed with an STI, and syphilis being the most frequently reported STI. In multivariate analyses, recent STI testing was associated with being older (>24 years old vs. 18-24), employed, having anal sex with only a main partner or with both the main partner or casual partner (vs. with a casual partner only), in a relationship, and substance use in the past six months (p<0.05 for all). Sexually active SMM were more likely to have tested recently for HIV than for STIs (70.1% vs. 44.7%, p<0.0001), with only 54.0% of those tested for HIV also tested for STIs.

Conclusions: The results highlight a concerning gap in recent STI testing among sexually active SMM in China and underscore the urgent need to implement routine and accessible STI screening services tailored to the needs of this at-risk population. Our analysis reveals a missed opportunity for dual STI/HIV testing, with a substantial proportion of SMM tested for HIV not concurrently screened for STIs. Integrating STI and HIV testing within a comprehensive healthcare approach presents a promising strategy to improve STI testing rates and address the intersecting epidemics of HIV and STIs among Chinese SMM.

TUPE123

Evaluation of point-of-care (POC) testing for sexually transmitted infections (STIs) and corresponding treatment rates in a large-scale HIV prevention implementation science project

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Background: Young people with sexually transmitted infections (STIs) are at increased risk of HIV acquisition. The availability of point-of-care (POC) Nucleic Acid Amplification tests (NAAT) for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoea (NG) allow for same-day, aetiological diagnosis and treatment, but understanding implementation and effectiveness of this in real world, pre-exposure prophylaxis (PrEP) settings is needed.

Methods: CT and NG treatment data was reviewed for young HIV-negative people (15-29 years old), initiating PrEP at mobile clinics in the FastPrEP implementation science project in Cape Town, South Africa, from July 2022-March 2024. CT/NG testing and treatment was offered as part of the HIV prevention and sexual and reproductive health services (SRHs) available. Testing was performed at point of care (POC) via Cepheid GeneXpert assay and clients were encouraged to wait for results (90 minutes). If POC testing was unavailable, samples were sent to an offsite laboratory for analysis. Follow-up of test-positive clients included an automated SMS and 3 telephone calls.

Results: In over 5000 young people tested for STIs (median age 23 years, IQR 19-29; female 59%, male 41%), CT and NG positivity was 26.8% (1447/5395) and 12.3 % (661/5395) respectively, with >90% being asymptomatic. Of the 1387 positive STIs diagnosed off-site at the laboratory (CT 28%, 938/3346; NG 13.4%, 449/3346), the proportion treated after recall was 33.6% (466/1387). Of the 721 positive STIs diagnosed at POC (CT 24.8%, 509/2049; NG 10.3%, 212/2049), the proportion treated was 30.2% (218/721), with only 24.7% (178/721) receiving same-day treatment. The main reason for not waiting for results was the long waiting time (90 minutes). Of those tested at POC, there was no significant difference observed between those who received same-day treatment and those who did not, when stratified by gender, age, STI symptoms, number of sexual partners, relationship status, and anxiety/depression scores.

Conclusions: Our findings show a high prevalence of treatable bacterial STIs among the youth accessing SRHs including PrEP in FASTPrEP. Concerning are the very high proportion of untreated STIs due to non-return rates. POC STI testing did not make a difference in treatment proportions in this study.

TUPE124

Exploring synergies and mitigation effects of social protection on HIV and Tuberculosis: a longitudinal study in 43 countries

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Background: The role of Social Protection has been evidenced in the literature as a way of improving the socioeconomic conditions of the most vulnerable, alleviating the worldwide burden of several diseases linked to poverty, mainly in low- and middle-income countries (LMICs). We aim to evaluate the associations between Social Assistance on the incidence and mortality rates of HIV/Aids and Tuberculosis (TB).

Methods: We developed a conceptual framework linking Social Assistance to HIV and TB incidence and mortality rates, adjusted for well described risk factors, populated with Global Burden of Disease (GBD) and World Bank data. We used multivariable regressions analyses of panel data with fixed-effects negative binomial models to estimate the associations of benefit levels on the selected outcomes in the period 2000-2019 for 43 countries.

Results: We found that increasing 10% in the adequacy of the Social Assistance benefits associated with reductions on 6% of incidence rate of HIV [Incidence Rate Ratio (IRR): 0.9914; 95% confidence interval (CI): 0.9914-0.9965], and 2.95% of TB incidence (IRR: 0.9970; CI: 0.9960-0.9981), while increasing 10% of benefit levels associated with reductions of 4.3% on HIV/Aids-related mortality (IRR: 0.9956; CI: 0.9939-0.9973), and by 1.78% of the TB mortality rates (IRR: 0.9982; CI: 0.9971-0.9993).

Disaggregated analyses by female and male and, for children under-5, average benefit levels incrementation was more pronounced on the infants, with reductions of 12.7% (IRR: 0.9865; CI: 0.9831-0.9899) and 12.26% (IRR: 0.9870; CI: 0.9836-0.9903) on HIV/Aids, and 10.38% (IRR: 0.9891; CI: 0.9872-0.9910) and 4.12% (IRR: 0.9958; CI: 0.9943-0.9974) on the TB, respectively, on the incidence and mortality rates.

Moreover, 1% increase on the HIV prevalence of population aged 15-49 associated with 4.5% (IRR: 1.045; CI: 1.032-1.058) and 1.21% (IRR: 1.012; CI: 0.999-1.024) increase of the TB incidence and mortality rates, respectively.

Conclusions: Our findings suggested that benefit levels should be part of any strategy of health policies when fighting to poverty-related infectious diseases and co-infections, mostly due to the potential effects on health, and indirectly via poverty alleviation, and may be a tool in the achievement of Sustainable Development Goals (SDGs), which advocates the end of Aids and Tuberculosis by 2030.

TUPE125

Anti-mpox-virus (MPXV) humoral (IgG and neutralizing antibodies-Nabs) and cellular immune response one year after mpox infection or MVA-BN vaccination

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Background: MPXV reinfection in convalescents (CONV) or breakthrough infection in MVA-BN vaccinated people (VAC) questioned the efficacy and durability of subsequent protection. The aim was to compare the immune responses in mpox CONV versus VAC one year after exposure.

Methods: Blood samples were prospectively collected one-year after infection or MVA-BN vaccination (single-dose course in previously primed with historical smallpox vaccination (hSV), two-dose course in non-primed). MPXV-specific IgG and NAb titers were measured by immunofluorescence assay and 50% plaque-reduction neutralization-test. Interferon- γ producing Orthopox (OP)-specific T-cells were assessed by ELISpot assay. Age and sex-matched healthy donors (HD; n=10) were used as a control. Mann-Whitney test was fitted to compare CONV and VAC. Intragroup comparisons, according to HIV status and hSV, were analysed by Kruskal-Wallis, Dunn's, and Mann-Whitney tests, as appropriate.

Results: All 65 VAC and 46 CONV were male. Median age 44yrs (IQR 36-53), 39 (34-45) for CONV, and 48 (41-55) for VAC ($p=0.0001$). Thirty-two (49.2%) VAC and 4 (8.7%) CONV had hSV. Fifty-three (48%) PLWH on effective ART. CD4 count >500cells/mm³ in 39 PLWH (73.6%).

Anti-MPXV IgG and Nabs titers were lower in VAC than in CONV (Fig1A), with the lowest levels in VAC not hSV primed compared to CONV ($p<0.0001$ for IgG and $p=0.0005$ for Nabs).

Higher OP-specific T-cell response was detected in VAC versus CONV (Fig1B). Evidence for a difference was found either between hSV primed and CONV (0.0016) or hSV non-primed and CONV ($p=0.0097$). It was not found according to HIV status for both humoral and cellular responses.

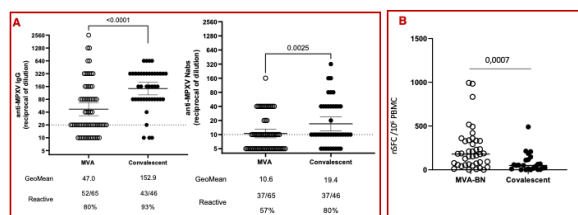


Figure 1. Anti-MPXV humoral and cellular response in mpox convalescent versus vaccinated (MVA)

(A) Geometric mean titers (GMT) of MPXV-specific IgG and Nabs. The dashed line refers to the starting dilution. Error bars refer to the 95% Confidence Interval of GMT.

(B) Frequency of T-cells responding to Orthopox peptides expressed as the number of SFC/10⁶ PBMC tested by interferon- γ ELISpot assay.

Inter-group comparisons were performed using the Mann-Whitney test.

Conclusions: One year after immune stimulation, convalescents retained higher antibody titers than vaccinated, especially hSV non-primed. T-cell response was higher in vaccinated, regardless of the hSV, than in convalescents. HIV infection did not influence both humoral and cellular responses. These results could be useful in targeting future vaccination strategies either in VAC or in CONV.





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WEPE122

High incidence of sexually transmitted infection among adults enrolled in an HIV vaccine trial in Uganda

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Background: Sexually transmitted infections (STIs) significantly contribute to global health burden and are recognized as major factors in the HIV epidemic. Understanding the incidence of and risk factors for STIs among individuals at high risk of HIV acquisition is crucial for targeted intervention efforts.

Methods: The PrEPVacc trial is a phase IIb, three-arm, two-stage HIV prophylactic vaccine trial with a second randomisation to compare Descovy to Truvada as pre-exposure prophylaxis. Consenting adults, 18-40 years participating in the trial had demographic data collected at baseline. Testing for STIs comprised serology using rapid plasma reagin (RPR) for syphilis (*Treponema pallidum* hemagglutination assay performed if RPR was positive) and nucleic acid amplification testing, performed on urine for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoea* (NG) at baseline, at approximately 26 weeks from the randomization visit, and each time a participant reported symptoms.

This analysis included data collected between November 2020 and November 2023. The incidence rate of STIs was estimated, overall, and for each STI in an analysis allowing for multiple-event-per-participant.

Results: A total of 512 participants, mean age 25 years (standard deviation ± 4.7). There were 218 cases of STIs in 394.9 person-years of observation (PYO), with an overall incidence of 55.2 per 100 PYO [95% confidence interval (CI): 48.3-63.0]. CT had the highest incidence rate (IR) [IR=30.1 PYO, 95% CI: 25.2-36.1, followed by NG (IR=23.3 PYO, 95% CI: 19.0-28.6) and Syphilis (IR=9.4 PYO, 95% CI: 6.8-12.9). Incidence was higher among males (IR=63.5, 95% CI: 49.0-82.3), those less than 25 years of age (IR=63.0 PYO, 95% CI=52.4-75.7), those not living with their partner (IR=62.5 PYO, 95% CI=48.0-81.4), and those who didn't report engagement in sex work (IR=62.6 PYO, 95% CI: 50.3-77.9). The age group 25-30 years was independently significantly associated with a lower risk of acquiring any STIs (adjusted rate ratio 0.68, 95% CI: 0.50-0.93) compared to those < 25 years of age.

Conclusions: These findings underscore the persistently high burden of STIs, particularly among younger individuals, emphasizing the urgent need for scaled-up prevention interventions. Additionally, STI vaccines could be explored and considered as part of comprehensive prevention strategies.

WEPE123

High burden of treatable sexually transmitted infection among AGYW aged 15-24 years in Uganda, Zambia, and South Africa: a multisite prospective cohort study

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Background: We aimed to establish a cohort of adolescent girls and young women (AGYW) aged 15-24 years who are vulnerable to HIV/Sexually Transmitted Infection (STIs) acquisition, for clinical trial preparedness and evaluation of future long-acting HIV prevention products in Eastern and Southern Africa.

Methods: In this prospective observational study, participants were enrolled at MAGY Clinical Research Centres (CRCs) located in Entebbe, Uganda, Lusaka and Ndola, Zambia, and Rustenburg, South Africa, with a target of 400 participants per country. Participants were aged 15-24 years, HIV-negative, non-pregnant, and met at least one of seven predefined HIV risk screening criteria. Participants completed a structured questionnaire on social demographics and HIV risk behavior. They provided blood samples and vaginal swabs for laboratory measurements of *Chlamydia Trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas Vaginalis* (TV), and Human Papillomavirus (HPV) infections by nucleic acid amplification tests via the GeneXpert platform; syphilis and hepatitis B virus surface (HBsAg) antigen by serology. Participants received a sexual reproductive health care package.

Results: Among 1210 participants (654 aged 15-19 years, median age of 19; IQR 17-22); overall 28% (N=328) were diagnosed with a curable STI, which varied significantly by CRC, including CT (18.4%, N=208; range:10.0%-28.0%, per CRC), TV (9.8%, N=110; range: 8.8%-15.4%, per CRC), NG (6.4%, N=72; range 5.8%-7.3%, per CRC) and syphilis (<1%, N=9, range: 0%-2%, per CRC).

Curable STI among participants aged 15-19 years were lower than among participants 20-24 years (25% vs. 31.5%, $p=0.013$), while NG (5.6% vs. 7.3%, $p=0.23$), CT (16.5 vs 20.6, $p=0.079$), TV (8.6% vs. 11%, $p=0.18$), and syphilis (0.3% vs. 1.3%, $p=0.16$) infections were not statistically significantly different between age groups.

Overall high-risk HPV infections, type 16 (5%, N=61), 18 (4.5%, N=55) and 45 (0.2%, N=3) and HBsAg (0.5%, N=6) were also not different between age groups. AGYW enrolled in MAGY bear a disproportionate burden of curable sexually transmitted infections.

Conclusions: The burden of curable STIs is high among AGYW in diverse settings in Eastern and Southern Africa with over one in four participants requiring treatment.

We found regional differences in STI prevalence requiring further research into risk behaviour and population characteristics.

WEPE124

Sexually transmitted infections among young cis/trans men and nonbinary people assigned male sex at birth who have sex with men (YMSM) in Rio de Janeiro, Brazil: results from Conectad@s study

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Background: Recent data points to steadily increases in bacterial sexually transmitted infections (bSTI) incidence in Latin America, disproportionately burdening sexual and gender minorities, people with HIV and youth. We aimed to explore bSTI incidence among Brazilian YMSM.

Methods: We evaluated participants enrolled in the Conectad@s study, an intervention study with respondent-driven sampling conducted in Rio de Janeiro, Brazil, between November/2021-October/2022.

Participants were followed for 48 weeks with quarterly visits. Syphilis testing was conducted quarterly, whereas multi-site sampling (including oropharyngeal/anorectal swabs and urine) for chlamydia/gonorrhea was performed every 24 weeks.

We estimated incidence rates of any bSTI (chlamydia, gonorrhea and/or syphilis) and each separately. We used a Poisson regression model to estimate 95% confidence interval (CI) for incidence rates and calculated person-years of observation considering the time between baseline and the last study visit performed.

Results: Among 409 participants contributing with 342.45 person-years, the incidence of any bSTI was 51.3 per 100 person-years (95%CI:44.1-59.7), with highest rate for gonorrhea (26.9 per 100 person-years [95%CI:21.8-33.1]), followed by chlamydia (16.44 per 100 person-years [95%CI:12.6-21.4]), and syphilis (15.9 per 100 person-years [95%CI:12.1-20.8]). The incidence of gonorrhea was higher in oropharynx (17.9 per 100 person-years [95%CI:13.9-23.2]) than in other sites (13.4 per 100 person-years [95%CI:9.5-18.8] for rectal swabs, and 2.7 [95%CI:1.4-5.2] per 100 person-years for urine).

Conversely, the incidence of rectal chlamydia (15.5 [95%CI:11.3-21.3] per 100 person-years) was higher than oropharyngeal (2.41 [95%CI:1.2-4.8] per 100 person-years) or urinary (5.11 [95%CI:3.2-8.2] per 100 person-years).

Most participants had no incident bSTI (63.6%, n=250), whereas 24.7% (n=97) had one incident bSTI, and 11.7% (n=46) had at least two bSTI during Conectad@s follow-up.

Conclusions: Our findings point to a high incidence of bSTI among YMSM in Rio de Janeiro, Brazil, outlining the importance of monitoring and prevention strategies for STI while implementing HIV prevention approaches and interventions. Multi-site chlamydia/gonorrhea testing potentially identifies additional bSTI diagnoses and might represent different sexual practices and networks. Concurrent bSTI are limited to a small proportion of participants and further exploring associated factors might inform targeted strategies to successfully prevent STI.

WEPE125

An mHealth app to support sexually transmitted infection prevention among Black Men who have Sex with Men PrEP users in New Orleans, Louisiana: app usability at week 48

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Background: Rates of sexually transmitted infections (STIs) are high for Black MSM (BMSM) including those taking HIV pre-exposure prophylaxis (PrEP), thus STI prevention strategies are critically needed. Using a user-centered design, we tailored PCheck—a PrEP adherence mHealth application— for BMSM taking PrEP, iteratively adapting it with STI prevention features (daily quizzes, sex diaries) and studied app usability in a pilot trial.

Methods: We enrolled BMSM PrEP users ages 18-35 in a randomized controlled pilot study (1:1 randomization, later amended to 2:1 randomization). App feasibility and utility were assessed using questions from validated questionnaires. We conducted in-depth interviews (IDI) with a subset of participants to ask about specific app features and the potential of adapting PCheck for doxycycline STI prophylaxis.

Results: Of 160 BMSM contacted, 32 were ineligible, 28 were unavailable to enroll, and 29 declined. Seventy-one participants were consented and enrolled, with 41 randomized to receive PCheck. Among these, 29/41 (70.7%) completed the Week-48 survey. Most participants reported that PCheck was mostly/very helpful (19/29, 65.5%), that PCheck would mostly/very much work for others (22/29, 75.9%), and that PCheck would mostly/very much work for long-term usage (20/29, 68.9%). (Figure 1) In IDIs conducted with 12 participants, many reported that PCheck increased their accountability and said they enjoyed



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sis. Prevalence of CT/GC at any site was 20.0%. Rectal (CT 8.2%, GC 6.8%) and oropharyngeal (CT 0.9%, GC 7.7%) infections were more common than genitourinary (CT 1.8%, GC 0.5%). Most MSM indicated willingness to start doxy-PEP (90.5%).

The figure depicts potential barriers and facilitators for doxy-PEP use. No significant correlates were found for willingness to use doxy-PEP.

Conclusions: Peruvian MSM initiating HIV PrEP who have inconsistent condom use indicate high willingness to use doxy-PEP. Implementation of doxy-PEP in Peru would benefit from routine STI testing as part of HIV PrEP services to encourage uptake among MSM with recent STIs. Willingness to use doxy-PEP among other groups, such as transgender individuals, remains to be explored.

Policy and advocacy

TUPE127

PrEP: show us the data! A guide to quickly apprehend data on PrEP research, development, access, and uptake, using free online databases

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Background: Staying on top of the latest advances in the HIV prevention field is key for advocates, researchers, funders, implementers, ministries of health, and other stakeholders—but how can one navigate the vast amount of online pre-exposure prophylaxis (PrEP) data?

This abstract presents the uses and complementarities of two public online databases compiling PrEP research, development, access, and uptake information at both country and global levels: LAPaL (developed by the Medicines Patent Pool), and PrEPWatch (developed by AVAC).

Methods: PrEPWatch, the online clearinghouse for resources and information on global PrEP delivery, sources materials from PrEP implementers, ministries of health, researchers, and other stakeholders, and includes the PrEPTracker which keeps tabs on PrEP projects and programmes through quarterly surveys, desk research, and outreach to partners.

The Long-Acting Therapeutics Patents and Licences database (LAPaL), is the first access-oriented collaborative database focused on long-acting therapeutics, showcasing information curated from scientific publications, clinical, regulatory and chemical data repositories.

Results: LAPaL and PrEPWatch are complementary evidence-based free online tools designed to increase transparency and information sharing on HIV prevention. These sites offer dynamic search and filter tools to support individual user journeys. LAPaL and PrEPWatch are also powered with interactive maps that can be tailored to show uptake data, clinical development and regulatory filings. The richness of these resources also lies in their unique angles: LAPaL is the go-to resource to learn about long-acting therapeutics, their properties, formulations and manufacturing requirements as well as their intellectual property landscape, development timelines and regulatory status worldwide. PrEPWatch includes resources to support every stage of PrEP introduction and scale-up, tracks and analyses the latest PrEP research, and features the PrEPTracker, the only place to find information on global PrEP initiations online.

Conclusions: PrEPWatch and LAPaL contribute to building momentum around the growing trend of long-acting therapeutics and support stakeholders in the PrEP space to navigate the data, inform programmes and enhance their work.

The platforms are evolving and will be improved in their next iterations, including with updated national guidelines and the addition of more long-acting technologies and compounds of potential impact in low- and middle-income countries.

TUPE128

Development of performance management key performance indicators (KPIs) to track implementing partners activities in the national HIV/AIDS response

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Background: The national response to HIV/AIDS in Nigeria necessitates a cohesive effort among various stakeholders, including implementing partners, MDAs, and state AIDS control agencies (SACAs). The National Agency for the Control of AIDS has a four point agenda: getting the data right, PMTCT, achieve sustainability and improve workplace policy across Nigeria. To ensure accountability, effectiveness and efficiency in tracking the quality of service delivery, a clear and measurable Key Performance Indicators (KPIs) must be aligned with National Strategic Plan. Despite notable progress towards the UNAIDS 95-95-95 target, Nigeria faces challenges such as treatment protocol non-adherence, interruptions in treatment, and poor



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data management, hindering epidemic control. Addressing these gaps requires innovative strategies and heightened collaboration among stakeholders.

Methods: A meeting with implementing partners, ministries, departments, agencies, and SACAs were convened to review and develop performance management KPIs for the national HIV/AIDS response in Abuja, Nigeria. Stakeholders were identified, and existing data on HIV/AIDS programs and outcomes were compiled and reviewed. Discussions, presentations, and reviews of stakeholders' performance work plans were conducted to inform the development of KPIs for performance tracking in Nigeria.

Results: The meeting aimed to assess existing KPIs' effectiveness, efficiency, clarify priorities of implementing partners in various states, and develop a comprehensive set of clear, measurable, and relevant indicators to track the performance management. A total of 46 participants attended, representing various stakeholders. Key outcomes included the development of a detailed action plan outlining responsibilities, timelines, and milestones for implementing the agreed-upon KPIs. Existing KPIs were reviewed and finalized to align with the National HIV and AIDS Strategic Plan, while new KPIs were developed and agreed upon for 2024 program performance monitoring and tracking.

Conclusions: The meeting underscored the commitment to strengthening the HIV/AIDS response through evidence-based decision-making, collaboration, and accountability. It highlighted the importance of aligning KPIs for performance tracking guide with national strategic plans and policies to enhance coordination and coherence in efforts to address the epidemic effectively. Moving forward, continuous monitoring and evaluation, along with the implementation of the developed KPIs, are recommended to track progress, identify areas for improvement, and accelerate progress towards ending the AIDS epidemic in Nigeria.

TUPE129

What do policies have to do with it? An analysis of PrEP implementation in USAID-supported sites through PEPFAR programs in Mozambique

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Background: Equitable access to pre-exposure prophylaxis (PrEP) is a key pillar of combination prevention. In February 2023, the Ministry of Health of Mozambique updated the PrEP national policy to align with WHO recommendations, thereby eliminating individual risk screening, and approving multi-month dispensing, event-driven PrEP, and HIV self-test use for PrEP continuation.

Methods: An analysis of routinely collected programmatic aggregate indicator data from 71 PEPFAR/USAID-supported health facilities in Manica, Sofala, Tete, and Niasa provinces was conducted for U.S. fiscal year (FY) 2022 through FY2024 Q1 (October 2022–December 2023).

We compared trends across geographies, age, sex, and pre- and post-policy revision which took effect in FY2023 Q2. Data for FY2020 and FY2021 were excluded because PrEP was only available in Manica during this time.

Results: More than half (51%) of cumulative PrEP initiations occurred across three quarters from FY2023 Q3 to FY2024 Q1 compared to 49% across six quarters prior to the policy change. In three provinces, FY2024 Q1 PrEP initiations exceeded initiations for every previous quarter. Following the policy change, the average initiations per quarter more than doubled across all four provinces from 5,316 to 10,882, with a 3.6-fold increase observed in Tete, and the number of females and males starting PrEP increased by 7% and 52%, respectively.

PrEP initiations among females ages 25-29 and 30-34 years were higher from FY2023 Q3 to FY2024 Q1 and among males 15-19 years old compared to the previous six quarters. Although PrEP expanded to 23 new sites following the policy change, this accounted for <500 new PrEP users.

Conclusions: PrEP initiations in four provinces in Mozambique increased over the past two fiscal years with a greater increase in the three quarters following the approval of policies expanding PrEP eligibility and access. The significant sex disparity in PrEP initiations is likely due to the disproportionate numbers of adolescents and young women acquiring HIV and programs and services focused on this population. Overall, the enabling environment helped to accelerate PrEP scale-up. In contexts with high HIV burden and high HIV incidence, addressing policy barriers and broadening eligibility is a critical step to rapidly increase PrEP availability and use.

TUPE130

The COMPASS Coalition Health Score Card: a tool for building and sustaining a robust transnational civil society coalition to strengthen the HIV response in Africa

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Background: The Coalition to build Momentum, Power, Activism, Strategy & Solidarity in Africa (COMPASS), is an innovative, Global North-South collaboration of civil society organizations advocating for comprehensive, effective programs that lead to measurable impact on HIV policies, programs, funding allocation and targets; in East and Southern Africa. Launched in December 2017, the COMPASS theory of change asserted that sharing tactics, skills and strategies between the Global North and South would catalyse the development of strategic and

iterative country-led campaigns. As COMPASS evolved, it became necessary to assess how partners were working together and continually determine ways of strengthening effective coalition functioning.

Methods: The COMPASS Coalition Health Scorecard was developed based on the theory of social capital, defined as "the networks of relationships among people who live and work in a particular society, enabling that society to function effectively". It was launched in 2020 and is administered to COMPASS partners annually. Indicators of a healthy coalition were defined and validated with coalition members. The scorecard is primarily a quantitative tool, with space for qualitative explanation of response choices. Using an online survey, respondents are asked to individually reflect on the "health of the coalition's governance model, strategy, partnership relationships and impact. Data from the survey are analysed and findings shared with the coalition, facilitating cross-country learning and identifying areas for improvement.

Results: Scorecard results inform the coalition's annual strategy and enables accountability among members. A shared appraisal of the coalition's performance becomes possible, and key factors, including decision-making, communication, conflict resolution and collaboration can be interrogated and addressed. As a result, there is shared decision-making and ownership of the coalition among partners. A comparison of current findings with previous results also helps track and tell the story of COMPASS's evolution.

Conclusions: The COMPASS Coalition Health Scorecard has proved to be an effective tool for rapidly assessing coalition members experiences and using this information to improve the quality of processes, performance, and impact of civil society collaborations. As COMPASS continues to evolve and expand, the Scorecard will serve as an effective tool for monitoring the coalition's continued health.

WEPE127

A legacy of impact: the power and reach of mentorship and sustained advocacy

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Background: Direct support for advocacy is indispensable to effective movements in pursuit of bold national, regional, and international agendas that advance HIV prevention and global health equity and lay a solid foundation against future pandemics. Funding to sustain advocacy is worth the payoff, as exemplified by almost 15 years of AVAC's advocacy program achievements.

Methods: AVAC has expanded the global network of HIV advocates through a variety of mentorship programs. Its flagship Fellows program and eight mentorship programs through the Coalition to Accelerate and Support

Prevention Research (CASPR) have been instrumental in expanding the reach of HIV prevention and advancing global health. These programs offer technical and financial support to individuals living where HIV incidence is high, with a focus on Eastern and Southern Africa. Select advocates receive intensive scientific literacy, mentorship, networking, salary (Fellows) and funding for advocacy campaigns. Participants develop expertise and skills to explain the science, define priorities, hold stakeholders accountable and influence the field.

Results: Over 300 advocates working with some 100 partner organizations across 15 countries have participated in AVAC Fellows and CASPR's advocacy programs, since 2009. In that time, they have reported gaining "knowledge", "confidence", "advocacy skills", and access to "high-level decision-making spaces". Specifically, program partners have changed more than 100 national policies in support of HIV prevention or greater equity in public health; won significant funding increases for high-priority HIV prevention programs and projects; have gone on to lead or found over 85 successful organizations; sit on global advisory groups; led nearly 200 high-impact efforts to create an enabling environment for HIV prevention such as rallies, media placements, and research literacy initiatives.

Conclusions: A review of AVAC Fellows and CASPR advocacy achievements shows that funding and mentoring contributes to the strength of a generation of leaders and their cumulative efforts shape the HIV response for the better. Adapting, scaling up and replicating supported advocacy programs, such as Advocacy Fellows and CASPR, is essential to the global AIDS response and to future pandemics.

WEPE128

Challenges and successes in global harm reduction: comparative lessons from South Africa and Brazil

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Background: This research analyzes trends and changes in global harm reduction policy, with a comparative focus on South Africa and Brazil. Despite similarities between the two countries, including stark racial and socioeconomic inequality, a prominent divergence exists regarding HIV policy and response. Whereas Brazil, through innovative health policy and the world's largest public health-care system, maintained its HIV positivity rate at 1% from 1991 to 2001, South Africa's rate rose from 1% to 25% in the same time period. This research focuses on changes that have taken place since, particularly the parallel politicisation of harm reduction, which threatens HIV prevention efforts in both countries, especially among key populations such as PWUD.

Methods: This project utilizes a mixed-methods approach consisting of archival analyses, policy analysis/review, and site visits, as well as nearly thirty long-form, semi-struct-



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tured interviews with government officials, PWUD, peer supporters, community leaders, policymakers, activists, and researchers in Cape Town, Johannesburg, and São Paulo. Interviews were conducted from December 2023 to March 2024, both in-person and virtually. This project expands on the author's prior research on HIV response in Brazil and South Africa and comparative global harm reduction research in Brazil and Portugal.

Results: Political changes in the past twenty years have greatly altered the policy landscape around harm reduction. In South Africa, despite significant national investment in the HIV response, syringe programs have faced serious threat from local, provincial, and federal leadership. The limited funding for harm reduction, largely in support of the national HIV response, seldom extends to additional services for PWUD. In Brazil, polarized federal governance, from which state and local health funding is largely derived, led to dramatic shifts in harm reduction funding and support. Rates of HIV have risen, especially at the intersection of neglected communities, including the Black, PWUD, and transgender communities. Significant inequality also remains between cities and states/provinces in both countries due to bureaucratic funding mechanisms and significant decentralisation.

Conclusions: This research presents the similar threats to harm reduction that exist in Brazil and South Africa, which have the potential to severely curtail progress made in both countries over the past twenty years.

WEPE129

Impact of HIV *test-and-treat* strategy and testing decentralization on AIDS hospitalization in Brazilian municipalities, 2000-2018: a longitudinal ecological study

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Background: Brazil is recognized for adopting a comprehensive approach to HIV/AIDS in the National Health System, ensuring universal access to testing and treatment, which has led to improvements in AIDS outcomes. By the end of 2013, Brazil took the initial steps towards decentralizing HIV testing by integrating these services into primary health care (PHC) facilities. In 2014, the *test-and-treat* strategy was implemented towards early treatment for people living with HIV (PLHIV). This study aims to evaluate the effects of the implementation of the HIV *test-and-treat* strategy and the testing decentralization on AIDS hospitalizations in Brazilian municipalities.

Methods: This longitudinal ecological study involved 5,565 municipalities, utilizing official HIV/AIDS surveillance data from 2000 to 2018. The age-standardized AIDS hospital-

ization rate for each municipality was computed as the number of hospitalization due to AIDS per 100,000 inhabitants. Rates were compared between the periods prior to (2000-2014) and following the *treat-and-treat* strategy and testing decentralization (2015-2018). The impact of both strategies was assessed using a difference-in-differences (DiD) framework, with adjustments made for year, municipality fixed-effect, and the number of specialized clinics, hospital beds, physician density, population size, and gross domestic product per capita.

Results: Over 90% of Brazilian municipalities have populations of 100,000 inhabitants or fewer, with a mean PHC coverage of 91.35%. Larger municipalities demonstrated a median PHC coverage of up to 38.58%. AIDS hospitalizations were predominantly observed in large municipalities (>100,000 people), with a median rate of 17.62/100,000 inhabitants in 2000, declining to 7.65/100,000 in 2018. We found a significant 78.84% decrease (p -value<0.01) in the AIDS hospitalization rate following the implementation of both strategies, irrespective of other factors. Stratified estimates for AIDS hospitalizations demonstrated a sustained decrease in all years post-implementation.

Conclusions: Following both implemented strategies, there was a notable decline in AIDS hospitalizations over a span of four years. While the *treat-and-treat* strategy is related to the improvement of the clinical condition of PLHIV, the decentralization of testing has increased the detection of new cases. These findings imply that both implemented strategies played a pivotal role in enhancing population access to prevention strategies, particularly early treatment, thereby aiding in the achievement of epidemic reduction targets.

WEPE130

Shattering boundaries: Dostana's courageous advances in MSM-focused HIV prevention in Lahore, Punjab, Pakistan

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Background: Dostana did Advocacy at National Level with Government Health Ministry and Provincial AIDS control Program's at Provincial level. That resulted in initiating six community based structures for MSM/MSW population all across in the province of Punjab in five Districts. the program exclusively targeted HIV testing services, Linkage, Condom and lube distribution, STI diagnosis and treatment, Prep and HIV self testing.

Methods: Since 2018 Dostana did series of advocacy events on advocacy to enhance the services of HIV prevention for MSM population across Pakistan, That aimed to include comprehensive HIV testing, STI diagnosis and treatment, and behavioral interventions. In 2023, remarkable milestones were achieved, with 27,580 MSM registered under behavior change communication (BCC), 7,434 STI diagnosis, 6,436 treatments, 13,009 HIV tests, and the distribution of 942,464 condoms and lubricants. Notably,

203 MSM were linked to PreExposure Prophylaxis (Prep) services, and 191 HIV positive MSM were identified, with 135 linked to Antiretroviral Therapy (ART) centers. Strong collaboration with the provincial AIDS control program underscores the program's structural strength.

Results: Dostana's successfully implemented the preventive model for MSM population, demonstrating the effectiveness of combining testing, treatment, and behavioral interventions. Lessons learned include the pivotal role of inclusive policies in addressing stigmatized populations, particularly in Pakistan a context where MSM behavior is criminalized. Collaborative support from Governmental health entities showcases progress in overcoming societal challenges and stigma associated with same-sex relationships.

Conclusions: Dostana's program stands as a beacon for effective MSM-centric HIV prevention in Punjab. The achievements underscore the significance of its multifaceted approach and collaboration with health authorities. The lessons learned emphasize the need for inclusivity in public health policies. Looking forward, sustaining and expanding these efforts is crucial for ongoing progress in HIV prevention, treatment, and care. Dostana's success provides a blueprint for future programs, encouraging inclusive approaches and collaborative efforts to address public health challenges in stigmatized populations.

WEPE131

Advocating for commitments to HIV prevention choice: a case study of the HIV Prevention Choice Manifesto for women and girls in Africa

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Background: The African Women's Community Prevention Accountability Board (AWCPAB) is a coalition of women living and working in Africa who are united in calling for continued political and financial support to expand choice in HIV prevention options through the HIV Prevention Choice Manifesto. This call comes at a crucial time for delivering new prevention options to meet the needs of women and girls in Africa.

Methods: The Choice Manifesto was launched in Kampala, Uganda, in September 2023. It outlines product-specific and field-wide concerns and opportunities, and calls on stakeholders to act on and reflect women's priorities. Focused on 'a future free of HIV for our daughters and women in Africa', the Manifesto elevates critical themes: a choice-centered approach for programming and procurement; centering people and communities in alignment with Good Participatory Practice guidelines; sustainable financing for choice; delivering HIV prevention choice; and the future for HIV prevention research and development.

Results: Organizations that sign the Choice Manifesto commit to working with global stakeholders in identifying the key actors responsible for ensuring that the language of choice translates into reality for women in all their diversities. Since its launch the Manifesto has been presented over 25 times at HIV and sexual and reproductive health convenings globally. Organizations such as AVAC, UNAIDS, IPPF, Frontline AIDS, IPM SA, UN WOMEN, ViiV Healthcare and HEP5-Uganda have signed onto the Manifesto. On World AIDS Day 2023, UNAIDS launched the report, Let Communities Lead, showing that AIDS can be ended as a public health threat by 2030 if communities get the full support they need from governments and donors. The report highlighted the Choice Manifesto as an example of community leadership.

Conclusions: The Manifesto exemplifies the crucial role and power of civil society advocacy in demanding action based on community priorities. It forces stakeholders to be accountable to their words and commitments. The diversity of Manifesto signatories signifies progress and an acknowledgement of the importance of choice in HIV prevention.

Moving forward, the Accountability Board will expand support for the Manifesto and hold stakeholders accountable to strategize, staff, plan, budget and procure for choice-based HIV prevention programming.

WEPE132

Policy and advocacy for trans and gender diverse people living with HIV: overcoming barriers to accessing comprehensive healthcare

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Background: Trans and gender-diverse people living with HIV face significant challenges in accessing comprehensive healthcare due to systemic barriers stemming from a lack of recognition of their rights. Discriminatory policies and societal stigma contribute to limited access to them.

Methods: This study was conducted in collaboration with the CeDoSTALC platform, employing a qualitative approach. Interviews and document analysis were utilized to explore the intersection of policy, advocacy, and healthcare access for trans and gender-diverse people living with HIV. Participants were recruited from diverse geographical locations to capture a range of perspectives and experiences.

Results: The findings highlight pervasive challenges faced by trans and gender-diverse people in accessing healthcare. Discriminatory practices, including misgendering and denial of services based on gender identity, were prevalent across healthcare settings. Participants reported experiencing heightened stigma and discrimination due to their intersecting identities as trans or gender-di-



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verse people living with HIV. Additionally, legal and policy frameworks often fail to protect their rights to gender-affirming care and identity recognition, exacerbating barriers to accessing essential healthcare services.

Conclusions: Addressing the healthcare needs of trans and gender-diverse people living with HIV requires multifaceted approaches that prioritize policy reform and advocacy efforts. Policy interventions must be enacted to ensure the protection of their rights to gender-affirming care and identity recognition. Additionally, healthcare providers must undergo comprehensive training to foster inclusive and affirming healthcare environments. Collaborative efforts between policymakers, advocacy organizations, healthcare providers, and affected communities are essential to dismantle systemic barriers and improve access to comprehensive healthcare for trans and gender-diverse individuals living with HIV.

It's crucial to acknowledge that trans and gender-diverse people are often victims of abuse and mistreatment by healthcare professionals. These incidents further underscore the urgent need for policy reforms and targeted interventions to address systemic discrimination and ensure the provision of respectful, culturally competent care for all individuals, irrespective of their gender identity or HIV status.

The enactment of the Gender Identity and Expression Law stands as a pivotal measure to mitigate these instances of violence, paving the way for a healthcare landscape that respects, protects, and affirms the dignity of trans and gender-diverse people living with HIV.

Lessons from SARS-CoV-2 research

WEPE120

Lessons from SARS-CoV-2 vaccines: delivering mutated RBD antigens to the CD40 receptor as a strategy for inducing long-term antibody responses

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Background: Insights from SARS-CoV-2 may aid HIV vaccine development by tackling immunity hurdles, including waning immunity. Swift access to COVID-19 vaccines was crucial, but variants sidestepping neutralization have lessened vaccine efficacy. Priorities include the development of new vaccines/strategies: i) targeting VOCs/VOIs; ii) inducing long-lasting Ab responses.

Methods: CD40.Pan.CoV is an antigen-presenting cells (APC) targeting vaccine consisting of a mAb specific to human (h)CD40 fused with RBD harbouring K417N, L452R, T478K, E484Q, N501Y mutations common to VOCs and a Nucleocapsid sequence, (>95% conserved across Sarbecoviruses). Immunogenicity and viral protection were tested in hCD40 and hCD40/K18-hACE2 transgenic mice, respectively. Animals were immunized at days 0/21 with the CD40.Pan.CoV vaccine (10µg) plus poly-ICLC (50µg, i.p.) or the mRNA BNT162b2 vaccine (1µg, i.m.) and either sacrificed (n=5-10/Group) 14 days post-boost or infected (Wuhan strain; n=6-11/Group) 7 days post-boost. Control mice received poly-ICLC or PBS. In another set of experiments, mice primed with two doses of BNT162b2 were boosted at month (M) 8 with either BNT162b2 or CD40.Pan.CoV+ poly-ICLC (n=4-5/Group) and serum was collected monthly till M16. The levels of binding and neutralizing RBD-IgG were assessed with MSD tests. Splenic B cells were analysed by flow cytometry.

Results: The rate of protection reached 100% in CD40.Pan.CoV and BNT162b2 vaccine groups with no animals exhibiting clinical symptoms or viral replication in the lungs unlike mock animals. CD40.Pan.CoV induced IgG-specific RBD responses as potent as the BNT162b2 vaccine but with a broader range of cross-reactivity and neutralization against δ/ε/γ/κ VOC and higher frequency of germinal centre B cells. In BNT162b2-pre-immunized animals, BNT162b2 or CD40.Pan.CoV boost (M8) increased IgG-specific RBD responses. However, post-boost dynamics revealed different decreasing slopes of binding and neutralizing Ab responses with CD40.Pan.CoV maintaining long-lasting responses.

Conclusions: Our study presents the proof of concept of the efficacy and immunogenicity of a vaccine targeting a mutated-RBD and a conserved nucleocapsid region to the CD40 receptor. CD40.Pan.CoV vaccine induced humoral and B cell responses against VOC/VOIs, complete protection against SARS-CoV-2 with potentially superior immune outcomes than BNT162b2, specifically antibody longevity when used as a boost. CD40.Pan.CoV vaccine will be moved to a phase I/II clinical trial in 2024.

WEPE121

Kaleidoscope of pleasure: chemsex and emerging challenges in Brazil post-COVID-19 pandemic

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Background: As a heritage of the COVID-19 pandemic, Brazil is experiencing a marked increase in the practice of chemsex, especially among men who have sex with men (MSM). This rise, linked to the use of psychoactive substances during sexual activities, stands out as an impactful legacy of the pandemic, highlighting significant challenges and the lack of spaces for discussions about sexual health.

Methods: Chemsex, short for chemical sex, is characterized by sexual intercourse under the influence of psychoactive substances, generally synthetic. The lack of official data in Brazil does not prevent the observation of an increase in this practice, especially among the MSM community, who, in search of disinhibition during sexual intercourse, find drugs as an answer to post-pandemic tensions. Parties, group meetings, and the emergence of motels exclusively for chemsex mark this reality, intensifying the challenges associated with the practice.

Results: Analysis of this phenomenon reveals significant risks, including a greater vulnerability to HIV and Sexually Transmitted Infections (STIs), as well as potential risks of overdose, addiction, and impacts on mental health, including anxiety and depression. The lack of awareness about these risks and the absence of spaces for discussion contribute to the growth of chemsex as a negative legacy of the pandemic.

Conclusions: The rise of post-pandemic chemsex highlights the urgency of addressing mental health issues and promoting open dialogues about sexual health. The lack of in-depth research, government initiatives, and training of health professionals indicates the need for efforts in this direction. Understanding the context of social and individual vulnerability is the key to providing an appropriate approach to those facing challenges associated with chemsex.

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EP001

Acceptability and preferences for a multicomponent HIV testing and linkage-to-services intervention among men who have sex with men in Peru: a mixed methods study

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Background: Despite the emergence of effective biomedical prevention methods and universal access to free antiretroviral treatment, HIV incidence in Peru has increased in recent years. New approaches are needed to promote HIV testing and timely linkage to treatment/prevention services.

We conducted a formative study to guide the development of "Project Mercury", a multicomponent HIV testing and linkage-to-services intervention for men who have sex with men (MSM) in Peru.

Methods: Using a convergent parallel mixed methods design, we explored the acceptability and preferences for "Project Mercury" and its two core components:

1. HIV testing offered at sex-on-premises venues (SOPVs), including rapid point-of-care tests, home self-tests, or a coupon for future clinic-based testing, and;
2. A mobile health application promoting linkage to treatment/prevention services.

Six semi-structured focus group discussions (FGDs) were conducted with HIV+ and HIV- MSM in Lima (3 FGDs each). Participants also completed a post-FGD survey assessing preferences for key intervention features.

We performed rapid qualitative analysis applying a mixed deductive-inductive approach. FGD transcripts were analyzed by three independent coders using a structured template with prespecified domains and categories. Quantitative surveys were analyzed using descriptive statistics, then integrated with themes from qualitative analysis to identify points of convergence and facilitate interpretation.

Results: Among 42 participants, median age was 32 (range 21 - 54). Overall, 92% reported they would be either 'somewhat' or 'very' likely to accept the "Project Mercury" intervention if offered to them at an SOPV.

The following key themes emerged related to venue-based HIV testing and app-supported follow-up: a desire for accompaniment, social connection, and emotional support delivered by empathetic, respectful, and competent providers; the importance of personal choice,

agency, and control over one's interactions with the intervention (e.g., type(s) of HIV test offered, where/when to test, personalization of app-delivered content); and the importance of making the intervention fun and not overly medicalized.

Conclusions: Among prospective users in Lima, Peru, we found high acceptability of the proposed "Project Mercury" intervention. Formative research revealed the need for supportive and competent providers to deliver the intervention, as well as a desire for personalization, choice, and incorporation of entertaining features to engage users.

EP002

Exploring the dynamics of community engagement in HIV prevention research

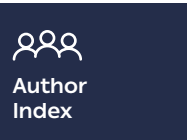
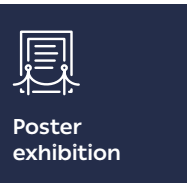
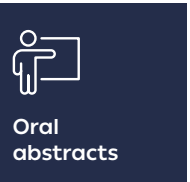
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Background: This research delves into the intricate landscape of community engagement within the realm of HIV prevention research, aiming to illuminate the multifaceted dynamics that underpin successful collaborations between researchers and communities. Employing a mixed-methods approach, we investigate various models of community engagement, assessing their effectiveness and impact on shaping prevention strategies.

Methods: Our study draws upon in-depth interviews, surveys, and case studies to capture the voices and experiences of both researchers and community members engaged in HIV prevention initiatives. By analyzing the qualitative data, we identify key factors influencing the success of community engagement, including trust-building, effective communication strategies, and the integration of local knowledge.

Results: Furthermore, our research evaluates the role of community advisory boards and their impact on study design, implementation, and dissemination of findings. We explore innovative approaches to community engagement, such as digital platforms and social media, and assess their potential in fostering broader community participation.

Conclusions: The findings of this study contribute valuable insights into best practices for community engagement in HIV prevention research, offering a nuanced understanding of the challenges and opportunities inherent in collaborative efforts. This research aims to inform future prevention strategies, fostering a more inclusive and impactful approach that addresses the unique needs and perspectives of the communities most affected by HIV.



EP003

Unity is strength: paving the way to generate a consortium for HIV cure research in Latin America and the Caribbean "LAC-Cura"

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Background: Achieving a widely applicable, acceptable, and affordable cure strategy for all people living with HIV was set as the top priority by the 2021 IAS Global Scientific Strategy. Worldwide, numerous initiatives (consortia, platforms, and collaborative projects) are working towards this goal. However, most HIV cure research is designed and conducted in high-income countries. This approach raises concerns about the accessibility of potential strategies for people in LMICs, where the disease burden is higher, non-subtype B viruses circulate, coinfections and inflammation are different, ART availability might be limited, and overall health conditions are not optimal.

There is an urgent need for more inclusive and diverse research efforts to address these disparities and ensure that advances in cure are equitably accessible to all communities worldwide.

Methods: A focus group of HIV researchers and advocates from Argentina, Chile, and Mexico gathered in 5 sessions (in-person and virtual). Presentations at international conferences, peer-reviewed publications, and grey literature were reviewed. On these bases, current gaps and potential solutions were identified.

Results: HIV cure research in Latin America and the Caribbean (LAC) is fragmented, scattered, and poorly integrated into the global agenda. Although there are some labs conducting studies on viral persistence, the overall context is characterized by limited resources and infrastructure. Potential solutions include facilitating interaction and collaboration among all research groups working in the region, increasing interactions with cure experts from other regions, mapping regional resources and capacities to promote collaborations, promoting educational activities that consider local languages to avoid linguistic biases, supporting local researchers to break the language barrier and other challenges to publish, engaging local communities in cure advocacy, among others.

All participants agreed that the creation of a regional LAC consortium could be the best vehicle to catalyze these recommendations.

Conclusions: Establishing a regional consortium will enable the development of efficient, productive and strong research and advocacy agendas that identifies and addresses the unique characteristics of constrained settings within the region, involving all stakeholders from all LAC countries. The group has decided to name itself 'LAC-Cura' for 'Latin America and the Caribbean Consortium for HIV Cure'.

EP004

Learnings from rolling out pre-exposure prophylaxis against HIV acquisition among men who have sex with men and transgender people in Kathmandu, Nepal

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Background: The National Center for AIDS and STD Control, Nepal based on its mathematical modeling of 2020, revealed that MSM and TG population account for 27% new HIV diagnosis in the country. Given the disproportionate burden of HIV on these key populations, use of PrEP is vital to mitigate the risk of HIV acquisition alongside other preventive measures.

This study explores the trend of PrEP use among MSM and TG population in Kathmandu since its inception in November 2020 through the support of PEPFAR/USAID through EpiC Nepal project and draws key way forwards from it.

Methods: We analyzed the routine program database from October 2020 to September 2023 to quantify the clients' sociodemographic status, HIV test result, PrEP eligibility and initiation status.

Results: In the three years, among 2,260 MSM and TG individuals tested negative and referred for PrEP, a total of 1,356 individuals (60%) initiated PrEP. As depicted in Figure 1, highest acceptance for screening and subsequent PrEP initiation was found in first fiscal year revealing extensive promotion of PrEP services.



Figure 1. Cascade of individuals tested HIV negative and referred for PrEP.

Over the three years span, common reasons for ineligibility (N=12) were diagnosis of Hepatitis C (58%) and Hepatitis B (17%). Similarly, most common reasons for refusal of PrEP among those screened eligible (N=17) was hesitance to take daily oral PrEP (29%) due to infrequent



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sexual risk behavior and PrEP related social stigma (12%). The acceptability for PrEP eligibility screening was highest among male sex workers (71%) however, among eligible individuals the largest proportion to start PrEP was from MSM group (99%).

Conclusions: Efforts are currently scattered on retention of previous PrEP users. Our results highlight the need of additional resources than what is prevailing to reverse the decline in new PrEP users. Similarly, alongside demand generation of PrEP, introduction of new innovative tools like injectable PrEP shall contribute to future uptake.

EP005

Safety and adherence to TDF-3TC or TDF-FTC as daily HIV Pre-exposure prophylaxis (PrEP) among Men who have Sex with Men, a phase II randomized clinical trial in Belo Horizonte, Brazil

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Background: PrEP is an effective method for reducing HIV infection in key-populations. WHO recommends TDF containing regimens as oral PrEP. TDF-FTC co-formulation is the most widely used model of PrEP and, since 2017 is provided by the Brazilian Public Health System. Clinical data on TDF-3TC as an oral PrEP strategy are scarce. Thus, this study aimed to compare safety, adherence, and risk compensation, between TDF-3TC and TDF-FTC as a daily PrEP regimen in MSM living in Belo Horizonte, Brazil.

Methods: From 2021 to 2022, MSM, 18 years or older, HIV seronegative were randomized, blinded to investigators and statisticians, to receive TDF-3TC or TDF-FTC in addition to male condoms, lubricating gel, and combination prevention debriefings. The 12-month follow-up included quarterly visits with rapid testing for HIV, STIs, clinical, laboratory, and psychosocial assessment and a scale of depressive symptoms (CES-D). The primary endpoint was safety in terms of frequency and severity of Adverse Events (AE).

Results: From the 265 MSM enrolled, 200 were randomized; 53% self-declared as Black, 5% bisexual and 86.5% had > 11 years of schooling. Arms were similar in baseline characteristics. 134 participants experienced a total of 180 AEs with no difference in frequency ($p=0.757$) and severity ($p=0.912$) between arms. Headache rate was higher in TDF-FTC arm (6% vs 15%, $p=0.001$), while nausea was in TDF-3TC (20% vs 9%, $p=0.008$). There were no significant decrease in serum creatinine in both arms. Using pill count, sufficient adherence (>70%) was found in 99.1% of participants who returned vials in visits, with no difference between groups. There were no differences in depression symptoms scores at month 12, nor from baseline through the end of study and neither in STI frequency: 24 (12%) had

27 STI: 16 (13.5%) syphilis, 5 (2.5%) herpes simplex, 3 (1.5%) urethritis, one (0.5%) HAV and HCV. Two participants acquired HIV during the study, one in each arm.

Conclusions: This first prospective, randomized study comparing TDF-3TC and TDF-FTC for daily PrEP in MSM, showed similarities in safety and equally good adherence. Our findings can help Brazil and other developing countries decide on expanding oral PrEP options in their public health system.

EP006

Empowering communities: a paradigm shift in strengthening HIV response through community system strengthening (CSS) under India's National AIDS Control Programme

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Background: Communities are at the center of the HIV/AIDS response in India, and strengthening community systems to achieve strategic outcomes has become the key priority for India to achieve the target of ending HIV/AIDS epidemic by 2030. The Foundation of CSS is to mobilize, link, collaborate and coordinate with Key Population, PLHIV, including youth and health systems aiming to support an enabling environment, demand generation for prevention, testing, care and support programmes and community monitoring for effective quality programme delivery.

Methods: Based on the NACP phase-V guiding principle, CSS implemented defined strategic modification involving concentrated focus on capacity building of communities resulting in strengthened leaderships, institutionalization of Community ed Monitoring (CLM), strengthened linkages and stakeholders engagement leading to zero stigma and discrimination by 2030.

Therefore, the community from all typologies are engaged through the constitution of Community Resource Group (CRG) at the National and State level across 35 States, and Districts CRG in 600+ districts under the leadership of NACO and State AIDS Control Society.

Further, to break the Silos and Build Synergies, a total of 100 Master trainers from the Community were trained last year, while through CLM, feedback is collected by Community Champions (CC) wherein identified issues are discussed, and actions are co-created and structured by service providers along with key beneficiaries.

Results: Ensuring community participation anchored by the National Programme resulted in active involvement of the community and shared responsibilities among service beneficiaries and service providers.

Further, through CRG, the scope has been developed for timely community recommendations and inputs, e.g., capacity building and leadership development, along with finalization of Guidelines, CSS framework, state action plans and programme evaluations leading to enhanced programme outcomes and ownership.

Besides, community field intelligence through CCs and CRG have contributed towards the finalization of community-centric and demand-driven strategies.

Conclusions: The national programme will engage CC per typology in 600+ districts of India. It is envisioned that this engagement of the community through the CCs and CRG at the most granular level will enhance a community-driven rights-based approach to reach the last mile, which will add value in scaling up and complementing the National HIV programme.

EP007

Influences of peer-delivered kits for PrEP on sexual reproductive health behaviour and self-esteem among adolescent girls and young women in Kisumu, Kenya

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Background: In settings of high HIV prevalence among adolescent girls and young women (AGYW), multi-pronged HIV prevention approaches are being used to reduce new infections. In addition to direct effects on viral transmission, these HIV prevention approaches often influence self-perception and sexual behaviour but are incompletely understood in the context of HIV pre-exposure prophylaxis (PrEP) use.

Methods: A recent randomized trial among AGYW aged 16-24 in Kisumu, Kenya evaluated community-based, peer-delivered PrEP combined with testing for sexually transmitted infections (STIs) and contraceptive options (intervention), compared to routine clinical care (control). Deliveries were offered at 1, 3, and 6 months after clinic-based PrEP initiation.

All participants completed demographic and socio-behavioural questionnaires at enrolment and Month 6; a purposively selected subset of 20 intervention participants were interviewed qualitatively at Month 6 to explore experiences with the intervention. Quantitative data were analysed descriptively and with paired t-tests: qualitative data were assessed by content analysis.

Results: The study enrolled 150 AGYW (75 intervention; 75 control) with a median age of 22.0 years and similar baseline indicators. At enrolment, participants reported behaviours commonly associated with HIV acquisition: mean multiple sex partners (2.2), transactional sex (56.7%), condoms used 'not at all' (56%), and sexual partners of unknown HIV status (71.3%).

Comparing baseline to Month 6, statistically significant improvements were seen in relationship control, alcohol, condom and other contraceptives use (all $p < 0.0001$) in the intervention group only. Improvements were seen in self-esteem, depression, PrEP attitudes, transactional sex, and number of partners with known HIV status in both groups (all $p < 0.05$). AGYW narrated more deliberate sexual and reproductive health (SRH) decisions during the intervention, attributing these changes to peer guidance and support. AGYW also reported reduced number of sexual partners, embraced couple-based HIV testing, increased HIV testing frequency, and confidence about negotiating sexual matters (e.g., condom use).

Conclusions: Community-based, peer-led intervention for PrEP and SRH may help reduce SRH behavior associated with HIV and STI risk among AGYW. Future research should explore how these factors may relate to specific PrEP program content and delivery methods with particular attention to the role of peers.

EP008

Female condom (FC) in Argentina: first year of implementation with an HIV/STI combination prevention perspective

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Background: The female condom (FC) is an effective and female-controlled tool for the prevention of HIV, STIs and unintended pregnancies. We describe the implementation process of FC as part of an HIV/STI combination prevention programme in Argentina.

Methods: Distribution and promotion strategies were conducted by the provincial HIV and Sexual Health Programmes. Monitoring consisted in collecting information related to FC distribution and characteristics of FC users using an online survey completed between November 2022 and December 2023 including gender, age, reported use of penile condoms (PC), emergency oral contraception (EOC) and later experience with FC.

Target populations were cis women (CW), transgender men (TM), young people and other identities with vagina (OIWV); these were selected based on local epidemiology and implementation experiences of other countries.



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Results: Implementation included 19 of 24 Argentinian provinces. 1859 individuals picked-up FC at least once. 90,6% were CW (n=1685), 2,2% non-binary people (n=41), 2,2% OIWW (n=41), 2% TM (n=38), 1,6% cisgender men (n=29) and 1,3% TGW (n=25). The most frequent age was 25-29 years old (n=387), followed by older than 40 years (n=347). Other characteristics are shown in Table 1.

User experience data was available for those individuals who returned after the first pick-up (n=95), and 68 informed the experience being very satisfactory (n= 46), satisfactory (n=20) and unsatisfactory (n=2). Some reported being in situations of gender-based violence, highlighting the importance of FC in these scenarios and others report that the placement was difficult at first, but improved with practice. It stood out that this method fuels empowerment to the people with vagina.

	N/%
Use of Penile Condom in the last 12 months	1495
Sometimes	631 – 42,2%
Never	391 – 26,2%
Always	466– 31,2%
No data	7 – 0,5%
Use of Emergency oral contraception in the last 12 months	1495
Yes	311 – 20,8%
No	1147 – 76,7%
No data	37 – 2,5%

Table 1 - FC users characteristics.

Conclusions: Expanding the options available for the prevention is essential to enhance the autonomy of people with vagina. FC was also picked-up by individuals who were not part of initial target population. Further results will contribute to a better understanding patterns of use. We expect to expand the implementation in our country and to improve the data collection to collaborate with other countries in Latin America.

EP009

Taking a step back in the PrEP cascade to make the leap – the science of scheduling and completion of first PrEP appointments in The United States

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Background: Decision around PrEP initiation is often complex and is characterized by ambivalence. PrEP clinics across United States experience high no-show rates. Cancellations or no-shows are not just missed opportunities to linkage to PrEP care, they also result in wastage of clinic time and resources. Appointment scheduling and prior follow up process before the appointment date by outreach/navigation team plays a significant role in getting the client to the clinic for their appointment - yet such role and the science associated with it is mostly overlooked and understudied.

Methods: We conducted a retrospective analysis of the appointment records from 2021-2023 year of a 340b certified organization running PrEP clinic in Tennessee that serves LGBTQ+ community and others vulnerable to HIV. We examined follow-up data, dates, waiting times, appointment features such as day, time slot etc; and conducted a descriptive and statistical analysis, calculating prevalence odds ratios (PORs) and p-values for first PrEP appointment completions with relevant parameters.

Results: Out of 6903 clients included, we found an overall conversion of 54% from scheduled to first completed appointments. Those with waiting time 0-2 days were more likely to complete their appointment as compared to those 14-30 days waiting times with prevalence odds ratio (POR) of 1.8 (p<.01). All other waiting time intervals also had PORs >1 or similar, as compared to 14-30 days. We did not find any statistically significant correlation between completions and the day of the week appointment was scheduled. However, the timeslot 1 PM to 3 PM had higher odds of completion with POR 1.26 as compared to 11 AM to 1 PM time slot (p<.01). We also found statistically significant correlation of completion with specific providers. When looking at follow-ups that were completed 24 hours before the appointment completion, texting was the most common mode of follow up (other modes being calls and emails). Appointment being telehealth had no correlation with completion of first appointment.

Conclusions: PrEP clinics should aim to reduce waiting time and increase capacity for slots that offer better completion rates. Further, blinding provider names may reduce any inherent biases and may also facilitate improvement in completion rate.

EP011

Assessing HIV prevention services for key populations within the State Program in Ukraine (2022-2023)

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Background: Since 2019, in Ukraine, state funds have been used to cover payment for the provision of an "HIV basic package of services" for the prevention of three key populations. The basic package of preventive services: distribution/exchange programs of needles and syringes, counseling/provision of informational products, HIV testing, TB screening, and distribution of condoms and lubricants. Due to the availability of normative regulation of HIV prevention services for three key groups (PWID, SW, MSM) and the full-scale invasion of russia into Ukraine, there was a need to study the existing barriers to receiving services and the factors that contribute to their receipt.

Methods: This is a one-moment cross-sectional study using a quantitative methodology. The target group is 3,200 people from PWID, SW, and MSM who are clients of preventive services.

Results: Among respondents, 89% reported no obstacles in accessing preventive services, while approximately one in ten encountered hurdles. Notably, 85% of sex workers (SW), 89% of people who inject drugs (PWID), and 94% of men who have sex with men (MSM) reported no obstacles. MSM were more likely than SWs and PWIDs to report no obstacles, with statistically significant differences observed due to non-overlapping 95% confidence intervals. Additionally, MSM were slightly less likely than PWIDs to report obstacles in accessing prevention services.

Do you have any obstacles to the possibility of receiving HIV preventive services? *95% confidence intervals for percentages are given in parentheses	SW n=576	PWID n=1984	MSM n=640	Total N=3200
Yes	10 (7.3; 12.3)	11 (9.4; 12.1)	5 (3.9; 7.6)	9
No	85 (81.3; 87.4)	89 (87.0; 89.9)	94 (91.5; 95.4)	89
Difficult to answer	6	1	1	2

Table. Presence of obstacles in receiving HIV preventive services (by key population).

Conclusions: The information obtained enables further planning and deepening of the integration of services into the public health system, taking into account the experience of service recipients.

EP012

Latent class analysis to understand how transactional sex fits with other HIV risk behaviours: implications for male-focused HIV prevention programming

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Background: Transactional sexual relationships place young women at higher risk of HIV acquisition, yet few HIV prevention approaches exist for men initiating transactional sex. In a setting where a large proportion of men use transactional sex, we conducted a latent class analysis (LCA) to explore how different groups of men engage in transactional sex and other risky sexual relationship behaviours, ultimately leading to better targeting of interventions.

Methods: We used cross-sectional endline data from a cluster randomised controlled trial with 1,509 men aged 18-42 years in a peri-urban setting near Johannesburg, South Africa. We piloted a new measure of transaction-

al sex. Respondents self-completed sociodemographics, criminal behaviour, sexual risk behaviours, Gender Equitable Men Scale, Sexual Relationship Power Scale, and the WHO multicountry instrument adapted for violence perpetration. We iteratively built models and assessed fit for each class using the likelihood ratio test, adjusted Bayesian Information Criterion and consistent Akaike Information Criterion. Multi-variable logistic regression in Stata v14 was conducted to determine associations between transactional sex and the classes controlling for sociodemographic, attitudinal and behavioural variables.

Results: Some 23.2% of sexually active men reported past-year transactional sex. A three-class solution of masculinity classes emerged from the LCA: 1) *nice enough guys* (69%) had relatively low levels of violence, 2) *paternalistic players* (24%) displayed higher levels of economic and emotional violence and risky sexual behaviours 3) *aggressors* (7%) displayed violent behaviour across all items, including criminal acts. *Paternalistic players* were 2.6 times more likely than *nice enough guys* to engage in transactional sex (AOR 2.56, 95%CI 1.91-3.53). *Aggressors* were nearly five times more likely to do so (AOR 4.49, 95%CI 2.74-7.35). These models adjust for age, food security, attitudes to gender equity and controlling behaviour in a relationship.

Conclusions: Designing HIV prevention programming towards highest-risk groups of paternalistic player and aggressor classes could better target scarce resources by addressing transactional sex together with other behaviours and drivers. Interventions pairing gender transformation with other skills around communication and economic strengthening could reduce risk of HIV acquisition due to transactional sex.

EP013

Change targets, messaging, and content delivery for a social media campaign addressing HIV-related stigma in Peru: a qualitative study

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Background: Mitigating HIV-related stigma is critical to improving HIV outcomes and reaching global HIV targets. Social media has the potential to deliver anti-stigma messages to a broad population. Using qualitative methods, we identified key characteristics of a social media campaign targeting HIV-related stigma among youth in Lima, Peru.

Methods: From November 2022 to July 2023, we conducted 13 focus groups and 16 in-depth interviews with a diverse group of young persons living with HIV, aged 15-29



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years (men who have sex with men, transgender women, sex workers, persons with perinatally-acquired HIV, cis-gender women, and Venezuelan migrants); HIV activists; and healthcare workers. Participants were asked to identify messages important for reducing HIV-related stigma and what they would like to change as a result of a social media campaign addressing HIV-related stigma. Audio recordings were transcribed verbatim and analyzed for emergent themes.

Results: 110 people participated. Two change targets were identified for campaign messaging: 1) changing how HIV and people living with HIV (PLWH) are perceived, and 2) changing attitudes and actions towards PLWH. Messages aligning with the first change target included education to raise awareness that anyone can have HIV; HIV is a chronic condition, not a death sentence; and “undetectable equals untransmittable”. Messages aligning with the second target included normalizing talking openly about HIV; encouraging support instead of pity for PLWH; fostering unity among HIV-affected communities; and promoting inclusion. See Table 1 for illustrative quotes. Participants also provided recommendations to achieve these messaging objectives, including how messages are delivered, and to whom and by whom they are delivered.

Change targets	Messaging	Illustrative quotes from young persons living with HIV
Changing how HIV and people living with HIV are perceived	Anyone can have HIV	That we are not free of it, [...] no one, I mean, that this condition doesn't distinguish social status, or it doesn't matter if you're a housewife or if you're faithful, or if you're not trans, you're not gay, the same, you can be part of the condition.
	HIV is a chronic condition, not a death sentence	The first important message would be for them to understand that their life is going to continue like always, and that it's not going to change, it's simply a [health] condition that will be there.
	“Undetectable equals untransmittable”	I think that for me, undetectability, because it's something that people still think, they continue to think that there is a “but”. [...] Even though there have been many campaigns, people are still afraid of transmission, even if you are undetectable, you know? I think that's a very important lesson.
Changing attitudes and actions towards PLWH	Normalize talking openly about HIV	I feel that what you want to achieve is that there's no longer that fear of, of talking about the subject. That there's not that fear that I don't want to talk about HIV precisely because I could be rejected, but instead that there's freedom to talk about it.
	Encourage support instead of pity for PLWH	First, I don't want them to feel sorry for me, because sometimes it's happened that, or that it's something negative, „oh, no, get away from me, you're going to give it to me”, and I don't want them to say „you poor thing” either. Because I'm not poor, I'm not poor for having this [...] I don't want them to feel sorry for me, it's been very difficult to pick myself up and I want them to see me like that, how I am now, on top [...] Like if I told a friend “hey I think I'm gaining weight” and she says “oh ok, let's go to the gym and slim down,” I want it to be like that.
	Foster unity among HIV-affected communities	I think it would also be good if you used the community to help too, to help the community to stop being so toxic, to stop being so toxic with ourselves. I think that, I mean, because you can help people from outside to understand, but our own community is the one that also has to heal, because it is like if we do not make a change, how do we expect that other people also accept and treat us differently.
Promote inclusion	Of course, that people know that just because someone has HIV doesn't mean their world is over. On the contrary, they should understand that they need support, help, that they keep, what's the word, there's a word, that they include us. [...] that we're part of, that they include us, not exclude us. Because a person with HIV can have a normal life, you know, that would be the most important thing.	

Table 1. Illustrative quotes of change target messaging.

Conclusions: A social media HIV anti-stigma campaign should address both the perceptions of and attitudes towards PLWH and HIV, and consider how, by whom and to whom the messages are directed. This study helps to move HIV-related stigma research from descriptive to interventional.

EP014

This truck is our clinic! – reaching high-risk migrant males with differentiated pre-exposure prophylaxis services in the Copperbelt Province of Zambia

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Background: Engaging men, who tend to shun health services, to uptake pre-exposure prophylaxis (PrEP) is critical to reducing HIV transmission and pushing Zambia towards epidemic control. This requires impactful de-medicalized male-friendly services to increase uptake of PrEP. In 2023, the USAID DISCOVER-Health Project launched Health Hub: Men on the Move, a mobile health intervention to increase uptake of PrEP as an HIV prevention method among highly mobile men, including truck drivers and cross border traders.

Methods: Health Hub: Men on the move provides high quality nurse-led HIV prevention services outside of the facility setting through mobile units that target migrant male populations at two border crossings between the Copperbelt Province of Zambia and the Democratic Republic of Congo (DRC). The units, Toyota Landcruisers, are equipped with a solar panel on the roof for electricity to power a small refrigerator and laptops, and consumables and commodities for service provision. Clients seeking services can ‘walk-in’ or utilize a digital platform that can be accessed through a quick response (QR) code. Available services include HIV testing, PrEP, outpatient services, including testing and treatment of malaria, linkage to treatment and condom distribution. Testing for HIV is conducted by community-based volunteers, who also provide key messaging on PrEP. Clients eligible for PrEP are initiated by a nurse and those that opted in are enrolled in a WhatsApp platform for adherence support.

Results: From November 2023 - March 2024, 1,226 men have been tested for HIV, with 16 testing positive and linked to ART at Sakania Border Post between Zambia and DRC. Among those who tested HIV-negative, 1,194 were initiated on PrEP, receiving 3-months of oral PrEP to ensure uninterrupted supply for these highly mobile clients and an HIV self-test for the required one-month review. 976 clients were reached after one-month and confirmed utilizing the HIV self-test to retest for HIV. Additionally, 39,286 condoms and 22,500 packets of lubricants have been distributed.

Conclusions: Expanding PrEP coverage among high-risk males is critical to reducing HIV transmission. Often in good physical health, these men rarely engage with the health system, thus requiring the provision of de-medicalized and differentiated HIV prevention services.

EP016

Addressing mental health disorders using tele-mental health business cards to reach hard-to-reach key and underserved populations in Zambia

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Background: Key population members can experience chronic high levels of mental distress and related challenges as a result of rejection, isolation and marginalization. Research suggests that key population members, especially gay men and other MSM and transgender people, are at increased risk for major depression, bipolar disorder, and generalized anxiety disorder, likely as a result of the stigma, discrimination and homophobia they commonly experience.

Sustained stress can also lead to key population members turning to drugs and alcohol to cope with their problems and even to contemplate suicide, while use of drugs themselves can lead to or aggravate mental illness.

The USAID CHEKUP II Activity envisioned to address mental health disorders by using cell phones which have had a potential to foster an open dialogue around issues of HIV-related mental health, sexuality, reproductive health, and HIV prevention.

Methods: Tele-mental health business cards were distributed to Client Advisors who in turn shared with KPs in their congregate settings in 4 districts. The health business cards contain a unique mobile phone number for a qualified psychosocial counselor who responds to the needs of KPs 24/7 with an interactive live online mental health session.

Sessions included mental health first aid, screening for intimate partner and gender-based violence (GBV/IPV), depression, suicidal ideation, substance abuse and anxiety disorders.

Results: Of the 200 tele-mental health business cards distributed, 51% (101/200) received interactive live online mental health sessions with a psychosocial counselor.

Common mental health disorders addressed included 10% (11/101) anxiety disorders, 44% (44/101) depression, 6% (6/101) suicidal ideation, 40% (40/101) substance abuse. 56% (57/101) were FSWs, 23% (23/101) MSM, 21% (21/101) TGs.

Conclusions: Young KPs want more information as they explore their sexuality, they want individualized channels that would respect their privacy, and they want to be at the centre of the response to their mental health challenges.

Tele-mental health business cards have proven to break geographical barriers, promote access to mental health at any time and HIV prevention services that are available for KPs in their congregate and closed settings.

EP017

Overview of Index testing to increase HIV case detection at AHF LaMvelase Clinic, Eswatini

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Background: The introduction of antiretroviral therapy (ART) has substantially reduced the burden of HIV by decreasing the risk of death, improving treatment response, and reducing transmission of HIV through achieving viral suppression. Eswatini introduced test and start treatment in 2016 which reduced new HIV annual incidence with the country standing at 94-967-96 of the UNAID 95-95-95 targets. To fully meet the HIV epidemic control, new targeted strategies were needed to increase HIV case detection and bring into care the positive clients who are not yet in care, hence the introduction of index testing in 2019 by the Eswatini government. We give an overview analysis of index testing results in a high volume facility in the era of low HIV incidence.

Methods: We conducted a descriptive analysis of routinely collected data at the AHF LaMvelase clinic among clients tested using index testing approach and initiated on ART from 1 January to December 31, 2023.

Results: 127 index cases were identified at AHF LaMvelase clinic in 2023, with an average of 10.8 per month. From the 127 identified, 78 (61.4%) were females. 417 contacts were elicited from the 127 index cases. From the 417, 335 (80.3%) contacts were reached out and 82 (19.7%) were not reached due to various reasons. Of the 335 reached out, 159 (47.5%), were found to be already on ART in different facilities across the country. Only 176 (52.5) of 335 were eligible for testing. Of the 176 who tested, 145 (82.4%) tested negative for HIV and 31 (17.6%) tested positive and were all initiated on ART, of which 13(41.9%) were males and 18(58.1%) females of the 145 negatives, 103 (71.0%) agreed to be put on HIV preventive services (Pre Exposure Prophylaxis). When using the recency test on the 31 positives, 4 (12.9%) were recent cases and 27 (87.1%) were long term cases.

Conclusions: Index testing is a promising strategy in increasing HIV detection and early initiation of people who are HIV positive. It is key in controlling the spread of HIV. The additional use of a recency test will help develop demographical strategies to control HIV.



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EP018

Barriers and facilitators to rapid PrEP in ending the HIV epidemic jurisdictions in the United States: key informants' perspectives

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Background: Rapid initiation of HIV pre-exposure prophylaxis, or same-day PrEP, enhances prevention outcomes. Despite evidence-based benefits of rapid PrEP, clinic, provider, and client adoption are not universal.

Our study identified facilitators, barriers, and contextual factors relevant to rapid PrEP implementation across six Ending the HIV Epidemic (EHE) priority jurisdictions in the United States (U.S.) to inform subsequent implementation strategies.

Methods: We conducted key informant interviews with 10 high-level decision-makers and administrators from local health department HIV programs across the U.S. from March to July 2023. Interviews were informed by the Consolidated Framework for Implementation Research (CFIR) to identify implementation determinants and categorize barriers and facilitators.

We applied rigorous rapid analysis including same-day data collection memos, frequency and thematic analysis using CFIR-informed matrices, six debriefing sessions, and one 3-day, in-person matrix and dialogue-based analysis session involving an interdisciplinary team of 11 study investigators.

Results: Key informants primarily identified barriers to rapid PrEP implementation across jurisdictions, with facilitators being a secondary outcome. Barriers included lack of government prioritization and funding illustrated by unclear directives issued by federal agencies. Frequent funding cuts, cost, and insurance considerations such as reimbursement concerns and dependency on pharma-

ceutical assistance programs, were shown to impede sustainable implementation within all jurisdictions. Inadequate education and outreach efforts contributed to low awareness of rapid PrEP among providers and clients. Moreover, providers' discomfort with prescribing hindered the delivery of PrEP to clients. Facilitators consisted of funding assistance programs, integrating PrEP services into ART programs with dedicated navigators and staff, co-locating HIV testing sites and PrEP services, and clinic partnerships with pharmacies.

Conclusions: Key informant perspectives across jurisdictions make clear that supportive, clear government funding is a critical prerequisite for successful rapid PrEP implementation.

Moreover, federally funded HIV treatment programs should integrate PrEP services due to pre-existing funding and workflow structures. Increased clinic, provider, and client adoption of rapid PrEP would benefit from improved education and awareness at all levels.

While implementation success depends on various factors, further research is needed to understand the magnitude and contexts of rapid PrEP initiation in other regions to better inform implementation strategies.

EP019

Use of OnlyFans stars and pharmacists to increase uptake of injectable PrEP among Black and Latinx sexual minority males

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Background: Pre-exposure Prophylaxis (PrEP) medication is the keystone of preventative measures to curtail the spread of HIV, but has been slow to proliferate among men who have sex with men (MSM). More recently, PrEP in the form of a long-acting injectable (LAI) is to be administered every two months intravenously and many MSM indicate preferring LAI-PrEP to the oral form of PrEP. However, uptake of PrEP overall remains low. Research is sparse that focuses on LAI-PrEP uptake among Black and Latinx men who have sex with men (BLMSM).

To better address this concern, we explored the willingness to uptake LAI-PrEP, and recommendations for increasing awareness and encouraging uptake of LAI-PrEP among BLMSM.

Methods: Qualitative data were collected through focus groups via Zoom with BLMSM (N=30; Mean = 23, SD = 3) in Los Angeles County, California. Participants were HIV negative or untested and had no history of PrEP use. Participants completed an online survey and participated in virtual focus groups lasting 75 minutes. Grounded theory was used to analyze the data, identify major categories and themes, and participants' responses were compared using Cohen's Kappa.

Results: Three major themes emerged from an analysis of the qualitative data:

1. Allow for self-administering LAI-PrEP at home after purchasing it at a local grocery or large "chain" drugstore pharmacy –similar to filling an insulin prescription and self-administering insulin by people with diabetes;
2. Training local pharmacists to screen for and administer LAI-PrEP, and;
3. Promote uptake on OnlyFans sites using high profile owners and content creators.

OnlyFans is a popular social media platform where creators own their own profile and the content posted to their profile (e.g., messages, pictures, videos, etc.).

Findings suggested that creators of a profile share about the importance and availability of LAI-PrEP, and encourage uptake among those BLMSM who view and interact with the creator's profile/site.

Conclusions: Increasing PrEP uptake, in all modes available, such as promoting awareness through popular social media stars, and engaging pharmacists in feasible ways (such as screening and providing LAI-PrEP at local pharmacies), is critical for addressing the disproportionate impact of HIV among the BLMSM community.

EP020

PrEP use by clients at a testing and counseling center. Municipality of São Paulo, Brazil, 2023

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Background: Brazil has been expanding the supply of HIV Pre-Exposure Prophylaxis (PrEP), reflecting the control of the HIV/AIDS pandemic. PrEP includes the use of antiretroviral medication before exposure to the virus, making it a safe and effective method.

The municipality of São Paulo (Brazil) is responsible for 33% of registrations for the provision of PrEP in the country, at the same time, in the municipality there was a reduction in the incidence of HIV for the six consecutive years, justifying the investigation of the functioning of this strategy in the Unified Health System (Sistema Único de Saúde) (SUS).

The objective of the study was to investigate difficulties and facilitators in the use of PrEP.

Methods: Cross-sectional observational study carried out with clients of a STD/AIDS Testing and Counseling Center (CTA) located in the city of São Paulo, Brazil. A data collection was carried out using a questionnaire to expand understanding of the difficulties and facilitators among people who choose to use PrEP.

The questionnaire was created using Gmail's Google Forms tool. The application was online, through WhatsApp, between February 2023 and June 2023.

Results: 1131 questionnaires were sent, with 262 respondents (24%). It was observed that 75.6% of people use PrEP as recommended by the Brazilian Ministry of Health. Aspects that most contributed to the correct use of PrEP were: humanized reception provided by the health team; concern about the possibility of acquiring HIV; associate taking PrEP with everyday activities. The main reasons for discontinuing PrEP were being in a monogamous relationship and forgetting to take the medication.

Conclusions: The professional preparation and suitability of the health team to care for key populations are recognized by the clients, with emphasis on reception. Risk perception favors conscious prevention. Among the challenges, it can be identified that aspects such as personal organization can interfere with the continued use of PrEP and that a monogamous partnership is not a protective factor.

EP021

"What about the Latinos?" A community-based participatory research approach for culturally informed molecular HIV surveillance and cluster detection and response interventions for Latino/a/x Sexual and Gender Minorities

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Background: The United States strategy for Ending the HIV Epidemic has prioritized Molecular HIV Surveillance (MHS) as a prominent approach for Cluster Detection and Response (CDR) to enhance prevention and treatment services for communities most impacted by HIV. Government health officials initially did not disseminate MHS/CDR related information to the general public. A lack of information related to MHS data collection of HIV genetic sequences and CDR investigation of molecular clusters have heightened government mistrust and concerns in the community related to informed consent, HIV criminalization, and persecution of PLWH and immigrants.

Methods: A Community Based Participatory Research framework was established between San Jose State University and Latino HIV Task Force to develop a qualitative research design to explore implications for the government's plan to End the HIV Epidemic among Latino/a/x Sexual and Gender Minorities (LSGM). This study recruited HIV service providers to participate in two focus groups for staff at community based organizations (n=4) and the local public health department (n=5). Focus group recordings were transcribed verbatim, cleaned, and prepared for data analysis. A thematic analysis was administered based on Braun and Clarke's recommended phases:

1. Becoming familiar with the data;
2. Generating initial codes;



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3. Searching for themes;
 4. Reviewing themes;
 5. Defining themes; and
 6. Summarizing research findings.
- Results:** The following five prominent themes were identified:

1. Government Response to Public Health Epidemic Outbreaks – “What about the Latinos?”
2. Informed Consent, Government, and Medical Mistrust – “They’re being tracked!”
3. Enhancing Trust and Community Engagement – “We need to have more Spanish-speaking people!”
4. Enhancing MHS/CDR Transparency – “The more transparent you can be, the better!”; and
5. Peer Networks and Cluster Detection and Response – “Word gets out quick!”

Conclusions: Health equity and inclusion must take into consideration representation of people disproportionately affected by HIV at the federal, state, and community level to End the HIV Epidemic. Structural racism, heterosexism, and cissexism have excluded LSGMs from playing an integral role in developing culturally informed interventions, which have impeded community acceptance of MHS/CDR activities and efforts to mitigate HIV transmission among LSGMs.

EP022

U=U messaging improves HIV testing uptake among men in South Africa

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Background: Globally, men’s uptake of HIV testing and treatment services is low. Undetectable Equals Untransmittable (U=U) messaging has not yet been widely utilized by HIV programs in South Africa, and its impact on programmatic indicators and individual health behaviors

not yet explored. Rigorous evaluation of U=U messaging interventions are needed, especially among men in high-prevalence settings.

Methods: We conducted a cluster-randomized trial to measure the impact of U=U vs Standard Care (SC) messaging on adolescent boys and men (ABYM) uptake of community-based HIV testing services (CB-HTS) and ART initiation; clusters were testing sites and the unit of randomization was site-days. Trained male peers distributed U=U or SC invitations for free CB-HTS at eight community sites in Cape Town, South Africa. Intervention group participants with HIV-positive results received U=U-based counselling. SC group participants received standard counselling. All individuals with an HIV-positive test result were immediately referred for ART initiation.

Results: Overall, 14,481 ABYM [median age: 28 years (IQR=22-37)] were invited for CB-HTS over a 152-day period. Of those, 979/7238 (13.5%) receiving U=U messaging and 648/7243 (8.9%) receiving SC messaging presented for CB-HTS, an increase of 4.6% for U=U. Both U=U (222/976; 22.7%) and SC (151/643; 23.5%) participants reported similar proportions of first-time testing.

Of those tested, 11/976 (1.1%) U=U arm and 20/643 (3.1%) SC participants received an HIV-positive result. Of those HIV-positive, similar proportions of U=U (4/11; 36.4%) and SC (8/20; 40.0%) participants initiated ART; 75% of initiations occurring within 30 days of testing.

Conclusions: U=U informed messaging increased uptake of CB-HTS by ABYM. U=U messaging did not increase positive test results, CB-HTS uptake by first-time testers or treatment initiation relative to SC.

These findings highlight U=U messaging as an effective tool in HIV testing uptake, urging exploration and integration into public health interventions.

EP023

Sexualized substance use among Sexual and Gender Minorities from Brazil, Mexico and Peru

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Background: Sexualized substance use (SSU) is rising among sexual and gender minorities (SGM) in Latin America. This practice increases vulnerability to HIV and other detrimental health outcomes (i.e., depression) that could weaken the HIV prevention efforts in the region. We aimed to identify factors associated with SSU in a sample of SGM from Latin America.

Methods: This was a cross-sectional web-based survey among SGM from Brazil, Mexico, and Peru conducted in 2021. Participants were ≥18 years old, male assigned at birth, and not living with HIV (self-reported).

We collected sociodemographic data, sexual behavior, substance use, depression, and mental health well-being. The question for SSU was: *In the last six months, have you used any illicit drugs before or during sex? (yes/no).*

We performed logistic regression analysis, keeping all significant variables ($p \leq 0.05$) in the final multivariable model.

Results: The final sample was 13,470 participants (60.6% Brazil, 29.2% Mexico, and 10.2% Peru) with a mean age of 32.9(±9.1) years; 12,918(96%) were cisgender men, 432(3.2%) non-binary, 111(0.8%) transgender women, and 68.7% had ≥secondary education.

Most participants were attracted only to men (85.6%), 75.6% had condomless anal sex in the past six months, 40.5% ≥6 sex partners, 22.4% reported SSU, and 9.9% transactional sex.

Conversely, only 1,295(9.6%) were currently using pre-exposure prophylaxis (PrEP), and 3.6% were past users. The mean score of mental health well-being was 20.4(±5.0), and 21.5% had depression.

Young individuals, Mexicans, non-binary, PrEP users and those with sexual HIV exposure had increased odds of SSU; meanwhile, Peruvians and those with higher scores of mental health well-being had decreased odds of SSU (see Table).

	OR (95% CI) (n= 13,470)	aOR (95% CI) (n= 11,701)
Country (ref. Brazil)		
Mexico	1.24 (1.13, 1.35)***	1.45 (1.28, 1.64)***
Peru	0.44 (0.37, 0.53)***	0.54 (0.43, 0.68)***
Age (≤30 vs. >30)	1.10 (1.02, 1.20)*	1.12 (1.01, 1.24)*
Gender (ref. cisgender men)		
Trans woman	0.92 (0.58, 1.45)	0.86 (0.49, 1.53)
Non-binary	1.40 (1.13, 1.73)**	1.44 (1.10, 1.87)**
Number of sexual partners (ref. 1-5)		
6-10	1.98 (1.77, 2.21)***	1.57 (1.38, 1.79)***
>10	3.06 (2.78, 3.36)***	1.83 (1.62, 2.08)***
Transactional sex (yes vs. no)	2.21 (1.96, 2.50)***	1.37 (1.18, 1.59)***
Condomless anal sex (yes vs. no)	2.84 (2.52, 3.19)***	1.26 (1.01, 1.56)*
PrEP use (ref. never)		
Past use	1.89 (1.55, 2.29)***	1.55 (1.23, 1.96)***
Current use	2.03 (1.80, 2.30)***	1.43 (1.22, 1.66)***
Depression (yes vs. no)	1.18 (1.07, 1.30)***	1.02 (0.89, 1.16)
Mental health well-being (score)	0.97 (0.96, 0.98)***	0.97 (0.96, 0.98)***

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

Table.

Conclusions: The proportion of SGM with SSU in Latin America is high, with high exposure to HIV and low PrEP use. Comprehensive HIV prevention services should include mental health care, substance use, and harm reduction counseling.

EP024

The impact of social media campaign in PrEP awareness and PrEP uptake: lessons and evidence from Myanmar

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Background: The surge in social media usage, particularly Facebook, with 37.7% of Myanmar's population engaged in 2022, offers a strategic avenue for health communication. Acknowledging this, a social media campaign launched via Population Services International Myanmar's Facebook pages in July-August 2022 aims to increase PrEP awareness among predominantly key populations (KP) and promote its uptake. The campaign also engaged with KP social influencers by posting the PrEP contents on their Facebook pages. The study aims to analyze the metrics of PrEP mentions and monitor audience reactions on different social media platforms after a two-month period of implementation.

Methods: This study used social media listening, a process of identifying and assessing what is being said about a particular topic on the internet. Contextual sentiment classification algorithms and statistical models were applied to run analysis on 4,698 relevant conversations on different social media platforms including more than 1,000 Facebook pages.



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Results: Ninety-five percent of the PrEP-related conversations came from Facebook and very few from other platforms. On Facebook, most posts were seen from PSI-affiliated pages during the campaign period. Social influencers' pages had the highest engagement posts. A total of 172 PrEP-related posts came from 35 Facebook Pages and 65 posts from 11 Facebook Groups. 33 posts were found on the Campaign page and its overall engagement was 41.1K reactions, 4.6K comments and 2.8K shares. Among the total 4,600 comments, a majority were neutral comments, 134 positive, 39 negative and 175 sentiments of interest towards PrEP. The top five conversation patterns seen were related to PrEP availability outside of Yangon (Myanmar's main city), how to get PrEP, where to purchase it, HIV inquiries and ART-related questions. Consequently, there was an increase in PrEP screening and newly uptake of PrEP, contributing to a total of 2310 screeners and 630 enrolled into the program.

Conclusions: The study findings indicated that the campaign and social influencers produced high media mention of PrEP and high audience engagement on selected social media platforms. The campaign is currently focusing on the availability and service delivery points of PrEP. We recommend scaling of such interventions as they proved to be effective.

EP025

Pre-exposure prophylaxis awareness and endorsement among adolescents and young adults in Tanzania. Analysis from the 2022 Demographic and Health Survey

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Background: Preexposure prophylaxis (PrEP) is effective in preventing human immunodeficiency virus (HIV) infection among people at risk, including adolescents and young adults (AYA). We evaluated prevalence of PrEP awareness and endorsement and factors associated with these outcomes among AYA using data from the 2022 Tanzania and Health Demographic Survey (THDS).

Methods: Participants, 15–24 years old were included in this analysis. Participants were asked if they had ever heard of medicine taken daily that can prevent HIV and, for those aware of PrEP, if they approve of people taking

PrEP every day to prevent getting HIV. TDHS also collected demographic characteristics and HIV testing information. Logistic regression models were used to assess factors associated with PrEP awareness and AYA endorsement of PrEP, and the weighted prevalence of these outcomes was computed.

Results: A total of 8,268 respondents aged 15–24 years were evaluated, of whom, 5,852 (70.9%) were female. Overall, the prevalence of PrEP awareness and endorsement was 6.9% (95%CI:6.2–7.7) and 5.7% (95%CI:5.1–6.4), respectively. Females (aOR=0.69; 95%CI:0.51–0.91), and rural residents (aOR=0.78; 95%CI:0.61–1.00) had lower odds of PrEP awareness compared to males and urban residents, respectively. Previously HIV testing and receiving test results (aOR=2.00; 95%CI:1.50–2.66) and age, 20–24 vs. 15–19, (aOR=1.54; 95%CI:1.20–1.96) were associated with increased odds of PrEP awareness. The odds of AYA endorsement of PrEP were higher among those aged 20–24 vs. 15–19 (aOR=1.39; 95%CI:1.07–1.83) and those who previously tested for HIV and received results (aOR=1.97; 95%CI:1.43–2.72), but lower among females (aOR=0.66; 95%CI:0.49–0.88).

Conclusions: PrEP awareness and endorsement among AYA in Tanzania were low with nearly seven in 100 aware of PrEP and six in 100 AYA approving of its use. Being female, having tested for HIV and receiving results and being in the 15–19-year age group were associated with both PrEP awareness and endorsement. Residents of rural areas had lower odds of being aware of PrEP. Targeted interventions focusing on adolescents, females, and rural communities are needed to increase PrEP awareness and use to achieve UNAIDS 95–95–95 goals for HIV epidemic control.

EP026

The role of Peer Navigator in linkage to care and treatment of HIV services for Key Population: the experience of PASSOS+ project in Mozambique

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Background: Mozambique is a high HIV prevalence country and among Key Populations (KP), men who have sex with men, female sex workers, people who inject drugs, transgender people, and prisoners are disproportionately affected. In a context of decreasing resources for HIV programming, Peer Navigators (PN) based at the Health Facilities (HF) play a major role in the continuum of care for KP living with HIV (KPLHIV).

Methods: Peer navigators are members of KPLHIV, who have an intimate understanding of the lived experience of the peers they support, who works full time at health

facilities and ensure new KP diagnosed with HIV are immediately linked to HIV care. In that context, PASSOS+ in collaboration with facilities staff in 2021 trained 87 PN on topics such as condom promotion and distribution, PrEP promotion, harm reduction and HIV counselling and testing, linkage to care and Treatment, the role of NP (warm welcome, counseling, flow, Stigma and discrimination, guide referral, navigation within health facility (HF), contra referral to community, myths and cultural aspect which may interfere with treatment, home visits, data capture and reporting). As of December 2023, 23,921 were linked to C&T out of the total 24,251 newly diagnosed HIV KP, representing 99% (23,921/24,251), compared to before intervention by PN (2018 to 2020) at 90% (12,417/13,842).

Results: Well profiled, trained and experience peers play a great role in increasing the linkage rate and eventually service uptake. Facility staff engagement during training and daily oversight of PN plays important role on performance of peer navigator.

Conclusions: Using peers in service delivery proved to be effective strategy for improving service uptake. Engaging KP PN in providing services, including treatment literacy at facility proved to improve KP linkage rate for newly KPLHIV and continuum of care. Facilities in-charges must be intentional in engaging KP PN to take advantage of PN. Additionally, this approach can help close the 95-95-95 gaps among key populations.

EP027

Identifying challenges hindering HIV research in Latin America and the Caribbean and proposing potential solutions

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Background: Latin American researchers are best poised to develop and test strategies to improve HIV prevention efforts in Latin America and the Caribbean (LAC), where over 2 million people live with HIV. However, to foster locally-led research, we must address power imbalances disadvantaging LAC researchers.

This study aimed to identify challenges hindering LAC-led HIV research and propose strategies to enhance equity in global health practices and research collaborations.

Methods: From June-July 2023, we conducted an exploratory sequential mixed methods needs assessment among US- and LAC-based public health researchers partnered with the Fred Hutchinson Cancer Center, such as HIV Vaccine Trials Network (HVTN) (USA), Impacta (Peru), UNAM (Mexico), and GHESKIO (Haiti) researchers. Key informant interviews were conducted virtually amongst purposefully sampled senior researchers.

Interviews were analyzed thematically and informed the development of a survey to quantify experiences with power imbalance in HIV research and gauge interest in strategies to improve equity.

This survey was then distributed in English, Spanish, and French to researchers of different levels at the above-mentioned institutions. Surveys were analyzed descriptively.

Results: Key informants included LAC researchers (US-based, n = 2; LAC-based n=3), and US researchers (LAC- and non-LAC based, n=2). Survey respondents included US-based (n=12) and LAC-based (n=50) researchers.

Three themes were identified from interviews:

- Bureaucratic US-imposed requirements hinder LAC researchers;
- Limited local funding creates dependency on NIH funding and prevents researchers from pursuing full-time research careers; and
- Opportunities for formal research training in LAC are limited.

To address (A), respondents stressed the need for US-based institutions to simplify administrative processes for international systems.

To address (B), they proposed interventions, including grant writing workshops, for LAC researchers to secure independent funding.

To address (C), 98% of LAC-based survey respondents were interested in the development of a fully funded, short-term research program in the US, with a preference for hands-on training in laboratory science (38%), clinical research (20%), and NIH grant writing (14%).

Conclusions: Significant barriers render the HIV prevention field inequitable for LAC researchers, but this study highlights feasible opportunities to improve equity and meet the urgent demand for locally-led HIV research.

EP028

Gender differences in sexual health priorities and interest in technology-based HIV prevention services among individuals in Substance Use Disorder treatment

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Background: People living with substance use disorder (SUD) have unique HIV prevention needs, which can vary across gender and therefore warrant gender-specific HIV prevention efforts. SUD treatment facilities are well-positioned to offer HIV prevention services, but barriers prevent the comprehensive integration of such services. Technology based interventions have shown promise in HIV prevention and could be leveraged to address this gap. However, more information is needed regarding client preference for technology-based HIV prevention services to ensure acceptability.

Additionally, the potential for gender-specific technology-based interventions should be further explored.



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The current study addressed these gaps through two aims:

1. Explore gender differences in sexual health priorities among individuals enrolled in SUD treatment, and;
2. Examine gender differences in interest in technology-based HIV prevention services.

Methods: Surveys were collected from 261 clients enrolled in 8 residential SUD treatment programs across Northern California. Clients were asked to rate the importance of nine priority areas for improving sexual health (e.g., knowing where to access condoms) and their interest in using technology in different ways to improve sexual health (e.g., receiving information about HIV/STIs). Chi-square tests were used to explore gender differences in sexual health priorities and interest in using technology-based services.

Results: Feeling positive about one's body and sexuality was reported as an important priority for maintaining good sexual health by 73.2% of the sample while knowing how to use birth control was rated important by only 44.1% of the sample. No gender differences were found across sexual health priorities. Most of the sample (65%) reported interest in using technology to improve sexual health. No gender differences were found across the different technology-based services.

Conclusions: Men and women in SUD treatment reported similar priorities for sexual health and HIV prevention. Most of the sample were interested in using technology to improve sexual health, with no gender differences noted in different ways that technology could be leveraged. Results of this study can inform the development of technology-based HIV prevention interventions that can be integrated in SUD treatment.

EP029

Examining the relationship between vaginally inserted product use by rural South African adolescent girls and young women, and the prevalence of acquiring sexually transmitted infections and cervical abnormalities

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Background: The use of vaginally inserted products (VIPs) is common in adolescent girls and young women (AGYW) in some parts of South Africa, which may influence the risk of acquiring sexually transmitted infections (STIs), including HIV.

This study aimed to investigate whether age-related reproductive tract characteristics coupled with the use of VIPs in adolescent females exacerbated injury to the cervicovaginal mucosa, and influenced prevalence of STIs.

Methods: Sexually active, HIV-uninfected adolescent girls (n=188, 14-19-years old) and adult women (n=64, 25-35 years old) were enrolled in KwaZulu-Natal, South Africa. Detailed questionnaires collected demographic, sexual behaviour, and vaginal practices data. Cervical abnormalities were identified by colposcopy. Molecular testing for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) was performed. Bacterial vaginosis (BV) was determined by Nugent scoring, and fungal hyphae were inspected on wet-mounts. Human Papillomavirus (HPV) genotyping of 36 high risk (HR) and low risk (LR) types was done using DNA Flow hybridization.

Results: Different types of VIP (n=78) were reported, and these were either made traditionally or available commercially. VIP use was common in both adolescents (66.5%) and adults (69.8%), with younger women reporting use of a wider range of products. Vaginal insertion of alum was more commonly reported by adolescents

(30/78), compared to adults (1/63), and linked to higher prevalence of colposcopic signs of injury compared to adolescents not using any products ($p=0.002$). Adult women using "Ibhodwe labafazi", a scented petroleum jelly, were more likely to have cervical ectopy ($p=0.004$, OR 20.0 [2.26 – 245.5 95% CI]). Adolescents using VIPs were more likely to be infected with HR HPV than non-users (75/175 vs 42/175, $p=0.0072$), including HPV-16 (24/175 vs 5/175, $p=0.0056$) but there was no significant association with prevalence of other STIs. In contrast, VIP use by adults was not associated with prevalence of STIs, including HPV.

Conclusions: Adolescents using alum were associated with cervical injury and higher risk of HR HPV infections, linked to cervical cancer risk. In adults, "ibhodwe labafazi" use was associated with higher prevalence of cervical ectopy. These findings suggest that use of VIPs may contribute to risk of STIs, including HIV and cervical cancer susceptibility.

EP030

Chemsex among young men who have sex with men in Thailand: qualitative findings exploring self-perceived pleasures and harms

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Background: Drug use to enhance sexual activity (chemsex) is associated with multifaceted impacts on young men who have sex with men (MSM). A comprehensive understanding of these impacts is pivotal for appropriate harm reduction interventions; however, little is known about the self-perceived effects of chemsex. This cross-sectional analysis under the Comprehensive Assessment in a Longitudinal Study on Young Men who have sex with men Attracted to Chemsex (CLYMAX), aims to assess self-perceived effects of chemsex to better tailor health-care services.

Methods: Forty MSM engaged in chemsex, aged 16-35, were recruited from the Institute of HIV Research and Innovation (IHRI), Thailand via purposive sampling. Participants underwent semi-structured, in-depth interviews (IDIs) in Thai, which were recorded, transcribed verbatim, and thematically analyzed using Dedoose software.

Results: Four key impacts of chemsex were identified from the interviews: physical health, psychological health, socio-economic factors, and legal issues. Physical harms associated with chemsex varied, including the effects of chemicals themselves or their use—such as soreness or

redness at the injection site and irritation of the upper respiratory tract mucosa. Additionally, harms related to sexual activities emerged, including non-consensual sex or sexual violence and an increased risk of sexually transmitted infections (STIs). Psychologically, while some maintained mental stability, others experienced severe anxiety, depression, and suicidal ideation. Socio-economically, chemsex was found to disrupt work and personal relationships, leading to financial instability. Legally, participants reported fear of arrest and skepticism towards law enforcement, contributing to paranoia and caution in their community's anti-drug environment, and deterring seeking medical care for drug-related issues. Importantly, participants reported self-perceived benefits of chemsex such as heightened sexual pleasure, increased social engagement, and a sense of community belonging.

Conclusions: Our findings delineate a multifaceted impact of chemsex among young MSM in Thailand, indicating its complex role in their lives that warrants a nuanced understanding in health interventions. Adopting a dual perspective is essential for healthcare professionals in crafting people-centered, pleasure-integrated, comprehensive chemsex care strategies that aim to alleviate harms associated with chemsex, while preserving or substituting the positive experiences of chemsex engagement. Such approaches are essential for enhancing clinical care and effectively guiding public health policies.

EP031

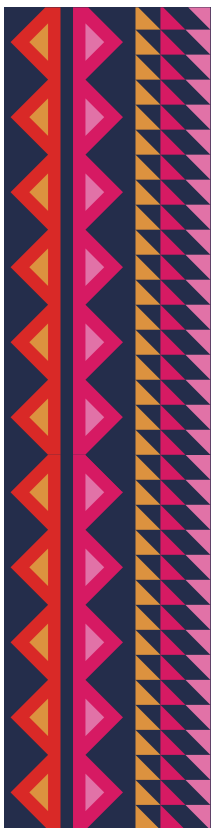
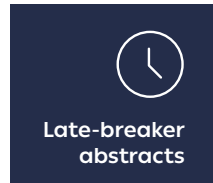
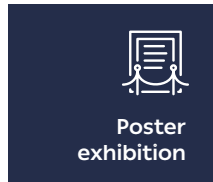
Coach Mpilo, a peer-coach blueprint model on improving ART initiation, treatment, and retention to care in two provinces in South Africa

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Background: An estimated 2.46 million adult males in South Africa are currently living with HIV. Among new infections in the country, approximately 39.2% occur among men, with a significant portion (10% to 49.5%), involving men who have sex with men (MSM). There is a pressing need for strategies aimed at identifying and effectively engaging this demographic, ensuring their linkage to care services. The Yim'Lo Project, in collaboration with the Department of Health and the Aurum Institute, has used human-centered design to co-create a 'true-peer coach model' to improve reach and uptake of HIV services among MSM.

Methods: Between September 2022-December 2023, the Yim'Lo project trained MSM with HIV (also known as coaches) in two provinces in South Africa on engaging male peers (also known as players) in their network, whereby they provided antiretroviral messaging, and support for initiating and staying on treatment. Programme data were descriptively analysed in stata 18.





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Results: Nine coaches engaged with a total of 1,984 MSM living with HIV services, aged between 19 and 46, with an average age of 30. Among them, 1,085 individuals (53%) did not openly disclose their sexual orientation. Out of the total, 527 (27%) were taking ART treatment, with 409 (78%) being newly initiated and 95 (18%) returning to treatment through the peer-coach program. The majority, comprising 1,439 individuals (73%), were on PrEP, while 18 (1%) declined it. Reasons for non-adherence to treatment included forgetting medication schedules, perceived stigma from friends and the community, and fear of treatment. All coaches provided psychosocial support and adherence counseling and facilitated the disclosure of HIV status to approximately 95% (1,880) peers who contacted them.

Conclusions: Initiating ART and PrEP and ensuring linkage to care for MSM living with HIV, using the coach modality of peer-to-peer support, proved to be both effective and viable. This approach showed promise in increasing the initiation and uptake of ART and PrEP among marginalized populations like MSM. The peer-coach model holds promise in enhancing the acceptability and uptake of ART and PrEP, while also facilitating linkage to care, especially individuals who may not openly disclose their sexual orientation.

EP032

Understanding barriers to pre-exposure prophylaxis (PrEP) uptake among African, Caribbean, and Black immigrants in high-income countries: a systematic review

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Background: African, Caribbean, and Black (ACB) immigrants living in high-income countries (HICs) face a disproportionately high HIV risk. Pre-exposure prophylaxis (PrEP) effectively prevents HIV acquisition, yet uptake is low among ACB immigrants in HICs. However, emerging qualitative literature describes the experiences and challenges faced by ACB immigrants in accessing and using PrEP in HICs. This systematic review synthesizes current evidence on barriers to PrEP uptake among ACB immigrants in HICs.

Methods: We conducted a systematic literature review search on several databases, including Medline, Web of Science, EMBASE, SCOPUS, Social Policy and Practice, CINAHL plus, Psych INFO, and Global Health, using specific search terms for appropriate studies. The aim was to identify peer-reviewed articles and grey literature describing barriers to PrEP access and utilization in HICs. No publish date limit was applied.

Results: Thirteen qualitative studies (12 articles and one thesis) were included in this review. Most studies were conducted in the United States (n=4), United Kingdom (n=3), and Belgium (=2); Australia, Canada, New Zealand,

and Switzerland had one study each. The temporal span of the studies ranged from 2014 to 2024. Studies captured the perspectives of ACB immigrants, healthcare providers, and community-based organizations working with ACB immigrants. At the Individual level, barriers to PrEP access and use included the difficulty of assessing personal HIV risk, limited awareness and knowledge of PrEP, and concerns about PrEP (i.e., effectiveness, daily pill taking, and side effects).

Interpersonal/community level barriers comprised the perceived adverse impact of PrEP on partner trust and relationship dynamics, limited PrEP knowledge among social networks, community stigma, taboos, and the cultural socialization shaping PrEP disinterest.

Institutional/organizational barriers were inadequate PrEP education, language barriers, lack of provider awareness, and gender discordance in healthcare preferences. Policy/system-level barriers included sociocultural factors, structural stigmas, legal and administrative issues, and healthcare access challenges.

Conclusions: Our findings indicate multifaceted barriers at individual, interpersonal/community, institutional/organizational, and policy/system levels, suggesting a need to develop targeted multilevel and multi-component interventions to improve PrEP access and uptake among ACB immigrants in HICs. Future research is needed to identify facilitators for PrEP access and utilization among ACB immigrants in HICs.

EP033

Fungal and TB co-infection among advanced HIV disease clients in Uganda

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Background: In 2022, WHO published Priority Pathogens (WHO, 2022), a global effort in the fight against fungal infections. In resource-limited countries, there is a need for awareness and improved diagnostics for invasive fungal diseases (Bongomin et al., 2022). In Uganda, fungal infections affect nearly 9% of the general population (Bongomin et al., 2024), while those with presumptive TB are at 70.7% (Njovu et al., 2021). Evidence of coinfections beyond TB and Cryptococcus among advanced HIV Disease (AHD) clients in Uganda is limited.

The study aimed to document the co-infection of fungal, TB, and associated factors among AHD clients in Uganda.

Methods: 334 AHD clients were recruited in a cross sectional study from across seven regions in Uganda between May and October 2023. Serum samples were tested for CrAg, and Aspergillus testing on the sōna Aspergillus Galactomannan Lateral Flow Assay (AGM LFA). Urine sam-

ples collected in sterile containers were tested for TB LAM and Histoplasmosis on the Clarus Histoplasma Galactomannan EIA (HGM201). At the analysis, logistic regression to predict the odds of having a co-infection versus no co-infection among AHD clients was used.

At bivariate analysis factors with a P value <0.2 were considered for multivariate analysis. Significance was set at $P \leq 0.05$.

Results: Of the 334 clients recruited in the study, 45 (13.5%) had a bacterial and/ or fungal co-infections. Majority of the co-infected participants were from out client department, and had TB cardinal signs alone. The highest co-infection observed was between Aspergillosis and Tuberculosis 9.0% (30/334) clients, of which 4 clients had TB, Aspergillosis and Cryptococcus. Independent factors associated with having co-infection in AHD clients were having TB cardinal signs, and being hospitalized. At multivariate, being on ART less than one month predicted increased odds of co-infection in AHD clients.

Conclusions: The study concludes that a significant proportion of clients have bacterial and/or fungal co-infections with common co-infections including Aspergillosis. clients with TB cardinal signs, those hospitalized, and those on short-term ART are at increased risk of co-infection highlighting the importance of early diagnosis and treatment for people with advanced HIV disease.

EP035

A mathematical modelling exploration of the role of violence on the HIV epidemic among female sex workers and their clients in Mombasa, Kenya

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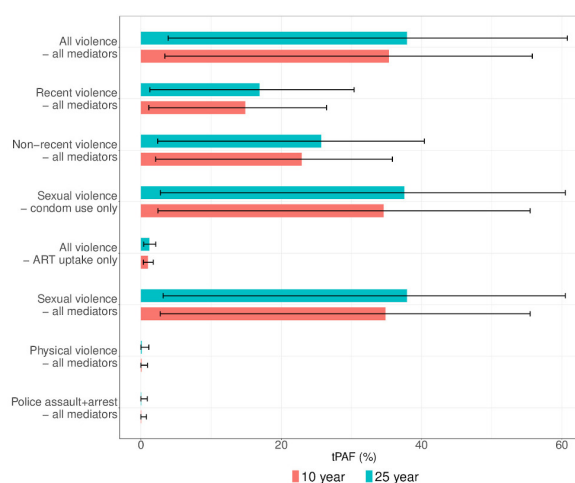
Background: Female sex workers (FSWs) experience a high burden of violence, including physical/sexual violence (PV/SV) from clients/intimate partners, and police assault and arrest (PAA). We quantified the contribution of these violence types to HIV transmission in Mombasa, Kenya.

Methods: Using recent recommendations for modelling structural factors, including violence, we developed a transmission-dynamics HIV model among FSWs and clients in Mombasa, incorporating recent (last 6 months) and non-recent exposure to SV/PV/PAA in FSWs. Cross-sectional survey data of FSWs from Mombasa provided prevalence

estimates of recent/non-recent violence (SV: 12.3%/17.5%; PV: 17.4%/13.1%; PAA: 19.6%/25.8%). Based on analysis of that data we assumed that: recent and non-recent SV affects condom non-use (relative risk, RR=1.01-2.97); recent and non-recent SV (RR=0.82-1.01), PV (RR=0.83-1.01), and PAA (RR=0.89-1.08) affect antiretroviral therapy uptake. We calibrated and cross-validated to Mombasa-specific HIV epidemiological and violence prevalence outcomes.

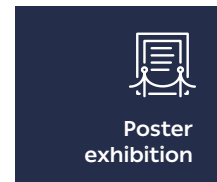
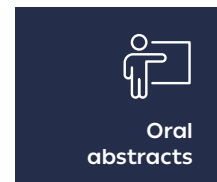
We estimated the median (and 95% credible intervals, 95%CrI) fraction of all cumulative infections (transmission population-attributable fraction, tPAF) due to violence, overall and by type, for 2023-2032 (10 years) and 2023-2047 (20 years). We examined correlations between the 10-year tPAF and calibrated parameters to identify sources of uncertainty.

Results: In Mombasa, a median 35% (95%CrI: 3-56%) infections in FSWs/clients combined over 2023-2032 may be due to all violence types (both mediators), mainly due to recent and non-recent SV reducing condom use (35%, 2-55%; Figure).



Non-recent violence contributed more over 2023-2032 (23%, 2-36%) than recent violence (15%, 1-26%) due to its higher prevalence. The parameters contributing most to uncertainty (correlation >0.6) were effect size for condom non-use when exposed to SV and effectiveness of condoms against HIV.

Conclusions: In Mombasa, addressing sexual violence, particularly long-term effects of non-recent violence, may help reduce HIV transmission. However, longitudinal studies are needed to provide more precise estimates of the influence of sexual violence on condom non-use, and improve modelling estimates.





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EP036

Impact of linkage to HIV pre-exposure prophylaxis (PrEP) on healthcare utilization: decreased emergency department and urgent care usage with increased longitudinal care engagement

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Background: Pre-exposure prophylaxis (PrEP) is a highly effective, yet underutilized, method for preventing HIV. A growing number of new HIV diagnoses occur in Emergency Department (ED) and Urgent Care (UC) settings and high-risk people for HIV often have limited engagement with healthcare before diagnosis. The ED/UC could provide unique opportunities to identify people at risk and offer referral to PrEP services.

We sought to identify the proportion of people referred to and linked to PrEP from our institute's ED/UC settings and the impact of linkage on longitudinal and non-longitudinal healthcare utilization.

Methods: We performed a retrospective chart review of people referred to PrEP among those seeking care for sexual health-related diagnoses (SHRD) in our institute's ED or UC from 1/1/2019 to 6/19/2021. Using Chi-Square test or Fisher's exact tests for any expected cell count <5, we compared linkage to each type of longitudinal care between people linked and not linked to PrEP.

We also compared the number of visits to the ED/UC overall and for SHRD in the two years before and two years after linkage to PrEP.

Results: Among 297,198 encounters in the ED/UC included, there were 10,894 unique people seen for an SHRD. The PrEP referral rate from the ED/UC for SHRD was 1.1% (n=123) and PrEP linkage rate after referral was 35.8% (n=44). There were no significant demographic differences between people linked and not linked except for gender identity (p=0.03). Linkage to PrEP was significantly associated with the odds of scheduling [OR 2.7 (95% CI 1.3-5.9), p=0.01] and completing [OR 2.4 (95% CI 1.1-5.1), p=0.03] a primary care visit.

Among those linked to PrEP, the mean number of ED/UC visits for any reason and for SHRD significantly decreased from 2 years before to after linkage (p=0.007, p=0.008).

Conclusions: Among thousands of people seeking care in the ED/UC for sexual health reasons, PrEP referrals were very low, revealing critical missed opportunities for HIV prevention in these settings. PrEP linkage was associated with subsequent usage of primary care services and a decrease in ED/UC visits, suggesting that PrEP may improve engagement with longitudinal health services.

EP037

Enhancing the informed consent process with visual aids: lessons from an HIV vaccine trial in southwestern Uganda

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Background: Ensuring informed consent in clinical trials is crucial, but the length and complexity of written trial information can hinder comprehension. Good Clinical Practice and Good Participatory Practice (GPP) emphasize the importance of accessible trial information.

Here, we share our experiences using visual aids guided by GPP to enhance participant engagement and comprehension of trial procedures.

Methods: The MRC/UVRI and LSHTM Uganda Research Unit is conducting the PrEPVacc phase IIb HIV vaccine efficacy trial, which also includes a PrEP trial. Stimulated by community feedback and counselling debriefs gathered by the PrEPVacc study social scientists, the trial communications team initiated the development and use of visual aids to support the informed consent process.

Using the approved consent document, we developed a simplified script in English which was discussed with a visual aid developer and used to develop a 13-minute voiced-over animated video featuring a dialogue between a woman who is familiar with the study and a man who is interested in exploring it.

The video was designed to introduce the trial objectives, its methodology and what participants can expect, to address commonly asked questions, and to explain vaccine-induced seropositivity (VISP). It underwent expert review and site staff piloting before production. It was translated, captioned and dubbed into Luganda, and all materials were reviewed and approved by the institutional review board and regulatory authorities before use. Before each visit, the video was shown to participants in the waiting area, followed by clarification and feedback sessions led by trial staff.

The video can be viewed here:

<https://www.youtube.com/watch?v=zHYC6SKKobc>

Results: The video, which has been in the field since April 2022, helped stimulate discussions among participants, particularly regarding vaccine-induced seropositivity (VISP) challenges. The majority of participants demonstrated comprehension of trial concepts, as evidenced by passing the assessment of understanding test.

The Community Advisory Board supported the video's use and advocated for its regular presentation during study visits, which promoted participant engagement and ultimately contributed to participant retention.

Conclusions: Visualizing trial information promotes participant engagement and comprehension of study procedures. This approach enhances the informed consent process and supports participants' understanding of trial conduct.

EP038

Integrating health services through a peer mentor model: a case study in Lilongwe District, Malawi

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Background: In 2017, mothers2mothers Malawi transitioned to integrated services, aligning with the government's National Community Health Strategy and WHO/UNICEF Nurturing Care Framework. Launched in 2018, a 3-year project in Lilongwe aimed to provide comprehensive PMTCT/RMNCH/ECD and Nutrition services for pregnant and breastfeeding women (PBFW) facing HIV and motherhood challenges, and their children.

The project contributed to ending AIDS by creating demand and facilitating referrals to access integrated health services.

Methods: PBFW and their children were enrolled through mothers2mothers digital tools. Peer Mentors strategically positioned in facilities and communities created demand and facilitated access to PMTCT/RMNCH/ECD and nutrition services. Collaborating with government Community Health Workers and Nutrition Facilitators, Peer Mentors conducted education sessions and nutrition assessments. They also organised evidence-based Nurturing Care Parenting Information Play (PIP) sessions. Growth monitoring was seamlessly integrated into routine PMTCT visits, with ongoing support during household visits. Routine monitoring data was analysed descriptively.

Results: Over 3 years, Peer Mentors reached 185,821 PBFW with comprehensive PMTCT/RMNCH/ECD and nutrition services. Of these, 47,718 (26%) were HIV positive. Among them, 36,602 had a known HIV status, and 11,116 were newly diagnosed, all successfully initiated on treatment and remaining in care.

Notably, 45,449 (95%) adhered to ART in line with global targets, reducing transmission risk. Peer Mentors also provided nutrition education and cooking demonstrations during PIP sessions led by Nutrition Facilitators.

Approximately 35,469 children under 3 received Nurturing Care services, with 14,283 (40%) undergoing assessments during growth monitoring and PIP sessions, and 14,047 (98%) having normal nutrition. Only 236 (1.65%) showed moderate acute malnutrition, and 6 (0.04%) were successfully referred.

Throughout implementation, 13,304 HIV-exposed children were tested, with only 90 (0.67%) positive, promptly initiated on treatment.

Conclusions: Integrating health services enhances person-centered care for PBFW and their children, ensures improved access and continuity of care throughout their healthcare journey. Addressing diverse health needs increases the likelihood of treatment adherence and engagement in preventive activities for better overall health.

Integrating nutrition education and MUAC assessments during PMTCT facility visits, and cooking demonstrations in Nurturing Care PIP sessions holds significant potential to strengthen early identification, facilitate linkages to nutrition rehabilitation services, and enhance ART adherence support.

EP039

Integrating HIV testing with value added services to reach the unreached Transgender to address the needs and vulnerabilities: results from Global Fund-supported One Stop Center project in India

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Background: Though the overall adult HIV prevalence remains low in India, as per preliminary analysis of data from HSS 2021, HIV prevalence was estimated to be at 3.78% among Transgender persons (TGs). Complementing Govt. of India's effort to end AIDS by 2030, Plan India is implementing innovative One Stop service solution for Transgenders in 25 Indian states through community led One Stop Centre project funded by The Global Fund.

Methods: The project is guided by three strategic objectives:

1. To reach out to and identify new & uncovered Transgender population through expanding service coverage beyond HIV prevention,
2. To provide enabling environment to the transgender community and thus, reduce Stigma & Discrimination,
3. Empowerment of the transgender communities by generating awareness and engaging in various skill development programme.

Six thousand TG has been registered in the project during October,22 to September, 23. SPSS 26 has been used for analysis using project MIS data.

Results: Six thousand Transgender has been reached through this intervention. Around 80% of the clients were aged less than 34 years with a mean age of 29 years, 32% have completed secondary education, and 17% have completed higher secondary education while 18% are illiterate. Mostly (78%) are dependent on daily wage earnings, while 15% are unemployed.

While overall positivity remained at 5.8%, the positivity remained higher among the illiterate group, compared to others. It is observed that the HIV positivity increases with the age in the registered population with 8% in 35-44



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yrs., compared to 5% in the age group 15-24 yrs. (OR=1.64; CI: 1.43 - 1.89); 23% of the client reached with awareness on awareness on TG Act / Legal Rights and 22% has been reached with TG Shelter Homes, Mental Health counseling, Social protection etc.

Conclusions: Expansion of services beyond HIV testing is a vital strategy to respond to the unmet needs of Transgender population with varied sociodemographic profile. While, Plan India's OSC project demonstrates a one stop solution of HIV testing and additional services for Transgender communities, it suggests that the service delivery needs to be prioritized based on sociodemographic profile of the client.

EP040

Progress, barriers, and a comprehensive agenda for the HIV elimination in the Dominican Republic: a national surveillance study

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Background: HIV poses a significant public health challenge in the Dominican Republic (DR), marked by diverse populations encountering distinct obstacles, including limited healthcare access, pervasive stigma, and varying risk behaviors. Seroprevalence studies play a crucial role in elucidating the epidemiological landscape, informing targeted interventions for key populations.

This study aims to refine prevention strategies and mitigate HIV's impact in the DR.

Methods: A national study, utilizing respondent-driven sampling, investigated men who have sex with men (MSM), transgender women (TGW), and female sex workers (FSW). Demographic, health, and behavioral data, along with samples, were analyzed for HIV, hepatitis B and C, and syphilis.

Results: A total of 4,362 samples were collected from the DR capital city (Santo Domingo), and the north-central and southern provinces. Mean age FSW and MSM was 25 years old. Primary education predominates in FSW, TGW, and those engaged in sex work, while approximately 50% of HSH have at least secondary education.

Although the majority has adequate knowledge about HIV transmission, there is low participation in recent educational programs related to STIs/HIV/AIDS, indicating a gap between theoretical knowledge and preventive practice.

Overall, FSW experience less abuse or disdain related to sex work compared to other key populations. However, TGW face high levels of rejection and physical, verbal, or sexual abuse due to their sexual orientation. Prevalence rates of HIV, HCV, and HBV vary among groups, with TGW

being the most affected group with alarmingly high rates (HIV prevalence 30%) and only 19% are currently on HAART. Awareness of HIV Pre-Exposure prophylaxis (PrEP) was only 15% among MSM/TGW.

Conclusions: This scientific analysis provides an in-depth insight into HIV dynamics in the Dominican Republic, highlighting areas of priority intervention to improve prevention, diagnosis, and treatment, as well as addressing social and structural factors influencing the virus's spread.

This research offers a detailed sociodemographic and behavioral analysis related to HIV in various key populations in the Dominican Republic. The findings reveal distinctive characteristics in terms of age, education, marital status, and sexual behaviors, providing a comprehensive understanding of epidemiological dynamics and associated risk factors. PrEP programs must be relaunched and improved in scope.

EP041

Use of human-centered design to co-develop a digital platform and evaluate its use to drive uptake of pre-exposure prophylaxis among Nigerian youths in Lagos, Nigeria through a pilot intervention study

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Background: Nigerian youths are at the heart of a growing HIV crisis, with the second-highest rate of new infections globally. HIV pre-exposure prophylaxis (PrEP) offers great opportunities to reduce the risk among youths.

This study assessed the delivery of HIV PrEP through a co-developed web platform for youths in Lagos, Nigeria.

Methods: This study employed five phases of human-centered design (HCD): empathy, define, ideate, prototype, and test. The empathy and define phases involved qualitative interviews with 21 youths (15-24 years old) aimed at understanding needs and barriers to accessing HIV PrEP. Expert interviews with 12 providers provided additional insights. An additional 106 youths filled out the self-administered questionnaires. Content extraction and thematic analysis of the interviews and questionnaires informed the ideation and prototyping phases, leading to a web-based intervention design called Binta. Binta was evaluated qualitatively for feasibility and acceptability during a six-month pilot using structured interviews with 42 youths at-risk of HIV.

Results: Among the youths we co-designed with, 65% were female, and 70% were at least 20 years old. Four key factors emerged as barriers to PrEP access and uptake among Nigerian youth: long distances to HIV clinics, confidentiality issues, low knowledge of PrEP, and high costs. Features of the web platform, co-developed with youths and providers, include: a reddit-like community to foster safe, anonymous, and open conversations around PrEP

and HIV/AIDS; a robust FAQ section with visual media; a PrEP eligibility section; and a pharmacy locator. The pilot study revealed widespread desirability of the web platform among youth at-risk of HIV/AIDS, including female sex workers.

Overall, 88% (n = 37) of youths interviewed in the pilot phase were comfortable with the platform's user interface and design. 100% (n = 42) of the youths used the PrEP eligibility feature and more than 80% (n = 34) used the pharmacy locator to pick up their PrEP bottles

Conclusions: Digital health technologies have the potential to expand PrEP services and show great promise in delivering health services to meet the needs of Nigerian youths. Engaging youths as partners in the design of interventions can help facilitate uptake and should always be considered.

EP042

One size doesn't fit all: self-reported reasons for low PrEP intentions and uptake among Black and Latinx sexual and gender-minoritized (BLSGM) individuals in Long Beach, CA, USA

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Background: Black and Latinx sexual and gender-minoritized (BLSGM) individuals are overrepresented among people with new HIV diagnoses in Long Beach, CA, and they have low PrEP engagement.

Using a community-engaged equity approach, we explored PrEP intentions and uptake among a sample of BLSGM community members.

Methods: Semi-structured interviews and focus groups were conducted with BLSGM community members (n=29) and analyzed using an inductive rapid qualitative approach to develop a community survey. Measures included reasons for not using PrEP, intention to initiate PrEP, PrEP Stigma Scale, Perceived HIV Risk (PHR), Group-Based Medical Mistrust Scale (GBMMS), and the Discrimination in Medical Settings (DMS) Scale. Participants were recruited using convenience sampling methods at community events. SPSS was used for all analyses.

Results: Among sixty-one (38.6%) BSGM and 97 (61.4%) LSGM individuals, fewer BSGM (9.8%) compared to LSGM (17.5%) reported prior PrEP use, $\chi^2(2,158) = 6.18, p = .045$. PHR was significantly and positively correlated with PrEP intentions ($p < .001$), DMS ($p < .001$) and GBMMS ($p = .025$).

Participants identified personally relevant reasons for not taking PrEP which were grouped into five categories: alternative protection (e.g., condoms) (n=44), no current perceived HIV risk (no sex or monogamous) (n=64), negative PrEP views (e.g., concerns about side effects) (n=28); access barriers (e.g., uninsured) (n=28), and medical constraints (e.g., kidney disease) (n=3). Eighteen made no selection. Some differences between the four largest groups were noted. Participants selecting 1) alternative methods had

higher PrEP Stigma ($p = .047$); 2) no perceived HIV risk had lower PrEP intention ($p = .009$) and higher GBMMS ($p = .034$); 3) negative PrEP views were lower on GBMSS ($p = .044$); and 4) access barriers had higher perceived HIV risk ($p = .003$) and PrEP intention ($p = .002$).

Conclusions: Findings indicate multiple barriers to PrEP-related intentions and use among BLSGM individuals. Additionally, potential influencers of poor PrEP uptake and intention vary depending on participants' assessments of barriers. This information may facilitate constructing PrEP readiness tools for community and health service settings that allow for tailored exploration and mitigation of PrEP-related barriers.

Additionally, they point to the importance of addressing PrEP access barriers to engage those who have positive intentions for adopting PrEP.

EP043

The impacts of medical mistrust and discrimination on engagement in the PrEP care continuum as reported by Black and Latinx sexual and gender-minoritized (BLSGM) individuals in Long Beach, CA, USA

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Background: Long Beach ranks third among California cities with the highest rate of HIV acquisition. Black and Latinx sexual and gender-minoritized individuals (BLSGM) are overrepresented among people living with new HIV diagnoses, and they have low PrEP engagement.

Using a community-engaged equity approach, we explored BLSGM perceptions about the impacts of medical mistrust and discrimination on effective engagement in the PrEP care continuum to inform PrEP-related interventions to support BLSGM.

Methods: Implementation science frameworks and established partnerships with community-driven HIV prevention and transgender wellness workgroups, informed study aims and the development of data collection instruments. Study staff conducted interviews and focus groups with BLSGM community members (n=29) and analyzed transcripts using an inductive rapid qualitative approach to develop a community-facing survey for PrEP and non-PrEP users. Measures included the Group-Based Medical Mistrust Scale (GBMMS), Discrimination in Medical Settings (DMS) Scale, Perceived HIV Risk (PHR) scale, and a single item on intent to initiate PrEP. SPSS was used for all analyses.

Results: Participants included 61 (38.6%) BSGM and 97 (61.4%) LSGM individuals. Fewer BSGM (9.8%) compared to LSGM (17.5%) reported a history of PrEP use, $\chi^2(2,158) = 6.18, p = .045$. There was a positive association between DMS and GBMM, $r(156) = 0.318, p < .001$. BSGM scored signifi-



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cantly higher on both DMS, $t(156)=2.35$ $p=.02$, and GBMM, $t(156)=3.71$ $p<.001$, but not PHR. However, PHR was positively correlated with both DMS, $r(153)=0.388$, $p<.001$ and GBMM, $r(153)=0.178$, $p=.027$. Non-PrEP users ($n=144$) were asked about PrEP intentions. In regression analysis including all scales, PHR was a significant predictor of intent for all respondents, $\beta = 0.381$, $p<0.001$, and DMS predicted intent only among BSGM, $\beta = 0.551$, $p=0.027$. GBMM did not predict intent.

Conclusions: PrEP engagement was low among our study participants, and particularly low for BSGM individuals who reported greater medical mistrust and discrimination in medical settings compared to LSGM individuals. Individual decisions regarding PrEP uptake appear to be influenced by the interconnected factors of perceived risk, experiences in medical settings, and trust in medical providers.

Integrated provider-level and systems-level interventions are needed to validate and address experiences of healthcare clients related to discrimination particularly as they impact BSGM individuals.

EP044

Perspectives on newer forms of pre-exposure prophylaxis (PrEP) among Black and Latinx sexual and gender-minoritized people in Long Beach, CA, USA

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Background: Pre-exposure prophylaxis (PrEP) use remains at suboptimal levels among Black and Latinx sexual and gender-minoritized people (BLSGM) to address the disproportionate rates of new HIV acquisitions experienced among this community in Long Beach, CA. Injectable PrEP, PrEP 2-1-1, and pharmacist-initiated PrEP could address barriers to PrEP engagement among BLSGM people. Our research team sought to identify local perceptions of these forms of PrEP among BLSGM to inform local strategies to improve PrEP uptake and engagement.

Methods: Semi-structured interviews ($n=22$) and focus groups ($n=3$) were conducted with 39 BLSGM who either lived in or received healthcare services in Long Beach, CA, to explore their:

1. Knowledge, attitudes, and beliefs about PrEP; and,
2. Experiences seeking PrEP and PrEP providers in Long Beach.

Interview and focus group recordings and transcripts were summarized using predetermined domains based on the interview questions that guided the discussions, and an inductive rapid qualitative analysis approach was used by four study team members to distill themes.

Results: When presented with the choice between injectable PrEP, PrEP 2-1-1, and once-daily PrEP, most participants preferred injectable PrEP due to not having to worry about missing PrEP doses. However, some were

worried about the potential for the medication to stay in their system even after wanting to discontinue using PrEP. Participants were hesitant about the efficacy of PrEP 2-1-1, especially for transgender men, and felt it was not fitting for those who engage in spontaneous sexual encounters. Regarding pharmacist-initiated PrEP, which is legal in California, most participants described themselves as comfortable talking with a pharmacist about taking PrEP. Still, participants not currently enrolled in PrEP lacked knowledge of which pharmacies offered pharmacist-initiated PrEP and which medical providers offered injectable PrEP.

Conclusions: Our findings highlight the acceptance of injectable and pharmacist-initiated PrEP among local BLSGM and the need to prioritize PrEP promotion that moves beyond building general awareness of PrEP and provides information on providers offering newer PrEP forms. Additionally, expanding the availability of injectable and pharmacist-initiated PrEP within agencies that BLSGM are currently accessing or aware of may also support uptake in PrEP among this population.

EP045

Recruitment and retention into a phase 1 HIV vaccine trial: experience from a rural clinical research site in South Western Uganda

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Background: HIV remains a global public health problem with about 1.5 million new cases reported in 2020 worldwide. Uganda has 1.3 million people living with the virus. An HIV preventive vaccine is considered the best hope for controlling the epidemic and clinical trials are a critical part of this vaccine development process. However, recruitment and retention of study participants in clinical trials remain challenging. We present our experience with recruitment and retention strategies for a phase I HIV vaccine trial in a rural clinical research site in south western Uganda.

Methods: HIV-CORE 006 was a phase I multicentre study looking at safety and immunogenicity of a prime-boost vaccine regimen utilizing non-replicating simian adenovirus (ChAdOx1) followed by non-replicating poxvirus modified vaccinia virus Ankara (MVA) in adults in Eastern and Southern Africa. The MRC/UVRI & LSHTM Uganda Research Unit was one of the four sites recruiting volunteers for this study.

It recruited eligible healthy adults from communities with low incidence of HIV aged 18-50 years and willing to keep at low risk for the entire study period.

Community leaders and village health teams (VHTs) mobilised the community for research literacy sessions, and those willing were registered and invited to the site. Two sessions were conducted in succession on vaccine development and study specific information.

The retention strategies included regular participant engagement through seminars, involvement of community leaders and VHTs, scheduled phone calls, visit reminder cards, collection of multiple phone contact details, mapping of physical addresses and home visits for participants who could not be reached via phone calls.

Results: A total of 47 Participants were screened from 12th Oct 2021 to 18th Nov 2021 and 22 enrolled. All the participants were adherent to their scheduled visits. The retention was achieved at 100%.

Conclusions: Recruitment and retention strategies in HIV vaccine study is crucial for its success. Community leaders and VHTs involvement, pre-screening meetings, participant seminars, stakeholder engagement, good rapport, and site ambience are effective in recruitment and retention of study participants.

Our efforts to enhance this will advance our understanding of HIV vaccine efficacy and accelerate progress towards combating this global health crisis.

EP046

HIV infection may be contributing to the development and progression of NADCs in PLWH

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Background: PLWH are prone to acquire and progress several types of cancer. However, the underlying processes that link HIV infection to these malignancies are poorly known. Previous *in vitro* studies have suggested that exosomes from HIV-infected cells can promote and exacerbate cancer. To test this hypothesis, we have analyzed the proteomic profile of exosomes from patients with active NADC, stratified according to the presence or absence of HIV infection.

Methods: Sixty individuals divided into four different groups were included: 15 PLWH on ART with NADC (HIV+NADCs+ group), 15 HIV-uninfected with NADC (NADCs+ group), 15 PLWH on cART without NADC (HIV+ group), and 15 healthy volunteers (HC group). HIV+NADCs+ and NADC+ groups were matched for type of NADC. Purified plasma exosomes were used to perform a comprehensive proteomic characterization.

Differential expressed (DE) proteins between groups was considered when ratio of abundance was ≥ 2 or ≤ 0.5 and FDR ≤ 0.05 . GO and KEGG enrichment analyses were used to identify functions and pathway enrichments with gprofiler2-Rpackage.

Results: 371 proteins were detected by label-free-based quantitative proteomic analysis. Compared with the NADCs+ group, 17 proteins were up-regulated and 23 down-regulated in HIV+NADCs+ group (adjp-value <0.05). Functional analysis of these proteins showed an enrichment of extracellular vesicle-related functions and depletion of immune response-related functions in HIV+NADCs+ (adjp-value <0.05). Interestingly, 5 of increased proteins in HIV+NADCs+ when upregulated and 3 of decreased proteins in HIV+NADCs+ when downregulated have been involved in development and/or cancer promotion. This was not the case in NADC+ group; however, it is worth noting that several of the 5 up (4/5) and of the 3 down (2/3) proteins associated to cancer initiation and promotion were also DE in HIV group. The distinctive proteomic profile in HIV+NADCs+ compared to the NADCs+ was corroborated by PCA.

Conclusions: Our data unravel a role of intercellular communication mediated by exosomes in the complex setting of PLWH with NADCs. Exosomes from PLWH who have not developed cancer carry important proteins in cancer development and progression.

Furthermore, PLWH with NADCs exhibit a unique proteomic profile associated with cancer initiation and progression which was not observed in the HIV-uninfected population with NADCs. Therefore, it appears that HIV infection may be contributing to the NADCs development and progression in PLWH.

EP047

Antiviral effects of biogenic metallic nanoparticles against HIV-1 infection

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Background: Human immunodeficiency virus (HIV) is a causative agent of acquired immunodeficiency syndrome (AIDS). The inability of the suppressive therapy to manage HIV/AIDS as it is associated with adverse side effects and drug resistance suggests that HIV/AIDS is still a major public concern as evidenced by the increase in number of HIV-1 transmission and AIDS-related deaths globally.

The purpose of this study is to synthesise biogenic metallic nanoparticles that can offer improved treatment options for HIV-1.

Methods: Silver and copper nanoparticles (AgNPs and CuNPs) were synthesized using Aloe Ferox, Carpobrotus Edulis, and Tulbaghia violacea plant extracts. Characterization of nanoparticles was performed using dynamic light scattering (DLS), UV/Vis Spectroscopy, transmission electron microscopy (TEM), and Fourier transmission infrared (FTIR) to determine the stability, nano-formulation, phytochemicals responsible for nano-formulation and morphology and size, respectively. The nanoparticles were tested for their toxicity in TZM-bl cells with the MTS



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cell viability kit. Neutralization assay was used to evaluate the antiviral activity of the nanoparticles against a subtype C HIV isolate, ZM53.

Results: DLS showed zeta potential values of 0.5-17.5 ± mV demonstrating good stability of nanoparticles. UV/Vis spectroscopy confirmed nano-formulation with an absorbance reading of 390-670 nanometres. Functional groups of the plant phytochemicals responsible for metals reduction were confirmed with FTIR spectrum while TEM revealed the nanoparticles' spherical shape and size of 20-100 nanometres. The MTS assay exhibited ≥80% TZM-bl cell viability which demonstrated that the nanoparticles are not toxic. Virus neutralization assay exhibited IC₅₀ values in a range of 16.0 – 44.0 µg/ml for all the AgNPs and 39.0 – 60.0 µg/ml for the CuNPs. Nanoparticles reached 100% viral inhibition at highest concentration of 500 µg/ml for Aloe Ferox AgNPs and CuNPs, Carpobrotus Edulis AgNPs and CuNPs and 1000 µg/ml for Tulbaghia Violacea AgNPs and CuNPs.

Conclusions: The metallic nanoparticles were successfully formulated with the desired size, stability, and non-toxicity and they effectively inhibited the HIV-1 ZM53 isolate. The data shows that the nanoparticles are potential agents that can be used to improve treatment of HIV-1 infection.

EP048

Development and evaluation of a dried capillary blood-based self-collection method (Tasso-M50) for monitoring HIV viral load

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Background: People with HIV (PWH) in cure-oriented studies or persons at risk of exposure in prevention programs (e.g.: pre-exposure prophylaxis (PrEP), perinatal or breastfeeding pediatric monitoring, analytical treatment interruption (ATI), etc.) require frequent viral load (VL) monitoring. Convenient, home-based VL testing could replace the need for frequent clinical access.

Methods: We enrolled 21 PWH (5% female, 67% African American, mean age: 51) undergoing planned ATIs as part of the BEAT-HIV trial (NCT03588715). At contiguous visits (mean= 20.5), we collected 400 µl capillary blood using two 4-well Tasso-M50 prototype devices, and matched plasma (pVL, venipuncture). Take-home devices were used between visits for self-collection. Automated RNA

extraction and duplicate RT-qPCR reads with dual LTR/GAG FAM-labeled primers were performed (up to 16 M50 PCR reads per timepoint, sourced from 400 µL dried blood collection).

Results: The M50 devices were well-accepted, with a collection failure rate <10%. We analyzed 5,392 M50 PCR reads (3,058 clinic, 2,334 home), with 99.5% specificity and an estimated 95% limit of detection of 150 c/mL for 16 reads (8/ device). 64% of collections with <20 c/mL pVL had median M50 read ≥ 200 c/mL: in these samples, M50 VL correlated with total integrated HIV DNA (IPDA; r = 0.95) and was stable on suppressive ART. DNase treatment indicated that ~72% of the stable M50 background is contributed by cell-associated RNA.

Among the 14 participants with established M50 VL background starting an ATI, M50 VL 2x the median background was predictive of matched pVL ≥ 200 c/mL (Sensitivity 66%, specificity 81%, PPV 71%, NPV 76%, ROC curve AUC 85%). An M50 VL ≥ 2x background was always followed by pVL rebound ≥ 200 c/mL within 4 weeks.

Conclusions: In a cohort of PWH undergoing ATI our new M50 assay has a good NPV for pVL > 200 c/ml and can detect cell-associated HIV in specimens with undetectable pVL. This suggests that, upon clinical validation, the assay could be used for home-based VL monitoring to reduce participants' visit burden and enhance participation in HIV prevention and research. Prospective studies to test the performance of the device in other frequent monitoring settings (e.g. PrEP) are warranted.

EP049

Does age make you vulnerable for late detection of HIV? A case study from Tajikistan in Central Asia

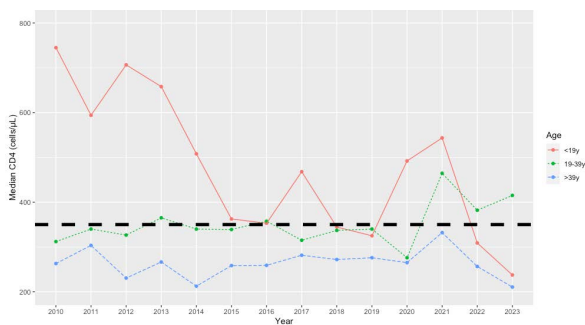
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Background: Late HIV detection (CD4 counts <350 cells/µL) reduces life expectancy, increases the frequency of HIV-related comorbidities, and is associated with higher health care costs. Older adults may be both particularly susceptible to late detection and more vulnerable if detected late. Targeted age interventions are key to prevention of progression of HIV or to stage of AIDS.

Methods: We analyzed cross-sectional national HIV data of 10,700 newly detected cases in Tajikistan (2010 to 2023). CD4 first result median was calculated for each year disaggregated by age.

Results: Those <19 years of age made up 12.39% of cases, those 19-39y made up 61.95% of cases, and those >39y made up 25.65% of cases. The median CD4 count for the group >39y was consistently lower than their younger

counterparts in the age groups <19y and 19-39y. Individuals <19y were consistently detected early for HIV, whereas those >39y were consistently detected late. Post-COVID-19 in 2022 and 2023, however, there was a sharp decline in median CD4 count among those <19y indicating potential barriers to early detection among infants/adolescents post-pandemic and among those >39y to some extent. Those 19-39y were the only group with a sizable improvement post-COVID-19.



Conclusions: Individuals above 39y are consistently detected at a late stage, suggesting a need for further attention and targeted interventions in this group. Those under 19 years of age require further attention after dropping to a stage of late detection after COVID-19.

Further investigation into the role and underlying factors of age as a predictor for HIV detection stage is necessary in Tajikistan and similar low- and middle-income countries to expand tailored HIV prevention and early detection interventions.

EP050

Scaling-up of HIV viral load monitoring using multi-strategy quality improvement interventions: a retrospective cross sectional study in Muchinga Province Zambia

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Background: The increased coverage of Antiretroviral Therapy (ART) has emphasized the critical need to expand ART monitoring, with Viral Load (VL) testing being the recommended gold standard. Muchinga province had notably low VL testing coverage reported at 79% at September 2022. USAID Action to HIV Epidemic Control project, working with Ministry of Health, used the performance improvement approach and introduction of Laboratory Information Systems to address this problem. The aim was to improve VL coverage in Muchinga Province from 82% in October 2022 to at least 90% by September 2023.

Methods: A retrospective cross-sectional study was conducted at Chinsali General Hospital Hospital in Muchinga province of Zambia from October 2022 to September 2023, Interventions included comprehensive IEC to clients, community sample collections, use of Dry blood spot (DBS) cards in hard-to-reach areas and populations, hiring of Laboratory support staff in Point of Care testing sites, weekly tracking of results uptake and installation of Laboratory Information system (DISA) to improve result turnaround time. To determine the outcome of quality Improvement interventions, retrospective data review of routine program reports on VL monitoring from 92 health facilities supported by USAID Action HIV were collected and analyzed. Descriptive statistics were presented as frequencies and percentages.

Results: Before implementing interventions in October 2022, Viral Load Coverage (VLC) was at 82% with Viral Load Suppression (VLS) at 97%. After implementing the highlighted interventions between October 2022 to September 2023, VLC improved from 82% to 92% with a suppression rate of 97%. Coverage among females reached 93% and VLS at 97%, Male VLC increased to 90% with VLS at 97% and pediatric coverage improved from 78% to 89% with VLS at 92%.

Conclusions: Muchinga province observed improvement in VLC following the implementation of multi-strategy QI activities. QI strategies that address gaps at different points in VL monitoring can have a significant impact in improving VLC and consequently, identify the actual suppression rate which plays a critical role in reaching HIV epidemic control. The findings contribute valuable insights and provide practical recommendations for shaping the future of HIV initiatives, programs and strategies toward achieving epidemic control.

EP051

Internal migration associated with new HIV diagnoses among MSM in Lima, Peru

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Background: Latin American MSM who migrate from their place of birth face increased vulnerability to HIV compared to non-mobile MSM. To inform HIV prevention strategies, we examined associations between location of birth and new HIV diagnosis.

Methods: Data are from screening for an STI control trial conducted with 1,397 MSM in Lima, Peru. Participants were tested for HIV, gonorrhea, chlamydia, and syphilis and completed a demographic questionnaire assessing sexual behaviors, HIV care, and location of birth. Poisson





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regression with robust standard errors estimated association between location of birth and new HIV diagnosis, adjusted for age, education, drug use, and sex work among participants who self-reported their HIV status as uninfected or status-unknown.

Results: The majority of participants (median age 31 years, (IQR 25-38), were born in Peru (95%). Most (65%, n=912) were born in Lima, while 115 (8%) were originally from the Coastal region, 119 (9%) from the Selva/Jungle, and 180 (13%) in the Mountains/Sierra. Among participants born outside of Peru (n=71, 5%), 68 (96%) were from Venezuela. Participants from the Selva (40%) and the Coastal regions (33%) were more likely to engage in past 6 months sex work compared to participants from Lima (24%; p<0.001). Among participants living with HIV (n=668, 48%), 166 (25%) were new diagnoses. HIV prevalence was highest among MSM born in the Selva (59.7%) and in the adjusted model, participants born in the Selva were 1.77 times more likely to have a new HIV diagnosis (95% CI: 1.10-2.75) compared to participants born in Lima.

	Proportion reporting past 6 months sex work	Prevalence of HIV (overall)	New HIV diagnosis (among self-report HIV negative)	Risk of new HIV diagnosis* PR (95% CI); p-value
Lima	217 (23.8%)	437 (48.0%)	97 (12.1%)	1.00 (ref)
Coast	37 (32.5%)	60 (52.6%)	20 (27.0%)	1.56 (1.02-2.39); 0.04
Selva	48 (40.3%)	71 (59.7%)	24 (33.3%)	1.77 (1.20-2.62); <0.01
Sierra	39 (21.7%)	79 (44.4%)	20 (17.0%)	1.00 (0.64-1.57); 0.99
Other Latin American Countries	9 (12.7%)	21 (29.6%)	5 (9.1%)	--

*Prevalence ratios adjusted for age, education, participation in sex work (past 6 months) and drug use (past 3 months)

Table 1: Sex work and Risk of New HIV Diagnosis among MSM by Location of Birth

Conclusions: Peruvian MSM migrating to Lima have higher frequencies of undiagnosed HIV as well as risk factors associated with HIV transmission, such as sex work. HIV prevention strategies are needed to address the unique needs faced by MSM who migrate.

EP052

Designing a sex-positive "do-it-yourself" intervention condition to promote sexual pleasure and health for gay/bisexual/same-gender loving, Black/African-American men in New York City

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Background: To end the HIV epidemic and enhance sexual health among African-American and/or Black gay, bisexual, same gender-loving, and other men who have sex with men (Black SGL/MSM henceforth) living in the United States, increasing PEP/PrEP uptake via consistent HIV testing is needed. Novel approaches that center sexual pleasure and community assets may advance this goal.

Methods: DIY is a hybrid (face-to-face and videoconference), sex-positive intervention condition designed as part of an NIMH-funded four-arm trial to increase HIV consistent testing and PrEP/PEP uptake. DIY promotes sexual health self-management ("do-it-yourself") by centering sexual pleasure, and self-determination and providing techniques to diminish the internalization of intersectional stigma. The centerpiece of DIY is the curation of a personalized sexual box/kit, the contents of which are informed by the results of web-based self-assessments. The box/kit contains participant-selected products that advance participant-defined sexual health/pleasure goals in four domains: sexual pleasure (sex toys, pleasure tools), self-screening (HIV self-testing [HST], STI self-swabbing), STI/HIV prevention (PrEP/PEP, doxyPrEP), relationships/communication (intimacy/communication games, influencers/content creators). DIY also integrates insights from the kink community (four Cs), applies asset-framing, and leverages social media (closed Instagram page), for user-driven content access and skills acquisition. Finally, DIY integrates creative content from a prior NIMH-funded study: original short films created by a Black queer collective depicting stigma resistance within the Black SGL/MSM community. We component-tested four DIY sessions (n=10, 9, 10, 5) and theater-tested the entire condition with 4 participants. All sessions were videorecorded and debriefed; select sessions were reviewed by study investigators. Qualitative feedback from participants was collected after each session.

Results: After component testing we reduced the number of sessions, added more self-assessments, and enhanced asset-/pleasure-framing. Feedback from participants was that the hybrid approach afforded flexibility and the self-assessments and kit curation encouraged active application of skills and knowledge. The sex positivity emphasis and celebration of Black SGL/MSM culture via empowerment, self-care and sexual pleasure was characterized as "unique" and "badly needed."

Conclusions: DIY encourages consistent HIV testing and PEP/PrEP uptake via curation of a sexual-health/pleasure "kit," self-assessment and -screening skills, and stigma resistance modeling, all complemented by print and social media campaign content.

EP053

Novel considerations for inventory management of long-acting PrEP in a supply constrained environment

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Background: Inventory management considerations are different for injectable cabotegravir for PrEP (CAB PrEP) vs. oral PrEP, especially guaranteeing supply for follow-up dosing. Gaps in CAB availability place HIV-exposed CAB PrEP clients at greater risk of HIV drug resistance. Countries will need to manage supply to maximize access while minimizing gaps in coverage. CATALYST, a PEPFAR/USAID implementation study offering PrEP choice in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe, has developed a forecasting model for managing a fixed CAB PrEP supply. Similar considerations may inform national planning for program implementation.

Methods: The model incorporates the following parameters: quantity and timing of product availability, rate of new PrEP initiations per month, percent of PrEP initiators eligible for CAB, percent of eligible clients choosing CAB, average percent of the maximum doses each client uses per year, number of times per year a client restarts CAB after missing a visit, rates of switching to and from CAB, and rate of wastage. It estimates the maximum number of people that can initiate CAB to avoid gaps in coverage prior to resupply under different scenarios for timing of PrEP initiation and resupply.

Results: To illustrate using the CATALYST model: if 50,000 doses are delivered annually and 80 people on average initiate PrEP per weekday, a country would need to stop initiating new CAB clients after approximately 7 months (7822 clients) to avoid gaps in CAB availability prior to resupply, assuming 5% product wastage, 71% of eligible clients choose CAB, clients access 70% of recommended doses and restart once per year, and the monthly rate of switching onto CAB minus switching off CAB is 1.34%. This provides a 2-month buffer for any resupply delays before running out of vials for existing and switching CAB clients.

Conclusions: Careful CAB supply management will be necessary to avoid forced discontinuations by clients with ongoing HIV exposure, potentially leading to drug resistance. When parameterized with real world data, the model can ensure availability by projecting the number of CAB clients to initiate per year based on supply and timing of new initiations, and it can inform buffer stock requirements for incorporation into logistics management systems.

EP054

Use of a soccer-based demand creation strategy to increase voluntary medical male circumcision uptake in Northern Province, Zambia

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Background: Voluntary medical male circumcision (VMMC) is associated with an approximately 60% reduction in the risk for female-to-male transmission of HIV. However, barriers such as fear, misconceptions, limited accessibility, and lack of knowledge hinder boys and young men from accessing VMMC. Using a 45-minute interactive, soccer-themed educational session Right to Care Zambia, through its sub-partner, Grassroot Soccer under the USAID Action HIV to Epidemic Control Project, in collaboration with local stakeholders targeted young males aged 15-24 to promote and increase VMMC uptake.

Methods: A mix of three trained Coaches and community Ministry of Health (MoH) VMMC providers, guidance teachers, ward chairpersons, and village headmen delivered messages on the health benefits of VMMC to young men aged 15 to 24 years. After each mobilization session using the soccer metaphor, a 45-minute interactive educational session was conducted where the coaches shared VMMC-related health talks and their personal circumcision stories.

All circumcised males less than 15 years consented to the service. Male Medical Circumcision was provided either on site for those that consented and were eligible or at facility following a scheduled appointment. Written consent was obtained from all participants.

Results: Over the one-year period, a total number of 6,542 aged 15-24 were circumcised. The total number of males significantly increased over time across the six health care facilities from 324 in March 2023 to 6,542 in March 2024.

Conclusions: The use of soccer proved to be an effective demand creation strategy of reaching large crowds, primarily composed of boys and young men who showed willingness to utilize VMMC services after receiving health education.



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EP055

Role of risky sexual behavior as a mediator between adverse childhood experiences and chemsex among African American men

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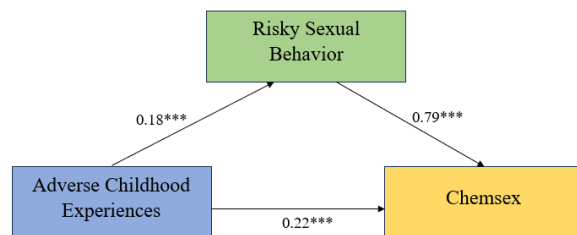
Background: Chemsex is a practice of drug use before or during sexual activity to facilitate, enhance, prolong, and sustain sexual pleasure. The relationship between chemsex and risky sexual behaviors has been associated with increasing HIV and sexually transmitted diseases (STDs). Whereas Adverse Childhood Experiences (ACEs) have been linked with risky sexual behavior in later life. African American men bear a disproportionate burden of HIV.

This study aims to determine the potential mediational role of risky sexual behavior between ACEs and Chemsex among African American men in the United States.

Methods: The study used data collected from adult HIV-negative African American men using a cross-sectional online survey conducted in October 2023 (N=568). Chemsex was defined (yes/no) based on ever use of substances to enhance sexual pleasure, while risky sexual behavior (yes/no) if the respondents had condomless sex, or transactional sex in the last one year.

The study used the 11-item ACEs module from the Behavioral Risk Factor Surveillance System (Cronbach's alpha=0.805) for measuring ACEs.

Results: Most of the participants were non-Hispanic (92.8%), heterosexual (95.8%), full-time employed (49.7%), single (64.8%), and housed (89.6%). Almost one-third (32.8%) of the men had a history of incarceration. Almost a quarter (22.5%) of the participants reported having chemsex ever, while three-fifths (59.7%) reported having risky sexual behavior. After adjusting for sociodemographic characteristics, risky sexual behavior was positively associated with chemsex (B=0.79; p=0.004). ACEs were positively associated with risky sexual behavior (B=0.18, p<0.001). ACEs were positively associated with chemsex (B=0.22; p<0.001). The indirect effect of risky sexual behavior on the relationship between ACEs and chemsex was statistically significant (B=0.04, p<0.001) (Figure 1).



Note: ***p<0.001
Solid arrows (→) indicate statistical significance at p<0.05.
=Adjusted for age, ethnicity, sexual orientation, education, employment status, marital status, homelessness, rural/urban location, history of incarceration, HIV risk self-perception.

Figure 1. Mediating pathway between childhood adverse experiences, risky sexual behavior and chemsex.

Conclusions: Results show that risky sexual behavior like condomless sex and transactional sex mediate the relationship between ACEs and chemsex among African American men. Therefore, trauma-informed intervention might prevent risky sexual behavior and chemsex among them.

EP056

Untapped potential of post-exposure prophylaxis in the HIV response and where to go from here: a comparative analysis of PEP implementation planning in Kenya, Mozambique, Nigeria, Uganda, and Zambia

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Background: In 2022, there were over 250,000 new HIV acquisitions in Kenya, Mozambique, Nigeria, Uganda, and Zambia collectively. While PrEP uptake has increased significantly over the past two years and there is growing interest in new PrEP modalities to reduce HIV transmission, there has been limited focus on expanding access to post-exposure prophylaxis (PEP). PEP remains an underutilized intervention in many high-burden countries.

With updated guidelines for PEP set to be released by WHO in 2024, there is an urgent need to reassess the current PEP landscape and identify opportunities for better integration into growing prevention programs.

Methods: This analysis reviewed and analyzed Global Fund country proposals for the Grant Cycle 7 (GC7) implementation period (2024-2026) and compared HIV prevention interventions prioritized in these proposals to the previous implementation cycle (2021-2023). The analysis focused on five high-burden sub-Saharan African countries with strong existing PrEP programming (over 140,000 PrEP initiations in 2023): Kenya, Mozambique, Nigeria, Uganda, and Zambia. We reviewed proposals to identify priority populations and planned interventions to support PEP access.

Results: In GC7 funding requests there was significantly increased focus on PEP, demonstrated by the number of references to PEP within prevention module activities (see Figure 1).

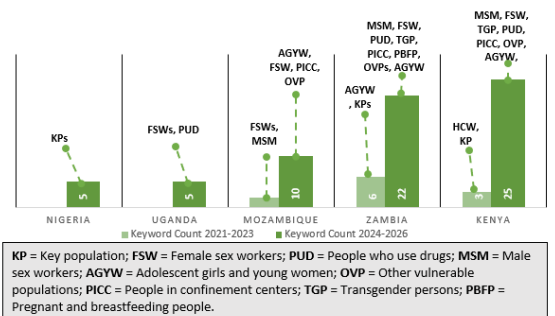


Figure 1. Count of PEP references in prevention modules and prioritized populations for PEP by grant cycle.

Funding requests also reflected a broader population focus in all five countries, reflecting a shift from viewing PEP as an intervention for occupational exposures and sexual violence to a critical intervention within combination prevention portfolios. Strategies for increasing access to PEP included activating community-based delivery channels, integrating PEP into existing PrEP delivery points, and investigating innovative distribution strategies, such as pharmacy delivery.

Conclusions: All five countries had a broader and intensified PEP focus in GC7 funding requests compared to the previous implementation cycle. Effective monitoring mechanisms will be crucial for understanding the impact of PEP and catalyzing broader expansion to unlock the untapped potential of PEP.

EP057

Media Advocacy for Transgender People and other Sexual Minorities – how intentional and strategic media engagement and coverage have contributed to better health outcomes for transgender people

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Background: Sexual orientation and gender expression in Zimbabwe is a controversial topic due to rampant homophobia and transphobia fuelled by a lack of knowledge about sexual orientation, gender expression, and identity. This is evidenced by stigmatizing language used in media such as “man pretending to be woman” or “person with double genitals” as well as the derogatory equivalent of “gay” in local languages. This has adversely affected LGBTQIA+ people who are who usually face stigma and discrimination from society which in turn affects health-seeking behavior for HIV and other SRHR services. HIFC, in conjunction with the Health Communicators Forum of Zimbabwe embarked on a series of awareness-raising trainings and capacity building for journalists which have led to a change in attitudes toward, and more human-centred stories in the media about transgender people and intersex people.

Methods: Five trainings for journalists were held from 2020 to 2023. A cohort of 20 journalists attended at least three of the trainings. Three media science cafes were held with experts addressing HIV prevention and how stigma and discrimination affect access to services for people whose gender identity, sexual orientation, and expression differed from cis-hetero populations.

Results: We followed the cohort of journalists between 2021 to 2024, with approximately 15 writing at least one story each. Overall, the stories were positive and explored

other aspects of the communities lived experiences. We observed increased visibility for people who are transgender through interviews with trans activists across media channels.

Here is an example of such stories: <https://www.263chat.com/is-there-space-for-the-lgbtqi-community-in-zimbabwe/>.

Conclusions: Training and capacity building for journalists and media can help change attitudes about transgender communities and other sexual minorities, and help create a more human-centred approach to the HIV response. This leads to positive reporting on sexual minorities and subsequently contributes to stigma reduction and encourages sexual minorities to seek and receive HIV and SRHR services.

EP058

Application of artificial intelligence and machine learning for prediction in HIV prevention: systematic review

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Background: Despite progress in reducing HIV-related mortality, incidence rate is still high in many countries. With the emergence of technologies such as Artificial Intelligence and Machine learning for predicting clinical outcomes and interventions. There is a need for an accurate appraisal of current efforts and a discussion of future paths in the application of AI and ML for HIV prevention interventions.

This systematic review and meta-analysis aim to assess the performance of AI and ML prediction tools in the prevention of HIV/AIDS.

Methods: Following the PRISMA guidelines, we conducted a systematic search in PubMed, Scopus, Embase, and ScienceDirect databases. Primary articles on application of AI prediction tools including ML or deep learning for HIV prevention were retrieved. Articles that were available in full-text, published in English and between December 2013 and December 2023 were included in the study. Two reviewers independently reviewed studies following the study protocol, extracted data from the selected studies, and assessed quality using the CASP Tool (clinical prediction rule checklist). The performances of the models were evaluated using sensitivity, specificity, f1-score, and AUC.

Results: Twenty-three (23) out of 377 original studies initially identified were included. Most (n=9) of the studies were conducted in the United States. A total of 13 prediction tools were developed for the key populations. Studies were group into four prevention methods based on the application of AI prediction tools. This included: monitoring, surveillance and evaluation of interventions (n=7),



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identification of suitable candidates for Pre-Exposure Prophylaxis (PrEP) (n=4), health promotion and awareness (n=4), and HIV screening and testing (n=10). A meta-analysis of results from 11 studies revealed an average best performance of algorithms as 79.7% for sensitivity, and 81.6% for specificity. Pooled average AUC of 72.0% for 15 studies. The best-performing algorithms were Random Forest (RF), and least absolute shrinkage and selection operator (LASSO).

Conclusions: AI/ML prediction tools have the potential for improving HIV prevention especially among key populations. However, assessment and reporting of factors such as quality of data, outcome definition, predictive performance and usability of the tools need to be standardized and evaluated.

EP059

Building HIV/AIDS prevention in three São Paulo state cities, Brazil, coproduced with disenfranchised youth during COVID-19 sanitary and social crisis: from "combination prevention" to "integral prevention" (2020-2024)

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Background: This presentation will discuss challenges and results of an STI/Aids intervention-research project developed in eight peripheral school territories in São Paulo state, intersected by the COVID-19 pandemic that enhanced the adolescent mental health epidemic in the context of conservative-denial governmental negligence and a major social crisis. Previously experimented vulnerability and human rights-based prevention methodologies were tailored to the context during 18 months of on-line schooling, school buildings closed, and internet-mediated research.

Methods: High school students and participant teachers co-produced school territory ethnography of daily life in this context, interviews, and small questionnaires to sustain research-intervention activities. Together, we designed and implemented online prevention workshops. Participant teachers and 150 students implemented prevention activities aimed at their school communities, such as webinars and masked cultural and cultural events(2020-2021). Back to face-to-face schooling and intervention activities (2022-2024), 1.200 senior-high students responded to a questionnaire in all schools, 100

newly integrated young-agents, and 45 teachers of 6/8 schools participated in prevention training and education. The Vulnerability and Human Rights (V&HR) approach to health and Paulo Freire's emancipatory pedagogy informed the project.

Results: The synergy of ongoing and new pandemics affecting adolescents in this period – Syphilis, HIV, COVID-19, mental health, and, recently, dengue - with the social and political crisis has challenged the process. The political polarization intensified the "fake news" about the severity and modes of infection. Conservative and denialist reactions to prevention actions, especially to sex education, never decreased in São Paulo State, where an extreme-right governor was elected with Lula - progressive president and HR supporter. The political context affected the sustainability of the prevention project in two territories, as the school coordination and the participant teachers feared parents' reactions and administrative stigmatization/persecution. Since 2023, the project has promoted the integration of schools with primary health-care units and their professionals within their territories, with productive results in promoting adolescent sexual health and rights.

Conclusions: This project emphasized *participation* and *community solidarity* as fundamental principles of the HR-based approach to health. Facing sindemy, the "integrity of prevention" notion allowed for re-conceiving "combined prevention", avoiding its "fractional universalization" of risk-exposure and preventive options to be individually "consumed."

EP060

An STI/AIDS prevention intervention sustained by youth in the first years of COVID-19 in a São Paulo city favela, Brazil (2020-2023): the high school students appraisal

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Background: In the context of conservative-denial governmental negligence and a major social crisis, young people sustained prevention actions of STIs/AIDS, unexpected pregnancies, and increased mental suffering combined, integrating the response to the emerging COVID-19 in the favela school territory.

Methods: The "integral prevention workshop" implemented in 2023, the focus of this presentation, summarizes the methodological innovations co-produced with students of seven other peripheral school territories. Its format resulted from on-line intervention-research activities (2020-2021): conversation circles with high-school

students living in the school territory to understand youth daily life marked by concomitant epidemics and social crisis, coproduced small questionnaires, and prevention actions aimed at peer adolescents. The same activities, face-to-face since 2022, resulted in the six three-hour sessions workshop synthesizing a young-agent handbook for integral prevention.

Results: The workshops we will describe and illustrate, fostered their autonomy to promote comprehensive prevention based on transversal skills applicable to scenes of simultaneous exposure to STIs/AIDS, other infections and obstacles to well-being.

Youths evaluation highlighted:

- The dynamics of stories and scenarios densely described, embodied characters facilitated role-playing the risk situations and understanding how to change them;
- The "practical and engaging" approach of the workshops facilitated open communication about sexuality and mental health;
- Stressing the relevance of preventing all STIs and pregnancy, fostered reflections on gender inequality and social pressure;
- Expanded knowledge about sexual health and its devices;
- Qualified participants to become prevention agents, improving communication, maturity, and ways to discuss sexuality and mental health creating a safe environment to discuss sensitive topics.

Conclusions: Using "everyday scenes" as a unit of intersectional analysis and human rights-based intervention, the methodology emphasizes the transversality of prevention skills. By recognizing their rights and understanding the reasons for using/not using this or that Aids prevention asset in that scene, young people transferred/reinterpreted skills to scenes with peers or adults where the critical task was to prevent COVID-19, pregnancy, stigmatization, discrimination, and violence. As young agents of "integral prevention," when denouncing fake news and disseminating correct information about COVID-19 prevention with appropriate peer language, they next did the same with HIV, syphilis, pregnancy, and race/gender-based violence.

EP061

Attitudes and perspectives among people assigned female at birth who decided not to start PrEP following discussion during a sexual health clinic visit in New York City

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Background: HIV pre-exposure prophylaxis (PrEP) is highly effective, but uptake remains low among people assigned female at birth (AFAB) vulnerable to HIV acquisition. Understanding attitudes and perspectives among potential PrEP beneficiaries can inform approaches to PrEP delivery.

Methods: Between April and June 2023, we conducted semi-structured interviews with eight participants AFAB who were offered and declined PrEP during a sexual health clinic visit in New York City. We conducted an inductive thematic analysis of PrEP attitudes and perspectives. Interviews were independently coded by two analysts and discrepancies were reconciled by a three-person panel.

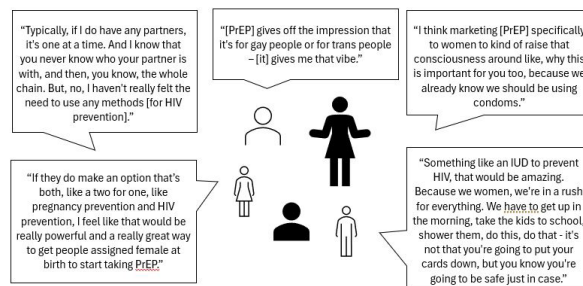


Figure 1. Selected quotations from semi-structured interviews regarding attitudes and perspectives surrounding PrEP among people assigned female at birth.

Figure 1. Selected quotations from semi-structured interviews regarding attitudes and perspectives surrounding PrEP among people assigned female at birth.

Results: Participants median age was 28.5 (IQR 7.5) years and identified as cisgender women (n=7) and gender non-conforming (n=1), Black or African American (n=3), White (n=2), Other (n=2), Asian (n=1), and/or Hispanic (n=1). Nearly all participants (n=7) described low personal vulnerability to HIV acquisition due to number of partners; low perceived HIV vulnerability was the main driver for non-uptake of PrEP for all participants, though some also reported concerns about side effects (n=4) and cost (n=1). All but one participant reported using condoms. PrEP knowledge was limited: two participants with prior post-exposure prophylaxis (PEP) experience were not aware of the PEP-PrEP distinction, and two thought PrEP



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was only for people assigned male at birth. Half of participants had felt disrespected by a sexual health provider during their lifespan. Six participants wanted to see new PrEP options, including longer-acting modalities like a vaginal ring or intra-uterine device (n=2), HIV vaccine (n=2), dual prevention (n=3), or options with fewer side effects (n=1). Most wanted greater community discussion/emphasis of PrEP as an option for people AFAB.

Conclusions: Future interventions to promote PrEP uptake among people AFAB in the US should incorporate strategies to help individuals understand their vulnerability to HIV acquisition and to improve PrEP knowledge among potential beneficiaries.

EP062

The engagement forum: evaluating a virtual monthly HIV prevention research platform for communities and advocates

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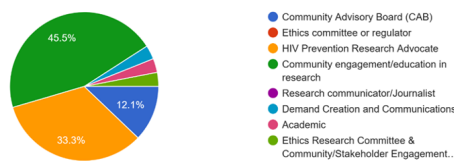
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Background: As the HIV prevention research field delivers options such as daily oral pre-exposure prophylaxis (PrEP) for HIV prevention, civil society groups voice a need to be engaged early on in efficacy trials to optimize policy and programming advocacy to ensure equitable product access.

Advocates for Prevention of HIV in Africa (APHA) engages community stakeholders and advocates through ground mobilisation and virtual platforms such as virtual Engagement Forums (EF) to provide a continuous learning, experience sharing and updates in the HIV prevention research and development processes.

Methods: In 2023, APHA asked communities about the benefits of the EF and other engagements they would like to see. A needs analysis was conducted, a self-administered google forms survey developed, using convenience sampling. 34 respondents completed the survey. African regions included the South (76.5%), East (17.7%), West (2.9%) and other (2.9%) regions. Respondents' roles are indicated in Figure 1 below:

What role do you play in the HIV prevention research agenda in your country?
33 responses



Rapid analysis was conducted, google forms organised quantitative data.

Results: Moderate (21%) to high (67.8%) satisfaction with the EF pertaining to occupations and interests. EF demonstrated impact beyond the virtual convening –

non-attendees received information from members, adding to their learning. Overall satisfaction with shared information–noting relevance and up-to-date. The EF knowledge on current biomedical research, assisted with advocacy, providing learning and addressed issues impacting research engagement and recruitment. Called on expansion of the geographic reach, include additional civil society organisations and other stakeholders. Address challenges and develop clear advocacy call-action, suggested in-person convening of regional leaders. Measurable goals be identified from meetings, resources and investment required to expand the platform. More “learning-platforms” be created, networks for HIV prevention advocates.

Conclusions: The EF found useful and urged platform expansion to encourage diversity, share knowledge and problem solve collectively. Increasing the platform scale will provide access for wider civil society to advance HIV prevention research, policy, and programming.

EP063

Expanding access to PrEP: testing and prevention on businesses in the MSM sexual scene in the city of São Paulo, Brazil

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Background: In 2021, the *PrEP na Rua* project, developed by the STI/Aids Coordination of the city of São Paulo (CIST/Aids), provided services with Rapid Tests (RT) for HIV and other STIs, as well as the distribution of pre- (PrEP) and post-exposure (PEP) HIV prophylaxes in key locations for the most vulnerable populations.

Among them are men who have sex with men (MSM), with an HIV acquisition rate of 18.4% in Brazil. The CIST/Aids and units of the city's Municipal Network Specialized in STI/Aids (RME) partnered with businesses that promote sexual encounters between MSM to carry out the *PrEP na Rua* project, aiming to facilitate access to HIV RTs and PrEP for the population attending these spaces.

Methods: From January/2023 to March/2024, 18 activities organized by the RME and CIST/Aids were carried out in the Central and Southern regions of the city, in businesses that promote sexual encounters between MSM (parties, saunas, nightclubs, and cinemas).

Before and/or during the events, PEP, PrEP, registration, HIV RTs, point-of-care testing of creatinine level and distribution of prophylaxes on site were offered, as well as RTs for syphilis in 6 of the activities.

These services happened in CIST/Aids mobile units (mini-buses and trailers), which were adequately structured for the comprehensive care of users, and/or in spaces provided by the businesses, with a reduced team of professionals.

Results: 404 HIV RTs were performed, with 13 new positive cases, 1 already using ART and 1 abandoning treatment. 115 syphilis RTs were also performed, with 35 positive cases, and 250 PrEP were initiated or continued on site. Adherence to PrEP was approximately 61.9%, given the number of users tested, all MSM. 13 PEP were distributed during the activities.

Conclusions: The connection between businesses that are part of the MSM sexual scene in São Paulo and the RME brings this segment of the population closer to Combined Prevention. Adherence to PrEP was significant in those locations, as were the rates of positive results for syphilis and HIV. Therefore, it is important to expand partnerships in the city regions.

EP064

Acceptability, feasibility and adoption of the UNICEF service delivery framework in pediatric HIV service planning and management in Mozambique, Nigeria, and Uganda as promoted through the Paediatric Breakthrough Partnership

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Background: Globally, 1.5 million children below 15 years were living with HIV in 2022, including 130,000 newly infected that year, and 660,000 not on anti-retroviral treatment. Only 63% of children living with HIV have their status established/tested; 57% are on treatment; and 46% are virally suppressed (UNAIDS, 2023). To address this immense problem, a service planning framework was launched in 2019; and focused efforts have been made to support its utilization in enabling the implementation of comprehensive, sustainable and scalable paediatric HIV services (UNICEF 2019).

This work is based in a study conducted in 2022 to assess the acceptability, feasibility and adoption of one such effort, the Paediatric Breakthrough Partnership (PBP); in Mozambique, Nigeria and Uganda.

Methods: A survey was administered to actors in pediatric HIV service planning and management at different levels. Qualitative data were collected through key informant interviews and focus group discussions. Secondary data on pediatric HIV services were abstracted from existing databases at selected health facilities in Mozambique, Nigeria and Uganda.

Results: Core PBP members and PBP In-country implementers demonstrated strong agreement on the acceptability of the Service Delivery Framework (SDF); with

an overall mean score of 4.6/5.0 (5.0 in Mozambique, 4.9 in Nigeria, and 4.0 in Uganda). Acceptability was enhanced by: having a shared vision and commitment to end pediatric HIV; previous collaboration on different aspects of the pediatric HIV response; and broad participation in the development of the SDF.

Acceptability was constrained by: limited clarity in respective roles of different stakeholders; poor coordination; and operational challenges during the COVID-19 pandemic. The PBP implementers and collaborators demonstrated strong agreement on the feasibility of the SDF; with an overall mean score of 4.4/5.0 (4.7 in Mozambique, 4.3 in Nigeria, and 4.1 in Uganda).

Conclusions: Perceived enablers of SDF feasibility include its fit with current capacities of key actors at national and subnational levels, and its alignment with and evident value addition to the routinely used service planning and management mechanisms by governments and partners. Noted barriers to SDF feasibility include limited appreciation of its process and benefits and operational gaps in government health systems.

EP065

COVID-19 vaccine hesitancy and under-vaccination among PLWH in North America: a scoping review

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Background: Vaccination is crucial for the care of people living with HIV (PLWH), including SARS-CoV-2 vaccines amid greater risk of severe COVID-19 outcomes. We explored multilevel factors associated with COVID-19 vaccination among PLWH and other marginalized populations in the US and Canada.

Methods: Using the scoping review methodology developed by the Joanna Briggs Institute, we searched peer-reviewed articles published from January 1, 2020 to October 25, 2022 that addressed COVID-19 vaccine hesitancy, confidence, refusal, mistrust or barriers among PLWH and other marginalized populations ≥ 18 years-old in the US/Canada, including quantitative and qualitative studies. Search results were uploaded into Covidence software and screened by two independent reviewers for inclusion. We reviewed data using quantitative (frequency) and qualitative (narrative) analysis and synthesized evidence on vaccination among PLWH.

Results: Four studies focused on COVID-19 vaccination for PLWH among 103 included articles on marginalized populations. Institutional and medical mistrust were associated with COVID-19 vaccine hesitancy among PLWH, including those with intersectional marginalized identities based on race/ethnicity, sexual orientation and gender identity, and people who use drugs. Factors associated with under-vaccination included unemployment,



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poverty, homelessness, indirect costs of vaccination (e.g., transportation to distant sites) and transphobia/fear of harassment/violence in unfamiliar vaccination clinics. Facilitators of COVID-19 vaccination included having a trusted regular healthcare provider and lessons learned about the importance of behavior change in response to the HIV pandemic. Some PLWH expressed concerns that their health condition might make COVID-19 vaccination unsafe. Across included studies among all marginalized populations, structural barriers rather than “vaccine hesitancy” were the most prevalent obstacles to COVID-19 vaccination.

Conclusions: Multilevel determinants of COVID-19 vaccination among PLWH indicate the importance of population-specific interventions that address concerns, such as perceived risks of vaccination, as well as strengths, including lessons learned from behavior change and advocacy in the HIV pandemic. Tailored vaccine outreach and education with and for PLWH, including trusted HIV healthcare providers, should be complemented by structural interventions that address adverse social determinants of health and intersectional discrimination, which produce systemic barriers in access to COVID-19 vaccination. Lessons for preparedness for future HIV vaccines include targeting structural barriers, addressing intersectional discrimination, and ensuring collaboration with PLWH.

EP066

HIV care continuum outcomes following implementation of an HIV self-testing program in Philadelphia

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Background: HIV testing must lead to engagement in care to maximize its impact, yet little is known about the HIV care continuum after self-testing. The Philadelphia Department of Public Health implemented a City-wide self-testing program (HIVSTP) in this priority jurisdiction in the Ending the HIV Epidemic initiative. The objective of this research was to

1. Determine the reach of the HIVSTP,
2. Characterize the HIV care continuum, and
3. Identify factors associated with obtaining post-test care.

Methods: We prospectively recruited individuals who obtained an HIV self-test through the HIVSTP. HIVSTP eligibility included residence in Philadelphia and age ≥ 17 years. We used linear regression to identify factors associated with intentions to seek healthcare after self-testing. Par-

ticipants were invited to respond to a follow-up survey 30 days after the initial survey. We assessed factors associated with seeing an HIV care or PrEP provider after self-testing using logistic regression.

Results: Between October 2022 and March 2024, 282 people met inclusion criteria and completed the survey, and 178 completed one-month follow-up. Twenty-eight percent were cis-gender men who reported prior anal sex with men and 22% identified as cis-gender Black women. Nearly a quarter (22%) reported no prior HIV test, 2% reported a positive HIVST result, and 40% had a prior STI. At baseline, intentions of seeking healthcare were associated with Black race, lower education, and increased PrEP self-efficacy. At follow-up, 55% saw a medical provider, 37% discussed sexual health, 13% discussed PrEP, and 2% initiated PrEP. Black race was associated with higher odds of follow-up, while other race/multi-racial race was associated with lower odds of follow-up in multivariable analysis (Table 1).

Characteristic	Adjusted OR (95% CI)	p-value
Sex at birth		
Male	Ref	
Female	1.00 (0.47, 2.13)	0.99
Age (Years)	1.04 (0.99, 1.09)	0.10
Race/Ethnicity		
White, non-Hispanic	Ref	
Black, non-Hispanic	2.42 (1.02, 5.79)	0.04
Hispanic, any race	0.72 (0.42, 2.54)	0.71
Other race/multi-racial	0.10 (0.01, 0.83)	0.03
Insurance		
Uninsured	Ref	
Public insurance	1.79 (0.53, 6.02)	0.35
Private insurance	3.22 (0.95, 10.95)	0.06
Intentions to seek sexual healthcare	1.52 (0.92, 2.50)	0.08

Table 1: Factors associated with one-month follow-up (n=178)

Conclusions: Implementation of a city-wide HIVSTP effectively reached key populations. Interventions targeting PrEP self-efficacy may increase motivation to seek care. Although over half of those who completed follow-up saw a medical provider, very few discussed PrEP. Future research needs to investigate why PrEP counseling remains so low.

EP067

Evaluating the integration of hypertension management into anti-retroviral (ART) programs for women in key populations, in Nigeria

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Background: Non-communicable diseases (NCDs) among Women in Key Populations living with HIV are a growing concern. While mental health and cervical cancer interventions have received attention, the integration of hypertension management into Anti-retroviral (ART) programs for Women in Key Populations living with HIV in Nigeria remains understudied.

This research aims to assess the implementation of hypertension interventions in these programs and identify potential gaps.

Methods: A random controlled trial design was used in assessing the Integration of Hypertension Management into ART Programs for Women in Key Populations living with HIV. This study focused on 500 stable Women in Key Populations living with HIV between the ages of 19 – 65 years, on ART from October 2019 to October 2022. Diastolic and systolic blood pressure data from 3 consecutive clinical visits were obtained from Client Care Cards from 5 One Stop Shops (OSS) facilities in Nigeria.

Results: It was observed that all 500 clients in the study were screened for hypertension during every clinical visit, indicating a proactive approach to monitoring blood pressure. In terms of specific sites, at the commencement of ART, Enugu OSS reported that 5% of clients had hypertensive blood pressure readings ranging from 140/90 to 150/103. After one year of good management, most of these clients achieved a normal blood pressure range, except for a female client who was further managed successfully. Heartland Alliance OSS in Minna, Warri South OSS, and Wavemakers OSS reported that 100% of their clients had regular blood pressure readings, suggesting effective hypertension control. At Oshimili South OSS, it was observed that 9% of clients had hypertensive blood pressure ranging from 180/80 to 130/90 at the start of ART; After one year of intense management, all clients in this sub-group achieved a normal blood pressure range, showing the effectiveness of the intervention in hypertension control.

Conclusions: The integration of hypertension management into ART programs for Women in Key Populations living with HIV in Nigeria has shown promising results. Implementing regular screening have led to improvements

in blood pressure control. Future research should use specific strategies employed at successful sites, assess long-term sustainability, and identify barriers to hypertension management.

EP068

Scaling-up of timely DNA-PCR HIV test for HIV exposed Infants at Family Hope Centre Kampala

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Background: The MoH recommends 4 HIV tests for children born to women living with HIV/AIDS. Timeliness for these tests measures the quality of services offered in EID programs. The new HIV guidelines therefore recommend a timely 1st PCR test at 4-6 weeks, 2nd PCR at 9 months, 3rd PCR at 6 weeks after cessation of breastfeeding, and an antibody test at 18-24 months. At Family Hope Centre, a Children's Aids Fund clinic based in Kampala offering HIV care and treatment services to children and their families, the number of HIV-exposed infants who were offered timely DNA-PCR tests was low compared to the recommended standard of care. 1st PCR tests timeliness was at 68.7%, 2nd and 3rd PCR at 33%. This was associated with non-alignment of the appointment of mother and child, lack of close peer-to-peer support, women's lack of knowledge on the importance of breastfeeding, and DNA-PCR tests.

Methods: A Continuous Quality Improvement project was opened on the 1st of August 2020 and planned interventions included the identification of a mentor mother (peer supporter) whose roles included filling the EID tracker for pregnant women living with HIV, line-listing of all women with children due for a DNA-PCR test, pre & post calling of women with HEIs due for PCR tests reminding them of their appointments, follow-up of women who are lost and organizing Family Support Group meetings for pregnant and lactating women living with HIV. The other intervention was to align the mother's appointments with the HEIs DNA-PCR schedules. This project was completed in July 2021.

Results: The results showed improvements in timeliness. 1st DNA-PCR test improved to 85.4%, 2nd DNA-PCR test to 53.7%, 3rd DNA-PCR test to 66.7% and the antibody to 80.6%. These are average percentiles for each scheduled test across the 12 months of the project.

Notably, the 2nd and 3rd DNA-PCR tests are still low; this is because some women living with HIV prefer not to breastfeed their infants.

Conclusions: We, therefore, recommend that peer-to-peer support (mentor mother) is a key intervention in the care and management of HIV-exposed infants.



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EP069

Pilot study of a digital health intervention to increase HIV and STI testing uptake, and reduce condomless sex and substance use among adolescents and young adults in the United States

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Background: HIV notably affects U.S. youth, making the enhancement of HIV/STI testing and the reduction of unsafe sexual behaviors and substance use vital to public health strategies. Although digital health interventions present a promising avenue, their efficacy, particularly in clinical settings, warrants further investigation.

Our pilot study examines the preliminary efficacy of the Storytelling 4 Empowerment (S4E) intervention in augmenting HIV/STI testing and mitigating risk behaviors among youth.

Methods: Utilizing a community-engaged research approach, we conducted an RCT at a youth-focused clinic in Southeast Michigan. One hundred adolescents and emerging adults (14-21 years; mean age 19.27, SD=1.62) with diverse racial (44.4% non-Hispanic White, 38.4% African American, 11.1% multiracial, 5.1% Hispanic/Latino, 1% Asian) and gender identities (65% female, 17% male, 15% transgender or other) were randomized to receive S4E—a mobile app-based intervention promoting HIV and substance use prevention—or usual care control condition. Both the intervention and control groups received the clinic's standard care, encompassing primary care, sexual and reproductive health services, substance use prevention, and gender-affirming care tailored for youth. Assessments were made at baseline, post-intervention, and at 3 and 6 months. Statistical analyses focused on descriptive statistics and estimates of mean and proportion differences to estimate effect sizes for the primary and secondary outcomes.

Results: Intervention participants exhibited significantly higher HIV (52% vs 12%; Cohen's $h=0.95$) and STI (52% vs 20.4%; Cohen's $h=0.74$) testing uptake than controls. Notably, there was a marked decrease in condomless sex (12.9% reduction; Cohen's $h=0.35$), and binge drinking (11.2% reduction; Cohen's $h=0.02$) at 3 months, indicative of behavior change.

Enhanced clinician-youth communication was reported in the intervention group, suggesting improved engagement (Cohen's d up to 1.19 for youth; Cohen's d up to 3.41 for clinicians).

These findings persisted over the 6-month observation period, highlighting sustained intervention impact.

Conclusions: The S4E intervention's pilot RCT reinforces its potential for scale-up, with significant improvements in both primary outcomes and communication dynamics. These promising directions justify a larger RCT to substantiate the intervention's utility in a clinical setting for youth.

EP070

Characterizing behavioral exposure patterns and predictors in PrEP users

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Background: When temporally aligned with sexual activity, requisite dosing of PrEP ("prevention effective use [PEU]") reduces the risk of sexually acquired HIV. Routine PrEP delivery programs often assume users experience sexual HIV exposure continuously, warranting indefinite PrEP use.

We sought to temporally characterize sexual exposure and abstinence among PrEP users (oral and ring) to better understand dosing frequency requirements for PEU.

Methods: Embedded in the PEPFAR/USAID-supported CAT-ALYST study, women in Kenya and South Africa completed daily questions about PrEP use and sex for six weeks on their phones.

Outcomes were the total and maximum contiguous days of sex, condomless sex, and abstinence.

Due to non-normality, median and interquartile ranges are reported. Kruskal-Wallis test compared differences in sexual behavior by PrEP method and socio-demographic characteristics. Data from 240 participants were analyzed.

Results: Median age of participants was 29 years (IQR: 24-35). The majority never married (77%), identified as female sex workers (FSW) (72%), and reported previous PrEP use (61%).

FSWs reported greater total ($p<0.001$) and contiguous days of sex ($p<0.001$), as did those with ≥ 3 partners prior to enrollment (Total: $p<0.001$; Contiguous: $p<0.001$). Total ($p=0.006$) and contiguous ($p=0.004$) days of abstinence were higher in those whose primary partner was HIV positive.

Participants with higher incomes reported greater total days of sex ($p<0.001$), while ring users had higher contiguous ($p=0.049$) and total ($p=0.008$) days of condomless sex.

	Oral PrEP (n = 140; 58%)	Ring (n = 100; 42%)
# days sex - total	24.5 (11.0-35.0)	24.0 (16.0-33.0)
# days sex - contiguous	16.0 (3.0-31.5)	19.5 (6.0-30.5)
# days condomless sex - total**	3.5 (0.0-11.0)	9.0 (3.0-14.0)
# days condomless sex - contiguous*	0.0 (0.0-6.0)	2.0 (0.0-7.0)
# days abstinence - total	10.0 (3.0-23.0)	12.0 (5.0-21.0)
# days abstinence - contiguous	2.0 (0.0-18.0)	5.0 (0.0-14.0)

All results presented = Median (IQR); n = number of participants; *p<0.05 **p<0.01

Table 1. Sexual behavior across methods.

Conclusions: PrEP users had sustained sexual exposure in a six-week period and few days of abstinence. Given the use durations necessary for sufficient protection by both methods, a goal of daily use remains warranted in this population, acknowledging that imperfect use may afford some protection.

Additional analyses are planned to temporally associate reported PrEP use and condomless sex to better evaluate PEU. Similar research to differentiate between FSW status, vaginal vs. anal sex, and measures across additional sub-populations, including men, is needed.

EP071

Tujuane tujamiini: community consultations mapping intersectional stigma

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Background: Despite stigma's well-recognized impact on HIV-prevention and treatment, community experiences of intersectional stigma are underexplored. LGBTQ+ members in Obunga, an informal settlement outside Kisumu Kenya, participated in adapted group concept mapping meetings organized by a community-based organization (CBO)-academic partnership to explore stigma experiences, expand understanding of intersectional stigma and generate recommendations for improvement.

Methods: A trained facilitator and CBO staff led consultations using a semi-structured facilitation guide to conduct brainstorming and synthesis of concept mapping. Results were recorded and thematically analyzed, generating a concept map of intersectional stigma.

Results: Between 17th-26th Nov '22, a total of 67 community members engaged in 1 of 5 community consultations; 12 gay, bisexual or other men who have sex with men (GBMSM), 13 GBMSM sex workers, 13 lesbian women, 15 transgender men and women, and 14 people living with HIV. Participants shared several overlapping stigmatized identities. Poverty and "slum"-residence amplified experiences of other stigmas and challenges in HIV-prevention and -treatment services. The findings mapped out the causes of stigma (laws and policies, community ignorance, negative attitudes and beliefs fueled by norms and institutions), ranging from public harassment to violence. Stigma related to poverty and residence limited one's sense of safety and acceptance at clinics, even those

engaging LGBTQI+ individuals; general discrimination at clinical care sites were common across consultations. Group recommendations included; Expanding inclusive services from HIV-defined key populations to all community members; Including poverty-stigma in sensitization efforts with service providers; and working to remove poverty-related barriers to accessing HIV prevention and -treatment services.

Conclusions: Stigma related to gender identity, sexual orientation, and sex work exerted unique influence on mental health and well-being on LGBTQ+ members within Obunga. Stigma related to 'slum'-residence intersected with marginalized identities when interacting with service organizations outside Obunga. Community recommendations should be considered in developing policies and programs to remove stigma-related barriers.

EP072

Keloids as a rare complication of voluntary medical male circumcision for HIV prevention: findings from PEPFAR's Notifiable Adverse Events Reporting System

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Background: Keloids, abnormal scars surpassing original wound borders, are a rare but challenging and poorly-understood complication of penile surgeries including circumcision. From 2015-2023, the President's Emergency Plan for AIDS Relief (PEPFAR) supported approximately 24 million voluntary medical male circumcisions (VMMC) in 15 sub-Saharan African countries; about 31% were in clients <15 years old. The minimum age of eligibility for surgical circumcision changed in 2021 from 10 to 15 years.

Certain VMMC-associated adverse events, including those causing definite or probable anatomic deformity like keloids, have been monitored through PEPFAR's Notifiable Adverse Event Reporting System (NAERS) since 2015, and are reported when programs become aware, potentially years after VMMC and/or initial keloid diagnosis.

Methods: All keloid cases in NAERS from 2015-2023 were reviewed. Key variables abstracted were client age at VMMC, time from VMMC to keloid development and diagnosis, symptoms, and scar description. Descriptive analysis was performed.



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Results: Ten keloid cases were reported, with associated circumcision dates between 2011-2019. Clients were <15 years old at circumcision in 9/10 (90%) cases with a median age of 11 years (range 10-18 years). Mean time to diagnosis was 1.8 years post-VMMC (range 0.9-2.9 years). Among six cases providing client reporting of timing of keloid development, five occurred approximately one year post-VMMC and one 4 months post-VMMC. Among five cases providing symptom data, one had no associated symptoms, three had itching, and one had pain. Among eight cases providing anatomic location, all involved the circumcision site and one also involved the penile base (potentially the anesthetic injection site). Among six cases describing extent of scarring, four had >50% circumferential involvement.

Conclusions: Keloids were a rare complication of PEP-FAR-supported VMMCs, although underestimation may occur due to passive reporting and the time lag between VMMC and diagnosis. Keloids were particularly rare in clients >15 years old and were not reported from VMMCs performed after the change in age eligibility. Programs may consider reminding clients to return to VMMC sites even for late complications and developing referral networks for appropriate treatment. Additional analysis for potential risk factors and treatment outcomes may identify opportunities to improve keloid prevention and management efforts.

EP073

Longitudinal dynamics of HIV transmission into and between stable sexual couples during antiretroviral therapy scale-up in Uganda

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Background: In sub-Saharan Africa, nearly two-thirds of the annual HIV incidence occurs in stable couples. Widespread ART scale-up and uptake has increased population HIV viral load suppression, but transmission persists across the general population. Disentangling drivers of HIV transmission between stable sexual partners (within-couple) versus from external sources (extra-couple) is key to uncovering remaining gaps in population-level ART effectiveness.

Methods: Longitudinal dynamics of sexual HIV transmission were estimated for 12,468 retrospectively identified stable, heterosexual couples between 1994-2021 from the Rakai Community Cohort Study (RCCS), a population-based open cohort in four districts in southern Uganda. A Bayesian proportional hazards modeling framework with frailty was used to disaggregate within- and extra-couple HIV transmission rates over three epochs of ART scale-up in Uganda: pre-ART, ART rollout, and Universal Test and Treat (UTT).

Results: Incident HIV was observed in one or both partners for 736 RCCS couples, while 11,733 couples remained HIV seronegative throughout their pairwise follow-up. Within-couple HIV transmission rates exceeded extra-couple acquisition rates by an order of magnitude irrespective of epoch, although difference declined over time (Figure 1). Within-couple transmission rates did not differ by index partner gender across all epochs. However, extra-couple acquisition rates were, on average, 1.36-fold (95% CI = 1.10-1.64) higher in men compared to women per epoch. Relative to pre-ART, initial ART rollout had no significant effect on HIV transmission, but subsequent UTT expansion reduced HIV incidence through both within-couple (-65.6%) and extra-couple (-60.6%) routes.

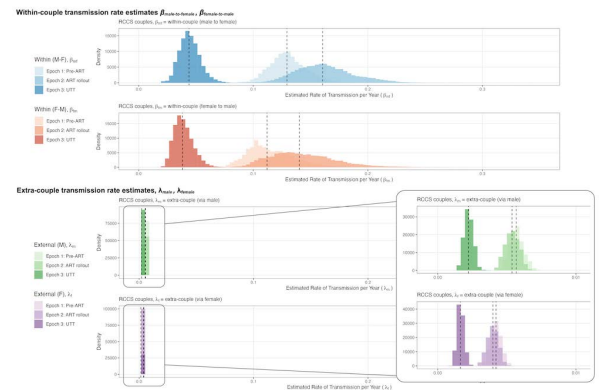


Figure 1. Estimated rates of HIV transmission per year among stable, sexual couples in the RCCS, over three ART scale-up epochs in Uganda (1994-2021). Posterior distributions were derived using an time-dependent Bayesian model with frailty and disaggregated by within-couple and extra-couple transmission routes.

Conclusions: ART scale-up is associated with significant – albeit non-linear – reductions in HIV incidence among stable, sexual couples in Uganda. Despite UTT expansion, both men and women in serodiscordant partnerships remain at risk of within-couple HIV acquisition. Men are also more likely than women to acquire HIV from extra-couple partners, which has further implications for HIV introduction into initially seroconcordant negative couples and onward transmission in serodiscordant couples.

EP074

Training community educators and recruiters for preventive HIV vaccine and broadly neutralizing antibody (bnAb) trials in the HIV Vaccine Trials Network (HVTN)

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Background: While many positions at HIV clinical research sites are defined by professional credentials or courses of study, the critical positions dedicated to community engagement lack a formal certification process. The need for a comprehensive training framework, which is unique to the HVTN, recognizes the unique and essential contributions of individuals in these roles, which extend beyond traditional qualifications to include innate social interaction and communication skills, familiarity with priority populations, and a foundational understanding of scientific principles.

Methods: The HVTN updated its Community Engagement Training Manual (version 4, 2022) comprising 18 modules, and conducted an interactive 2-day workshop for Community Educators/Recruiters (CERs) from the US and Latin America in Seattle, Washington (October 2022), and a second workshop for African staff in Johannesburg, South Africa (February 2023), training over 80 CERs.

Training objectives included building knowledge of vaccine and bnAb science, understanding research ethics, learning how to review a protocol, understanding the role of Community Advisory Boards, and understanding TB vaccines.

Presentations and interactive lessons were led by experienced CERs and Network staff. Small group discussions enabled attendees to consider how they might use the manual in their own local settings.

All participants received digital copies of the manual in English, Portuguese and/or Spanish.

Results: CERs often learn best using interactive methods and practical applications of knowledge. In training evaluations, 93.7% of attendees strongly agreed that the training objectives were accomplished. 87.5% agreed that they understood the new tools and how to use them.

The experts in this field are experienced CERs who have been doing community engagement work for years, and attendees gave peer-led learning opportunities high ratings. Interactive training techniques added value, and time for small group discussions was appreciated.

Using diverse trainers (race, sexual orientation, gender) was also valuable. Provision of Spanish and Portuguese interpretation services enhanced the participation of Latin American staff members.

Conclusions: The HVTN will continue to offer workshops of this type to ensure consistent levels of training among

CER staff across sites. Adaptations can be made for regional cultural issues or population differences, and new lines of work such as TB vaccine trials can be incorporated.

EP075

Perceived neighborhood disorder and achieving HIV viral suppression among adults living with HIV: a cross-sectional study

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Background: Adherence to antiretroviral therapy (ART) is crucial for achieving and maintaining viral suppression in people living with HIV (PLWH). While individual factors affecting HIV viral suppression have been extensively studied, there is less attention on community-level factors, specifically perceived neighborhood disorder.

This study aims to assess the relationship between perceived neighborhood disorder and achieving virologic suppression among people living with HIV.

Methods: One hundred and eighty-eight PLWH 18 years of age and older from two HIV clinics completed a cross-sectional study. We evaluated the relationship between perceived neighborhood disorder and both ART adherence self-efficacy and HIV virologic suppression status, factoring in relevant covariates. HIV viral loads were obtained from the clinical record.

The analysis involved the use of Fisher's Exact test, Spearman's Rank test, Wilcoxon rank sum test, and firth logistic regression. All analyses were conducted using STATA 17.

Results: Most participants were male (79%), white (62%), and identified as non-Hispanic (66%). Individuals with no perceived neighborhood disorder had median scores of 10 for integration and perseverance in ART self-efficacy. Those with high perceived disorder displayed decreased scores of 8.4 and 8.3 for integration and perseverance respectively.

Both integration and perseverance showed statistically significant negative correlations with perceived neighborhood disorder, (Spearman's rho -0.2966; $p < 0.000$ and -0.2387; $p = 0.0010$ respectively). Individuals with virologic suppression ($n = 167$) reported significantly lower perceived neighborhood disorder scores (median = 0.9 [IQR: 0.2-2.0]) compared to those without virologic suppression ($n = 10$, median = 3.2 [IQR: 2.4-4], $p = 0.0012$).

Conclusions: The study highlights a notable correlation between perceived neighborhood disorder, ART adherence self-efficacy, and virologic suppression. This indicates that improving HIV treatment outcomes needs to extend beyond individual-level factors and include strategies



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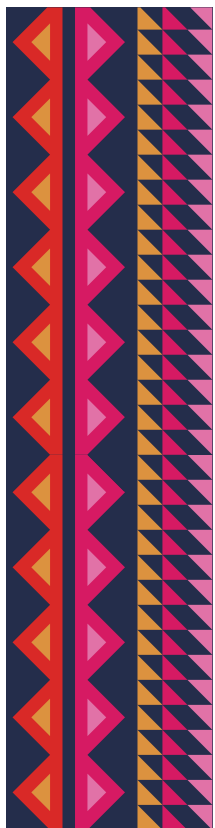
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to address neighborhood-level conditions. Public health policies and programs should consider the broader social and environmental contexts in which people living with HIV reside.

EP076

Validation of the Simplified Medication Adherence Questionnaire (SMAQ) in people living with HIV from a National Hospital in Mexico

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Background: Adherence to antiretroviral therapy is a critical component for achieving viral suppression in people living with HIV, as well as generally increasing quality of life. Various indirect methods have been used to measure adherence, including the SMAQ.

The aim of this study is to evaluate the reliability and validity of the Simplified Medication Adherence Questionnaire (SMAQ) in men living with HIV/AIDS who are treated at a national hospital in Mexico.

Methods: An analytical cross-sectional study was conducted at a National Mexican Hospital in Jalisco, including men >18 years old with at least three months of antiretroviral treatment. Those with cognitive difficulties in responding to the survey were excluded. A minimum sample of 100 subjects was calculated.

The analysis includes descriptive tests, confirmatory factor analysis, reliability and validity assessment, correlation between adherence and viral load, and association between viral load and adherence.

Results: The final analysis included a total of 260 patients with an average age of 43 years and an average of 9 years on ART. The SMAQ showed sufficient structural validity (CFI=1.000, RMSEA=0.000, 90% CI 0.000-0.085) with satisfactory factor loadings for most questions, except item 2. The scale's reliability is acceptable ($\alpha=0.702$, $\omega=0.718$). Adherence was significantly correlated with viral load but not with recent CD4 T lymphocyte levels. Patients classified as adherent were three times more likely to be undetectable than those classified as non-adherent (RR=3.31, 95% CI [1.13-9.64], $p=0.042$).

Conclusions: The SMAQ represents an adequate tool for assessing adherence in men in the Mexican context, which will contribute to the study and understanding of adherence to establish future intervention programs.

EP077

Assessing oral pre-exposure prophylaxis (PrEP) awareness and willingness to use among sexually active adults in five African countries: results from the population-based HIV Impact Assessment surveys

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Background: Pre-exposure prophylaxis (PrEP) is a vital tool for reducing HIV risk in sub-Saharan Africa. This study assessed PrEP awareness and willingness to use among sexually active, HIV-negative adults in Eswatini, Lesotho, Malawi, Mozambique, and Zimbabwe, aiming to inform targeted interventions.

Methods: Data from recent, nationally representative Population-based HIV Impact Assessment (PHIA) surveys (2020-21) were analyzed. Participants were introduced to oral PrEP and asked about their awareness and willingness to use it. Regression models identified sociodemographic and behavioral factors associated with PrEP interest. All results were weighted.

Results: We included 61,878 HIV-negative sexually active participants (Eswatini 6,882; Lesotho 10,539; Malawi 18,389; Mozambique 11,530; Zimbabwe 14,180). The level of PrEP awareness varied significantly across countries, with Eswatini (47%, 95% CI 45%-48%) and Lesotho (40%, 95% CI 39%-42%) showing the highest levels, and Malawi (15%, 95% CI 14%-15%), Zimbabwe (9%, 95% CI 8%-10%), and Mozambique (7%, 95% CI: 6%-8%) reporting the lowest.

Age group	Ever heard about PrEP?						Willingness to take PrEP					
	Female			Male			Female			Male		
	aPR	(95% CI)	P-value	aPR	(95% CI)	P-value	aPR	(95% CI)	P-value	aPR	(95% CI)	P-value
15-29	-	-	-	-	-	-	-	-	-	-	-	-
30-44	1.1	(1.01 - 1.20)	0.036	1.22	(1.09 - 1.36)	<0.0001	0.99	(0.96 - 1.02)	0.359	0.95	(0.92 - 0.98)	0.001
45-59	0.84	(0.73 - 0.97)	0.014	1.03	(0.88 - 1.19)	0.746	0.93	(0.89 - 0.97)	0.001	0.93	(0.89 - 0.97)	0.001
60-80	0.62	(0.46 - 0.84)	0.002	0.76	(0.61 - 0.94)	0.011	0.71	(0.65 - 0.78)	0	0.83	(0.81 - 0.90)	0
Urban	-	-	-	-	-	-	-	-	-	-	-	-
Rural	0.83	(0.73 - 0.93)	0.002	0.91	(0.80 - 1.03)	0.13	1.06	(1.00 - 1.12)	0.036	1.05	(1.00 - 1.11)	0.036
Less than Secondary Education	-	-	-	-	-	-	-	-	-	-	-	-
Secondary and above Education	1.59	(1.43 - 1.77)	<0.0001	1.79	(1.62 - 1.98)	<0.0001	1.06	(1.03 - 1.09)	<0.0001	1.00	(0.98 - 1.03)	0.802
Wealth, lower 40 th Percentile	-	-	-	-	-	-	-	-	-	-	-	-
Wealth, Upper 40 th Percentile	1.36	(1.21 - 1.53)	<0.0001	1.4	(1.26 - 1.55)	<0.0001	1.04	(0.99 - 1.10)	0.083	1.05	(1.00 - 1.10)	0.033
Did NOT use a condom in the last sexual act	-	-	-	-	-	-	-	-	-	-	-	-
Used condom in the last sexual act	1.13	(1.01 - 1.26)	0.041	1.12	(0.99 - 1.26)	0.07	1.08	(1.04 - 1.11)	<0.0001	1.06	(1.03 - 1.10)	<0.0001
One sexual partner in the past 12 months	-	-	-	-	-	-	-	-	-	-	-	-
Two or more sexual partners in the past 12 months	0.84	(0.77 - 0.92)	<0.0001	0.79	(0.69 - 0.91)	0.001	0.89	(0.87 - 0.92)	<0.0001	0.86	(0.82 - 0.89)	<0.0001
Does not drink alcohol	-	-	-	-	-	-	-	-	-	-	-	-
Drink alcohol	1.33	(1.18 - 1.49)	<0.0001	1.14	(1.04 - 1.25)	0.004	1.07	(1.03 - 1.12)	<0.0001	1.08	(1.05 - 1.10)	<0.0001
Not circumcised	-	-	-	-	-	-	-	-	-	-	-	-
Circumcised	-	-	-	1.15	(1.04 - 1.26)	0.005	-	-	-	0.99	(0.96 - 1.03)	0.758
Observations:	23,210			19,593			21,868			18,709		

Notes: aPR= Adjusted prevalence ratio
 Countries' fixed effect estimates are not shown.

Table 1. Factors associated with awareness and willingness to use oral PrEP among sexually active HIV-negative participants in population-based HIV impact assessment (PHIA) surveys Eswatini, Lesotho, Malawi, Mozambique and Zimbabwe.



The willingness to use PrEP exceeded the current use in all countries (ranging from 54% in Lesotho to 71% in Malawi and Mozambique). Regression analysis showed that PrEP awareness was highest among the 30-44 age group for both sexes, declining in older age groups. Rural residency and 2+ sexual partners were significantly associated with lower PrEP awareness. Secondary+ education, upper wealth index, alcohol use, male circumcision, and condom use at last sex were significantly associated with higher awareness. Younger age, rural residence, condom use at last sex, and alcohol use were significantly associated with willingness to use PrEP among both sexes. Significant inter-country differences in awareness and willingness were identified.

Conclusions: This study revealed disparities in PrEP awareness across five African countries but consistently high willingness to use it. Demographic and behavioral factors influenced PrEP awareness and willingness. Targeted interventions are crucial to increasing awareness and bridging the gap between willingness and PrEP use.

EP078

Factors associated with HIV testing repetition among European community-led testing centres from the COBATEST Network, 2014-2022

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Background: Community-led testing centres play a crucial role in HIV prevention and sexual health promotion, reaching highly vulnerable populations as alternative to traditional healthcare. Repeated testing at these centres indicates confidence in services and individual health awareness.

This study describes the population utilizing community-led testing centres for HIV between 2018 and 2021, identifying factors associated with repeat testing.

Methods: Cross-sectional study in centres from the COBATEST Network, which collect anonymised demographic, health, and bio-behavioural data, using the COBATEST online tool. All those tested for HIV at least once were included. Dependent variable was repeating testing in the same centre. Independent variables were gender, age, country of origin, being gay, bisexual or other men who have sex with men (GBMSM), sexual work, intravenous drug use (IDU), condom use in the last sexual intercourse, and STI during last 12 months. Descriptive analysis was carried out, and a multivariate logistic model was set to determine associated factors with testing repetition.

Results: In total, 80,684 individuals were included from 59 centres in 12 different countries. Men represented 66.0% (n=53,263), women 32.0% (n=25,844) and transgender people 1.9% (n=1,532). The main age category was 25-34 years old with 55.7% (n=44,909), 31.5% (n=25,390) were foreign-born, and 13.8% (n=11,122) repeated testing in the same centre at least once. GBMSM was reported in 41.3% (n=33,362), sex work in 9.6% (n=7,713) and IDU in 1.2% (n=945). Factors associated with testing repetition after multivariate analysis were being a man (aOR=1.10; CI:1.02-1.18), a transgender person (aOR=1.95; CI:1.68-2.25), being more than 25 years old (aOR=1.31; CI:1.25-1.38), being migrant (aOR=0.81; CI:0.76-0.85), GBMSM (aOR=2.43; CI:2.28-2.59), sex worker (aOR=1.68; CI:1.56-1.82), IDU (aOR=1.29; CI:1.05-1.58), using a condom in the last sexual intercourse (aOR=1.20; CI:1.14-1.25), and having any STI during the last 12 months (aOR=1.43; CI:1.33-1.54).

Conclusions: Community-led centres often cater to a significant portion of vulnerable populations. Identifying factors associated to repeat testing can inform targeted interventions aimed at enhancing testing coverage. These centres can serve as pivotal platforms for ongoing promotion of testing, thereby contributing to the reduction of HIV risk.

EP079

Outcome of scaling up HIV case finding among Key populations, Gender and sexual Minorities through Social Network Strategy; a retrospective analysis in the Coastal region of Kenya

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Background: USAID Stawisha Pwani a USAID funded project implements comprehensive high-quality HIV prevention, care and treatment programs in four counties in the coastal region of Kenya. In addition to the general population, the project serves Key Populations (KPs), Gender and Sexual Minorities (GSM) who experience higher risk of HIV acquisition, transmission and morbidities due to their specific socio-cultural vulnerabilities and high-risk behaviors. The project currently supports 68,886 persons living with HIV (PLHIV) with 5,904 newly diagnosed in the last year (Oct 2022 – Sept 2023) where KPs and GSM contributed to 4% of PLHIV.

Social Network Strategy (SNS) is an evidence-based approach to identify, engage and motivate people with undiagnosed HIV infection to accept HIV testing services (HTS) and is amongst the strategies towards achieving the UNAIDS goal of 95-95-95. The project focused on the strategy to describe the implementation and the results towards bridging the KPLHIV identification gap with the assumption that persons in the same social network share similar risky behaviours and vulnerabilities.

Methods: The project trained and sensitized the technical leads, health service providers and program volunteers. The trained officers conducted HTS testing at all levels,



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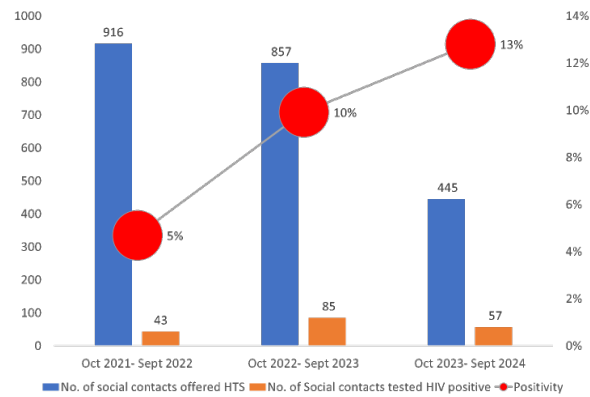
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offered recruitment opportunities to the willing newly diagnosed PLHIV. Those tested mobilized their peers and were provided with funds for phone communication as a motivation to create demand for HIV testing, mobilization and referrals.

Results: Progressive increase in identification of PLHIV from 5% in FY 2022 when SNS commenced to 10% in FY 2023 and 13% by February 2024.



Conclusions: SNS as a client centred approach has enhanced enrolment of new KPs and GSM, and improved HIV case identification. The approach can be scaled up to reach other hard to reach populations including Adolescents and Young persons (AYP). Referral by a peer for HIV testing and linkage demonstrated less stigmatization leading to 100% proxy linkages.

EP080

Factors associated with cardiovascular diseases among HIV-positive Hispanics

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Background: This retrospective cohort study aimed to identify factors associated with incident cardiovascular disease (CVD) among HIV-positive Hispanic individuals in Puerto Rico, where HIV acquisition bears a disproportionate burden. With advancements in antiretroviral therapy (ART), mortality from HIV has significantly decreased, leading to an aging population with an increased risk of developing age-associated diseases, including CVD.

Previous research indicates that HIV-positive individuals are about twice as likely to develop CVD compared to HIV-negative individuals of the same age.

Additionally, exposure to specific antiretroviral treatments has been linked to an increased risk of myocardial infarction and injectable drug users (IDUs) potentially have a more compromised immune system.

Methods: This study involved 766 participants from an immunological research center in Puerto Rico, aged 21 years and older, enrolled between January 1, 2005, and December 31, 2015, without pre-existing cardiovascular disease. The primary outcome analyzed was incident CVD, defined as either a self-report or a medical record

diagnosis of heart, cardiovascular, or coronary artery disease among individuals who initially reported no CVD diagnosis. Risk factors including sex, age, education, alcohol consumption, illicit drug use, and body mass index were also considered.

Results: Results showed that among the participants, only a prior diagnosis of diabetes mellitus significantly associated with the development of CVD, with an odds ratio of 5.51 ($p < .001$). This finding underscores the heightened risk of CVD among HIV-positive individuals with diabetes mellitus.

In contrast, factors such as age, high viral load, ART, and CD4 levels were not significantly associated with incident CVD in this study, suggesting the complexity of CVD risk factors in HIV-positive populations and highlighting the need for further research to explore these associations in greater depth.

Conclusions: This study contributes to the understanding of cardiovascular risk among HIV-positive individuals in a unique demographic context and the potential immunological difference between IDUs and other individuals.

Also important to monitor comorbidities such as diabetes mellitus in the management of HIV-positive individuals to mitigate the risk of developing CVD.

EP081

A snapshot: characteristics of Latin American (LATAM) Community Advisory Boards (CABs) in the HIV Vaccine Trials Network (HVTN)

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Background: HVTN requires involvement of local CABs at each clinical research site (CRS) implementing studies. Maintaining a CAB is complex and there is limited published information about CAB operations and structure, and even less for LATAM.

Methods: Drawing from the HVTN Community Engagement (CE) site preparation visit checklist and the CE Annual Plan, we developed a questionnaire to assess CABs at CRSs in Lima and Iquitos, Peru and Rio de Janeiro, Brazil. Data was collected during March 2024 and included demographics, CAB operational procedures, and CAB scope of work performed from January 1 to December 31, 2023.

Results: The 3 CRSs each had an operating CAB for over 20 years. All CABs worked with multiple research networks. The Impacta CAB serves 4 CRSs in Lima. The ACSA CAB serves ACSA CRS in Iquitos. The Fiocruz CAB served two CRSs in Rio de Janeiro until one site established its own CAB with Fiocruz' assistance.

CABs identified several factors contributing to their success: The establishment of bylaws; clear internal organization, including elections; a staff liaison; and resources to support CAB operations. CAB members review research protocols, informed consent forms, study educational materials, and community engagement plans.

The average length of CAB membership is 11.4 years, with 12% of members having <5 years' experience. The average age of members is 51 years and 62.5% are >45 years old, however, none are under 25 years old. Communities represented include LGBTQ+, people with HIV and/or tuberculosis, and other stakeholders.

CABs also have local initiatives beyond HVTN requirements that contribute to their strength, such as: Peruvian CABs convene annually for a joint CAB retreat where they exchange experiences; ACSA CAB has an annual plan of activities that are implemented with site support; FioCruz CRS provides support for CAB initiatives within the community.

Conclusions: LATAM CABs have robust structures with extensive experience in and support of a wide range of site research activities. LATAM CABs need to recruit younger members to build capacity and ensure that over 20 years of knowledge and experience are sustained into the future, and to ensure the inclusion of those most vulnerable to HIV acquisition.

EP082

Postpartum contraceptive uptake among women who participated in MTN-042/ DELIVER, an HIV prevention study for pregnant women in Kampala

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Background: In Uganda with modern contraceptive uptake at 35%, unintended pregnancies persist. Post-partum contraceptive uptake at 6 weeks is inadequate due to low postnatal care attendance and limited access to options for immediate postpartum family planning following delivery.

We described factors impacting contraceptive choices among postpartum participants to improve family planning integration in HIV prevention programs.

Methods: In MTN-042/DELIVER, a safety study of the dapivirine vaginal ring, HIV-negative pregnant women were enrolled and followed for 6 weeks postpartum. During study follow-up visits, participants were counselled about contraceptive use. Reasons for declining and choosing various contraceptive methods were documented in the chart. We summarized participant demographic data, pregnancy history and family planning utilization before and after pregnancy. These data were obtained from

medical records, contraceptive counselling worksheets, chart notes, family planning cards and concomitant medications log.

Results: Of the 154 enrolled participants, 95 (61.7%) took up contraception at 6 weeks post-partum yet before pregnancy, only 33.8% of the participants had been using contraception. 57 (37%) declined and 2 (1.3%) did not make a choice due to a missed study exit visit. Of those who accepted, 55.8% were 18-24 years old, 67% were married, 52% had attained secondary education and 65% had more than one child. Reasons for those that declined contraception were: being unready (45.6%), undecided (40.4%), uninterested (5.3%), absent partner (3.5%), desire to conceive (3.5%) and religious reasons (1.8%).

Conclusions: Contraceptive uptake from the baseline of 33.8% to 61.7% in the study population suggests that family planning counselling during the study follow-up visits enhanced contraceptive uptake among postpartum women. This calls for strengthening and integration of family planning services and counselling into HIV prevention programs right from the outset.

EP083

Intervention of reaching men with HIV testing leveraging on public-sector innovations in Kenya

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Background: Since 2014, Kenya Government streamlined the public service delivery system by establishing central public service delivery hubs, commonly known locally as **Huduma Center** for delivery of services such registration of persons, issuance of birth/death certificates, driving licenses and business permits and payment for various public utilities bills such as water and electricity. Analysis of the service uptake data in these hubs reveals that between 2017 and 2022, the centers served more men than women (57.7% M to 42.3% F) - making them favorable men-serving points. HIV testing lower among men than women in Kenya. Through a multi sectoral partnership, Mombasa County, the National AIDS Control Council (NS-DCC) and AIDS Health Foundation (AHF) initiated HIV testing service targeting men leveraging on Mombasa hub.

Methods: This further involved deployment of HIV service providers equipped with male engagement skills. Data capture and transmission, linkages and referral mechanisms were streamlined. Further, Center management and staff were trained on prevention, testing and community mobilization skills using peer to peer approach.

Results: The uptake of HIV testing by men increased by within the first six months of initiation. Young men of 15-24 years particularly preferred accessing testing in this center compared to the nearby traditional, stand-alone sites and sites within the health settings. The strategy offered a chance to leverage on 'extra health' sector innovation to reach men with basic HIV services.



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Conclusions: There is a need to leverage on sectors outside health to offer HIV services on hard-to-reach population such as men, young people and key population. Greater partnerships and networking between health providers and other sectors is necessary for success of HIV interventions. With success of this intervention in Mombasa, *Huduma* Center management has issued guidelines for all centers across the country to initiate or scale up delivery of HIV related services.

EP084

Preferences for HIV Pre-Exposure Prophylaxis (PrEP) formulations among young women with experience using oral PrEP in Kisumu, Kenya

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Background: Adolescent girls and young women (AGYW) in Africa face challenges using PrEP. Longer-acting formulations are becoming available, but preferences are poorly understood. The PrEP My Way study involved peer-supported, community delivery of oral PrEP and co-packaged sexual health services. We assessed participants' PrEP formulation preferences, views on nurse-delivered injectable PrEP and concerns about novel formulations in the community.

Methods: In Kisumu, Kenya, 16-24-year-old women were recruited at PrEP initiation (2021-2022) and followed for 6 months. At exit, a convenience sample ranked their PrEP formulation preferences and provided opinions on comfort with nurse-delivered injections and concerns about injections and vaginal rings in the community. We used regression models to assess factors associated with their preferences.

Results: Of 75 AGYW participating in the intervention, 57 (76%) completed the survey. Median age was 21.4 years. Formulations ranked as first choice were: 28 (49%) injectables, 14 (25%) vaginal rings, and 15 (26%) oral pills (Figure).

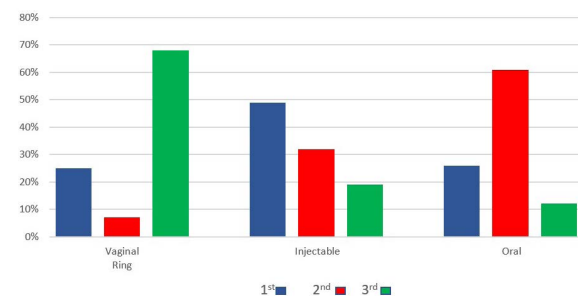


Figure 1. Ranking of preferred PrEP formulation: 1st=top choice, 2nd=second choice and 3rd=third choice.

Participants with higher PrEP stigma were more likely to rank the ring first (vs second/third; $p=0.01$) and trended toward being less likely to rank pills first ($p=0.07$). A trend

was seen with higher scores on a sexual relationship power scale and first choice for injectables ($p=0.08$). Forty-six (81%) AGYW were comfortable/very comfortable with nurse-provided injectable PrEP in the community. Twenty-one (37%) and 7 (12%) participants had concerns about inadequate privacy with injections and vaginal rings, respectively. Seven (12%) and 31 (54%) participants had concerns about the injections (e.g., pain) and vaginal rings (e.g., partner reaction), respectively.

Conclusions: Nearly half of AGYW with experience with community-delivered oral PrEP would most like to use injectable PrEP. PrEP stigma and sexual relationship power influenced formulation choice. A nurse-delivered model for injectable PrEP is promising, but privacy concerns need attention, and more instructional support and guidance may be needed for vaginal rings.

EP085

Advancing HIV treatment as prevention: Rwanda's experience with differentiated service delivery model implementation

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Background: Rwanda is one of the pioneer countries to implement the Differentiated Service Delivery Model (DSDM). Launched in December 2016, this model aims to provide care to people living with HIV (PLHIV) based on their clinical needs, reducing the burden on healthcare facilities, and improving outcomes. The model categorizes PLHIV into stable and unstable groups, offering varying levels of care frequency which optimize resource allocation and enhance client outcomes. The Government of Rwanda initiated the national DSDM rollout in collaboration with international partners like PEPFAR.

This abstract examines Rwanda's experience with DSDM implementation, highlighting its methods, results, and implications in reduction of HIV transmission.

Methods: Over the course of five months, Rwanda conducted thorough planning, training, and logistical preparations to implement the DSDM nationally. Important parties, such as the CDC and the Ministry of Health, worked together to create methods for evaluation and monitoring that would guarantee successful program execution and advancement. The approach included developing monitoring and assessment techniques in conjunction with international partners, preparing medical facilities logistically, and providing comprehensive training to pertinent staff.

Results: The DSDM significantly reduced the frequency of healthcare visits for stable clients, allowing healthcare providers to focus on higher-risk individuals. Through proactive efforts, Rwanda achieved impressive outcomes, with over 82% of PLHIV established on antiretroviral therapy as of February 2024. Notably, the success of DSDM contributed to Rwanda's achievement of the 95-95-95

UNAIDS target making 95% of people taking ART suppress viral load thus leading to "Undetectable = Untransmittable" (U=U), which highlights the ability of PLHIV who can reach and sustain undetectable viral loads not to spread HIV through sexual contact.

Conclusions: Rwanda's successful DSDM implementation exemplifies the efficacy of personalized healthcare in enhancing HIV care outcomes and mitigating transmission risks. Moving forward, refining DSDM categorization and expanding services for clients with comorbidities are imperative. This will enhance treatment adherence, improve PLHIV outcomes, and prevent new HIV acquisitions, notably achieving U=U targets. Such a comprehensive approach marks a significant stride in the global fight against HIV/AIDS, promising healthier futures worldwide.

EP086

Impact of the COVID-19 pandemic on biomedical research: a case study from the first Pre-Exposure Prophylaxis demonstration project among Men having Sex with Men and Transgender Women in India

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Background: We present the impact of the COVID-19 pandemic on the recruitment of Men having sex with Men (MSM) and Transgender Women (TGW) and innovative strategies used for recruiting MSM/TGW during pandemic for Pre-Exposure Prophylaxis (PrEP) demonstration project in India.

Methods: MSM/TGW at substantial risk for HIV were recruited in Punjab and Maharashtra in India between December 2019 and July 2022. Monthly rate of enrolment against the set target was compared preceding COVID-19 pandemic (December 2019- February 2020) and during the 3 waves of the pandemic (March 2020- March 2022). Theory informed socio-culturally acceptable strategies for recruitment of MSM/TGW and newer data collection techniques like telephonic surveys, telemedicine, sample collection in mobile vans/ clinics, dispensing near participant's homes were used and its impact on recruitment was assessed.

Results: Overall, 650 enrolments were completed by July 2022 against the target of 660 enrolments with a delay by 14 months. Compared to the pre-pandemic phase, enrollments dropped to 60% and 46% in Maharashtra and Punjab respectively during the first wave of the pan-

dem. In response to reducing screening numbers, Peer Change Agent (PCA) Model, adult education techniques and tailored communications to understand HIV risk and HIV prevention, night vigil, social media, confidential doorstep/ convenient location services during pandemic phase resulted in increase in screening by 15 times (from 60 to 932) during pandemic. PCA Model strategy reduced average dropdown in enrollments by 38% in Maharashtra and 28 % in Punjab during unlock period between the second and third waves of the pandemic (Figure 1).

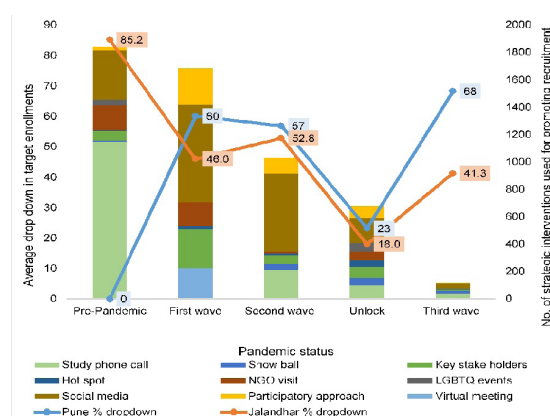


Figure 1. Trend in average dropdown over study recruitment period along with the strategic used for promoting recruitments among MSM and TGW.

Conclusions: The COVID-19 pandemic wedged recruitment of hidden vulnerable key populations in HIV prevention research studies. COVID-19 has confirmed that the behavioral and social sciences guided understanding of the drivers of transmission and how to design and deliver effective interventions such as PrEP among key vulnerable populations in pandemic situation.

EP087

"Now I feel comfortable counseling index and contact clients": qualitative insights on the impacts of blended learning training on capacity to implement index case testing

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Background: Index case testing (ICT) is an evidence-based intervention strongly recommended to increase the identification of people living with HIV. However, ICT's success depends on its implementation, including health care worker (HCW) capacity to counsel index clients. To enhance capacity, HCWs were trained using a blended learning training approach (integrating digital and face-to-face and training modalities) as part of a larger cluster randomized implementation study. The training



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was decentralized, and the digital portion comprised of learning ICT processes and watching videos modeling different counseling scenarios while the face-to-face portion comprised of practicing ICT counseling and receiving feedback. We interviewed HCWs in two districts (Balaka and Machinga) to assess the impact of blended learning training approach on HCWs' capacity to implement ICT by comparing the responses of HCWs from enhanced and standard clusters.

Methods: From November 2022 to January 2023, individual, semi-structured interviews lasting approximately 60 minutes were conducted with 26 HCWs: (15 HCWs in standard clusters and 11 in enhanced clusters) following implementation of the training. Interviews focused on HCWs' acceptability providing ICT including experiences counseling index clients and tracing contact clients. Using rapid qualitative analysis methods, interview transcripts were summarized using standardized summary sheets and input into extraction matrices, organized by construct and domain for each transcript. Key findings from the matrices were then assessed across transcripts, constructs, and domains.

Results: HCWs from enhanced clusters reported improved knowledge, self-efficacy, and skills in counselling index clients and tracing contact clients. Improvements described by HCWs from enhanced clusters included being able to handle more nuanced, difficult counselling situations, feeling more comfortable eliciting contacts, and using ICT processes and tools to do so. They also reported improvements in how ICT checklists were used in their facilities, strengthening counselling sessions. HCWs from standard clusters reported improved knowledge but requested additional tools, training, and more ICT-related supervision, reflecting less comfort implementing ICT.

Conclusions: Blended learning training approach makes HCWs more capable of implementing ICT and increases the acceptability of ICT among HCWs. To improve delivery, national and regional efforts to implement or scale-up ICT should consider this training strategy for HCWs.

EP088

Potent cross clade protein-based HIV inhibitors targeting highly conserved gp41 epitopes

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Background: The development of HIV-1 fusion inhibitors is a major focus of research efforts towards the discovery of novel protein therapeutics for the treatment of HIV/AIDS. Among these, chimeric proteins mimicking the N-terminal heptad repeat (NHR) of the viral glycoprotein gp41 in a trimeric helical conformation are promising candidates because they bind the highly preserved C-terminal repeat (CHR) and block the conformational changes of gp41 that drive the fusion process. Due to their small size, they display higher accessibility to obscured epitopes than conventional mAbs. However, the inherent instability and aggregation propensity of the NHR region can limit their activity. Our aim was to develop new NHR-mimetic mini-proteins with high stability and broad and potent HIV inhibitory activity.

Methods: We designed new NHR-mimetic mini-proteins targeting the C-terminal half of the CHR region and part of the MPER region of gp41 and produced them by recombinant *E. coli* expression with high yields. Their inhibitory potency was analyzed *in vitro* using the conventional TZM-BI and primary cell based inhibitory assays.

Results: We found that our new NHR-mimetic mini-proteins showed high stability and solubility, as well as high affinity for peptides representing their target. Moreover, they exhibited potent *in vitro* inhibitory activity at nM concentrations against different HIV-1 strains in the TZM-BI conventional assay. Noteworthy, these potent activity was conserved or even enhanced when using primary CD4 T lymphocytes and primary Tier 2 HIV strains.

Conclusions: Our findings indicate that the conformationally stabilized gp41 NHR-mimetic mini-proteins displayed potent HIV inhibitory activity. Moreover, their small size allows to conserve the inhibitory potential on primary Tier 2 viruses with tightly closed trimeric envelopes that mask their conserved epitopes. These findings show that this new design of HIV-1 fusion inhibitors is a promising strategy and may have important implications for the development of novel therapeutics for the treatment of HIV/AIDS and other viral infections.

EP089

Empowering AGYW mothers' PrEP choices: qualitative insights into PrEP decision-making and preferences during pregnancy and breastfeeding in South Africa and Botswana

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Background: Adolescent girls and young women (AGYW) in sub-Saharan Africa are at a disproportionate risk of HIV acquisition, and their vulnerabilities are further intensified during pregnancy and breastfeeding. Understanding AGYW mothers' attitudes towards new PrEP modalities is vital for developing effective PrEP strategies and reducing HIV incidence in this vulnerable population.

Methods: In-depth interviews were conducted with thirteen pregnant and postpartum AGYW (18-24 years old, median age=22; n=9 pregnant, n=4 breastfeeding) from March-June 2023. Interviews were conducted in three sites: Cape Town, East London (South Africa), and Gaborone (Botswana). We conducted thematic analysis on the data focusing on HIV risk perception, and attitudes and preferences towards different PrEP modalities.

Results: There was a strong desire among AGYW to protect themselves and their fetuses/infants from HIV, with their motivations strengthened during pregnancy and breastfeeding. Cape Town participants (n=4, all PrEP-exposed) showed higher acceptance of PrEP, most likely due to having more PrEP exposure and/or greater perceived HIV risk, which they demonstrated compared to the other two sites (all PrEP-naïve).

The most preferred modality overall was monthly oral pills compared to vaginal rings, injectables or implants. Fear of pain from injections or inserting implants influenced choice, and vaginal rings were least preferred overall as participants expressed aversion toward the

concept of vaginal insertion and concerns over its lower effectiveness. As participants learned about each modality's long-acting properties during the interview, they often changed their preferences from daily oral PrEP to injectables/implants, as it would alleviate daily pill burdens and result in fewer clinic visits. Participants' main concerns for new modalities included side effects, discomfort, and accessibility and/or availability.

Conclusions: The desire among AGYW to protect themselves and their fetuses/infants underscores the potential benefits of integrating PrEP into broader maternal health services.

The study suggests a need for enhanced, context-specific PrEP strategies, especially raising awareness for new modalities as lack of familiarity might deter use. Targeted PrEP counselling is needed and should prioritise addressing concerns around safety and side effects and provide product demonstrations. Empowering AGYW with knowledge to make informed PrEP choices and ensuring accessibility and availability of different PrEP modalities could enhance PrEP utilisation.

EP090

Uptake of oral pre-exposure prophylaxis among adult participants in a HIV vaccine trial in southwestern Uganda

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Background: While pre-exposure prophylaxis (PrEP) is recognised for its efficacy in reducing HIV infection risk, its uptake is low. To address this issue, we assessed the willingness of adults enrolled in a vaccine trial in Uganda to take oral PrEP.

Methods: The PrEPVacc trial is a phase IIb, three-arm, two-stage HIV prophylactic vaccine trial with a second randomisation to compare Descovy to Truvada as PrEP. Adults (18-40 years) at risk of HIV infection provided consent and received counselling regarding the use of PrEP, its benefits, and side effects during the enrolment visit. Participants were randomized to receive either open-label Descovy or Truvada in a ratio of 1:1. Those who declined oral PrEP could still participate in the vaccine trial and receive alternate forms of HIV prevention. Demographic data were collected on case report forms, and reasons for declining oral PrEP were documented in counsellor source notes. Data were analysed descriptively.

Results: A total of 512 adults participated in the trial, with 80.7% being females. The median age was 25 years (interquartile range 22-29). Of these, 80.9% (n=414) accepted oral PrEP. Among those who declined oral PrEP, the majority were female (n=88, 89.8%), commercial sex work-



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ers (n=71, 72.5%), aged ≤25 years (n=55, 56.2%), and living in non-fishing/low HIV prevalence communities (n=94, 95.9%). The most common reasons for declining oral PrEP included concerns about pill burden (n=54, 55.1%), fear of side effects (n=25, 25.5%), partner/guardian concerns (n=13, 13.3%), and fear of stigma (n=6, 6.1%).

Conclusions: While there is a significant interest in PrEP usage, improving uptake necessitates the implementation of more effective counselling strategies to address concerns about pill burden and fear of side effects. Additionally, offering alternative PrEP options could be beneficial for certain individuals.

EP091

Sexual intimate partner violence targeting gender non-affirmation is associated with HIV vulnerability among transgender women in the Eastern and Southern United States

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Background: Transgender women (TW) are disproportionately impacted by both HIV and gender-based intimate partner violence (IPV). Prior qualitative research has explored how IPV and non-affirmation of gender identity can increase HIV vulnerability among TW; however, few studies have assessed the association between unique forms of sexual IPV that are experienced by TW (i.e., transgender-specific IPV; T-IPV) and HIV vulnerability.

Methods: Between 2018-2022, we enrolled 1,314 adult TW without HIV (biomarker-confirmed) residing in the Eastern and Southern United States in The LITE Study. Participants completed a baseline sociobehavioral survey, which asked a validated measure of lifetime and past 12-month sexual T-IPV ("an intimate partner pressured you to have certain kind(s) of sex by telling you that a 'real' woman would do it") and questions related to past 6-month PrEP

indications (e.g., condomless sex, sex work, number of sexual partners). We descriptively characterized lifetime and past 12-month T-IPV, and fit Poisson regression models with robust errors to estimate crude and adjusted prevalence ratios (PR) and 95% confidence intervals (95% CI) to quantify the cross-sectional association between past 12-month T-IPV and past 6-month PrEP indications.

Results: The mean age was 31.1 years (range=18-77); 22% identified as Black and 18% as Latina; 47.2% had one or more past 6-month PrEP-indications. More than 1 in 10 (14%) reported lifetime sexual T-IPV; 7% in the past 12 months. TW with past 12-month sexual T-IPV were more likely to identify as Black and/or Latina, report adverse childhood experiences before age 18 years-old, experience food insecurity, and were less likely to report receipt of gender-affirming hormones (all p<0.05). Those reporting past 12-month sexual T-IPV had 63% higher prevalence of one or more PrEP indications (PR=1.63; 95% CI=1.41-1.87). In the sociodemographic-adjusted model, this association was partially attenuated but remained a statistically significant correlate of PrEP indications (adjusted PR=1.48; 95% CI=1.28-1.71).

Conclusions: T-IPV targeted at gender non-affirmation in a sexual context is a unique form of sexual gender-based violence experienced by TW associated with HIV vulnerability. Our findings, though lacking temporal ordering, highlight the need to address sexual T-IPV within comprehensive HIV prevention interventions and programs tailored for TW.

EP092

Effect of an individual-level training intervention for triage nurses to increase HIV screening in a Miami emergency department

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Background: Jackson Memorial Hospital (JMH) Emergency Department (ED) instituted a triage nurse-initiated, routine, opt-out, HIV screening program for its patients in 2017. Unfortunately, many patients were designated as either ineligible, having "opted-out," or "N/A" (not applicable) for screening, resulting in missed opportunities to diagnose unrecognized HIV infections. We instituted an individual-level training intervention designed to decrease inaccurate screening designations and increase HIV screening.

Methods: With the assistance of the JMH ED and hospital staff, we designed an individual-level intervention for triage nurses that emphasized effective communication with patients, HIV screening importance, and the princi-

ple of opt-out, rather than opt-in, testing. We conducted in-person observations of triage nurses initiating HIV screening during the pre- and post-intervention periods. Post- and pre-intervention period observations (n=112 each period) were matched by triage nursing shift times, day of the week, and years of nursing experience.

We compared patient HIV screening eligibility assessments and HIV testing in post-intervention and pre-intervention observation periods using chi-square testing.

After both observation periods were complete, we also assessed the additional effect of removing the "N/A" designation from the eligibility assessment at the JMH ED compared to 3 other affiliated EDs in Miami.

Results: More patients were designated as eligible at triage and willing to participate in HIV screening in the post-intervention period compared to pre-intervention period (36.9% vs. 16.5%; p=0.005), and fewer patients "opted-out" of HIV screening (14.4% vs. 1.8%; p=0.025). We did not find evidence that nurse experience or time of visit affected screening outcomes.

HIV screening increased 38% (compared to 2022) in the 3-month period after the "N/A" designation was removed as an option at the affiliate EDs.

However, after both the intervention and "N/A" option removal, HIV screening had increased more (74%) at the JMH ED.

Conclusions: This individual-level training intervention, instituted at an ED serving a community with the highest HIV incidence in the United States, conferred substantial increases in HIV screening, both as a stand-alone measure, and in conjunction with the removal of an N/A screening option during triage. The intervention may have promise and could be adapted elsewhere to increase ED HIV screening success.

EP093

Ultra-long-acting injectable, biodegradable, and removable in-situ forming implant with dolutegravir for HIV prevention: pushing the boundaries with a potential once-yearly injectable

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Background: Long-acting injectables (LAIs) for HIV PrEP can increase user acceptability and adherence. Current LAIs require 2-6 doses per year, are not removable, and elicit a long pharmacokinetic (PK) tail. Previous studies investigating LAI of Dolutegravir (DTG) have demonstrated limited success in achieving sustained plasma DTG concentrations above its 4x PA-IC90 beyond two months. We propose to develop an ultra-long-acting (ULA) biodegradable and removable in-situ forming implant (ISFI) with DTG.

Herein we present the long-term safety and time-to-completion (TTC) PK studies.

Methods: Female BALB/c mice were injected subcutaneously (SC) with 50 μ L of DTG ISFIs containing 350 mg/mL of DTG. Plasma samples were collected longitudinally to quantify drug concentration for PK until TTC, and TNF- α and IL-6 levels for systemic inflammation over 180 days. To assess local inflammation, histological examinations of the implant site and surrounding SC tissue were performed at 7, 30, 60, 90, and 180-days post ISFI administration.

Results: DTG ISFIs elicited sustained plasma concentrations of DTG above the 4 PA-IC90 for an unprecedented duration of 390 days, with zero-order release kinetics (Fig. 1A).

Systemic inflammation, as indicated by TNF- α and IL-6 plasma levels, remained within mild to moderate ranges, suggesting an acceptable safety profile (Fig. 1B).

Histological analysis demonstrated the biocompatibility of the DTG ISFI, with overall minimal-to-marked foreign body responses and fibrosis levels ranging from mild to moderate, based on blind scores from a certified pathologist (0-none to 5-severe, Fig 1c).



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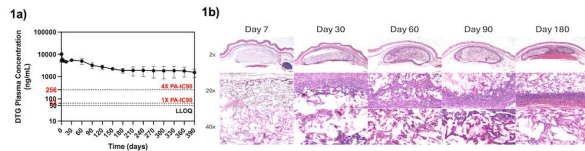


Figure 1. (1a) Plasma concentration of DTG ISFIs over 390 days (last timepoint analyzed; ongoing time-to-completion study). (1b) Histological evaluation of the implant site and surrounding subcutaneous tissue up to 180 days.

Conclusions: Herein we report on a biodegradable, removable, and ULA DTG ISFI that elicited sustained zero-order release for 390 days (last time point analyzed, ongoing) and biocompatibility. This study underscores the potential of DTG ISFIs in bridging the gap between efficacy, safety, and user convenience in HIV prevention. Ongoing and future investigations will further explore comprehensive pharmacokinetics and efficacy in non-human primate models, paving a way for clinical translation.

EP094

Leveraging conversational AI in STI/HIV prevention to combat health inequities and stigma in communities of Color and LGBTQ+ populations

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Background: In the context of HIV prevention, Pre-exposure Prophylaxis (PrEP) stands out as a highly effective measure, reducing the risk of acquisition by up to 99%. However, significant gaps in PrEP accessibility and uptake persist, particularly among communities of color and LGBTQ+ populations, who are disproportionately affected by HIV. These gaps are exacerbated by factors including stigma, health literacy, medical mistrust, and access to conventional healthcare services. This study, conducted by Healthvana in collaboration with the AIDS Healthcare Foundation (AHF), evaluates the impact of a Conversational Generative AI Navigator on improving PrEP-related education, engagement, and operational efficiency in public health settings serving high-need client populations.

Methods: This qualitative and quantitative study was implemented from December 2023 to March 2024 across AHF Wellness Centers in Georgia, Florida, Texas, and California. The Conversational AI, integrated into the Healthvana portal, was made available to 4,900 clients, providing personalized, nonjudgmental health information and navigation for PrEP services without offering medical advice. The study assessed engagement metrics, analyzed the content and outcomes of interactions, and surveyed client perceptions, focusing on disaggregated data by age and gender to understand diverse client needs and experiences with the AI platform.

Results: Early findings revealed that 70% of interactions were initiated by clients from communities of color, with women representing 38% of the user base. Engagement remained consistent across age groups, including those over 50, suggesting broad applicability of AI tools for

health communication. The AI effectively facilitated discussions on PrEP, including appointment scheduling for PrEP consultations and refills, demonstrating a potential reduction in barriers to PrEP access

Conclusions: The introduction of Conversational AI by Healthvana within AHF clinics has shown promising results in addressing the critical gaps in PrEP education and uptake among underserved populations. By providing a readily accessible and stigma-free platform for PrEP information and navigation, the AI has the potential to significantly enhance PrEP outreach and adherence, aligning with national goals to reduce HIV diagnoses. These findings advocate for the expansion of AI-driven interventions in HIV prevention strategies, emphasizing the need for innovative approaches to overcome health disparities and improve outcomes in HIV prevention and care.

EP095

Perspectives on gamification and digital platforms for enhanced training on HIV prevention strategies: a cross-sectional study among young pharmacists in Enugu, Nigeria

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Background: Traditional interventional methods for HIV prevention strategies have often faced challenges that include effective engagement and attention retention among young people. There is a growing realization that introducing gamification and digital platforms as educational tools in HIV prevention campaigns will produce better outcomes. This study assessed the perspectives of young pharmacists in Enugu, Nigeria, on gamification and digital platforms for enhanced training on HIV prevention strategies.

Methods: This study adopted a cross-sectional design to obtain responses from 676 randomly sampled young Pharmacists in Enugu Metropolis, Nigeria, within the ages of 18–40 years in August 2023 using a validated 29-item questionnaire. Their understanding of HIV prevention strategies and the impact of gamification and digital platforms for enhanced training was assessed. Frequencies and percentages were used to summarize the study's findings. Ethical approval was obtained from the state hospital review board.

Results: A total of 532 young pharmacists responded to the questionnaire (78.7% response rate). The modal age was 18–24 years: 276 (51.9%). The majority of the young pharmacists had a bachelor's degree as their highest qualification, as expressed by 516 (97%). When asked about their understanding of HIV prevention strategies, 288 (54.1%) responded good and 120 (22.6%) responded very good. On the concept of gamification, 176 (33.1%) were familiar, and 448 (84.2%) believe that gamification

can make learning about HIV prevention trainings more engaging. Almost half, 256 (48.1%) of respondents, think that a lack of modern resources is the biggest barrier for young pharmacists to taking HIV prevention training, and 312 (58.6%) of the respondents would prefer to receive HIV prevention training through gamified digital platforms.

Conclusions: The majority of young pharmacists believe gamification can make learning about HIV prevention strategies more engaging. Most young pharmacists would prefer to receive HIV prevention training through gamified digital platforms than traditional, existing methods. Stakeholders should ensure that gamification is implemented in designing future training programs on HIV prevention.

EP096

Navigating misinformation and disinformation: mitigating the challenges in social media advocacy for new biomedical HIV prevention methods

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Background: The landscape of HIV prevention has evolved significantly in recent years with the introduction of new biomedical methods, forming part of combination prevention strategies aimed at ending the HIV epidemic and promoting choice among Adolescent Girls and Young Women (AGYW). The adoption and effective use of these methods by AGYW are not solely determined by their scientific validity but also by community acceptance. Social media has emerged as a powerful tool for advocacy, but it has also facilitated misinformation and disinformation, the spread of false/inaccurate information about HIV prevention strategies. False narratives have contributed to stigma, exploitation of existing cultural bias; hindering the adoption of evidence-based prevention strategies to end the HIV epidemic.

This project aimed to explore the intricate relationship between misinformation and disinformation, social media advocacy, and the adoption of novel biomedical HIV prevention methods by AGYW.

Methods: In-depth interviews were conducted, using semi-structured questionnaires, among 20 purposively sampled journalists from various Zimbabwean media houses who reported on HIV prevention through social media platforms within six months prior the study. Data was transcribed and thematic analysis done exploring challenges and mitigatory strategies.

Results: Misinformation and disinformation about the novel HIV prevention methods such as Cabotegravir injection, are prevalent compromising uptake and effective use whilst driving stigma, unethical reporting and hate speeches. Addressing these challenges necessitates multifaceted approaches, leveraging diverse communication channels to disseminate evidence-based information

about the safety, efficacy, and accessibility of new prevention methods. Collaboration between stakeholders is essential to amplify credible voices and combat misinformation at the grassroots level. Engaging with local communities in culturally sensitive ways can build trust and foster greater acceptance of new HIV prevention technologies by AGYW. This will foster knowledge-based information sharing on social media to counter false narratives enhance, effective media advocacy and collaboration between public health authorities, community organizations, and trusted influencers.

Conclusions: The intersection of misinformation and disinformation, media advocacy, and policy formulation presents a critical challenge in the fight against HIV/AIDS. Addressing these challenges demands capacitating journalists to understand how to use appropriate language in HIV prevention messaging to counter misinformation and disinformation.

EP097

Challenges to meet the 90:90:90 targets in a cohort of female sex workers

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Background: Sexually transmitted infections (STI) are prevalent in high risk groups including female sex workers (FSW). FSW face barriers to access sexual and reproductive health services including HIV testing, prevention and treatment. There is scarce information in Argentina of this population.

Methods: "MAS por Nosotras" a prospective cohort of cisgender (CGW) and transgender (TGW) FSW was established through a collaboration between a non-governmental research organization in Buenos Aires, the Ministry of Health of Buenos Aires City, and a Canadian research team. After providing written consent, participants underwent HIV/STI assessment. We aimed to describe the prevalence of HIV and the frequency of HIV testing. Descriptive analyses are presented.

Results: Between June-December 2023, 116 participants were enrolled: 52.6% TGW and 47.6% CGW. Median age was: TGW 29 (IQR: 24-37), CGW 41 (IQR: 33-50) ($p < 0.001$). Overall median time of sex work was: 12 years (IQR: 6-19).



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51.7% of TGW and 26% of CGW reported more than 20 sexual partners in the previous month, with 55.7% TGW and 47.3% CGW reporting at least one episode of condomless anal or vaginal intercourse.

Baseline HIV prevalence was 20.7% (TGW: 37.7%; CGW: 1.8%), including 3 new diagnoses, all in TGW. Among those with HIV, 61.9% had an undetectable viral load (VL), median CD4 cell count was 731 cells/ul (IQR: 497-892.5). Within those with detectable VL (38.1%), median VL was 594 copies/ul (IQR: 51.9- 22012.3), and median CD4 cell count, 205 cells/ul (IQR: 51.3- 300.5).

Among those without HIV, 25.9% of CGW reported never having tested for HIV, while 7.3% of TGW did have prior testing. Median time since last HIV test was 3 months (IQR: 1-9) for TGW and 20 months for CGW (IQR: 9.5-51) ($p < 0.001$). Only 26.8% TGW and no CGW were on PrEP.

Conclusions: Despite high risk sexual activity, HIV prevalence in CGW was low and a high percentage had never had an HIV test. Although TGW tested more frequently, HIV prevalence was considerably higher with suboptimal viral control.

Our findings highlight the need to enhance access to healthcare to improve HIV prevention and treatment with a gender specific perspective in FSW in order to reach the 90:90:90 targets.

EP098

Bar hotspots: leveraging KP-Peer modality to promote oral PrEP uptake and adherence among BCSW in Rwampara District

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Background: In Uganda, Bar Commercial Sex Workers (BCSWs) are disproportionately diagnosed with HIV, with a prevalence rate of 37.2%, significantly higher than the 6.2% in the general population, contributing to a substantial portion of 18% of new HIV transmission rate annually (Owachi 2021). Despite the efficacy of oral Pre-Exposure Prophylaxis (PrEP) 99% in preventing HIV transmission, uptake among BCSWs remains low, with notable discontinuation rates (Rugira 2023).

The objective of this study was to determine oral PrEP uptake and adherence among BCSW and behavior change using community KP-PEERS in the four hotspot areas in Rwampara district.

Methods: Between January 2023 and December 2023, 200 BCSWs from the ages of 18 to 40, as well as providers—KP-Peer, health workers, clinicians, and counselors—at four bar hotspots in the Rwampara district participated in a cross-sectional study.

To acquire more profound understanding, meaningful interviews were conducted and recorded from every client for about 20-30 minutes. NVivo 11 was used for thematic analysis of interview data, and STATA 13 was used for survey data analysis.

Results: 13.8% of clients identified as current users, 24.1% as "Ever used", and 62.1% as "Never used" PrEP groups. Fear of community stigma and concerns about side effects were primary barriers to PrEP initiation. Conversely, reasons for initiating and continuing PrEP were related to perceived risks associated with sexual activity. The presence of KP-PEER significantly influenced the decision to initiate PrEP for 76.3% of participants. Two out of 58 participants on PrEP developed new HIV infections during the study period, attributed to poor adherence, accounting for 3.4% of PrEP users.

Conclusions: The study highlights the urgent need to address barriers to PrEP uptake and adherence among CSWs in Uganda, compounded by the illegal nature of sex work, poverty, and distrust in health workers. Community-led interventions, such as the KP-Peer Linkage approach, have demonstrated promise in improving PrEP uptake and adherence. However, ongoing support and education are crucial to ensure consistent medication, adherence and maximize the effectiveness of PrEP in HIV prevention efforts among key populations.

EP099

Pregnant women in Rio de Janeiro, Brazil: preventing the transmission of associated antiretroviral resistance to HIV-1

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Background: Pregnant women in Brazil are more severely impacted by the HIV/AIDS epidemic, with a significant percentage of HIV-1 diagnoses occurring during pregnancy and neonatal monitoring. Understanding the resistance levels in pregnant women is essential to preventing vertical transmission and tracking primary resistance in Brazil, given the steady rise in resistance transmitted in the treatment-naïve population. In Rio de Janeiro, Brazil, we conducted an epidemiological study to assess the distribution of the HIV-1 subtype, the incidence and patterns of HIV-1 resistance mutations in newly diagnosed pregnant women, who had not yet received antiretroviral treatment.

Methods: Three public prenatal care reference centers in the State of Rio de Janeiro provided blood samples from expectant mothers. An internal genotyping method that has been verified for HIV-1 was used to establish the genotypes of the protease, reverse transcriptase, and integrase genes. Using the Stanford HIV Sequence Database, were characterized the resistance mutations, HIV-1 subtypes were identified and phylogenetic analysis was used to corroborate them. The most recent World Health Organization Mutation List was used to evaluate transmitted resistance mutations.

Results: Between 2018-22, 58 samples from pregnant women were analyzed. Subtype B was the most prevalent (70%), followed by subtype F (22.5%), recombinant forms of BF (5%) and CRF_02_AG (2.5%). No transmitted resistance mutations to integrase inhibitors were detected. Protease inhibitor (PI) mutations were found in 7.5% of samples such as D30N, M46I and V82L.

Mutations associated with resistance to reverse transcriptase inhibitors (RTIs) were present in 10% of the samples, 2.5% to nucleoside reverse transcriptase inhibitors (NRTIs) and 7.5% to non-nucleoside reverse transcriptase inhibitors (NRTIs). The NNRTI mutations were K103N, Y188H and L100I detected in three infected woman each.

Conclusions: The most common subtype was subtype B, while women were found to have a larger proportion of subtype F1. The CRF02_AG was identified in a pregnant woman for the first time, indicating the African virus's possible transmission to Brazil.

Notable frequencies of transmitted mutations, primarily from NNRTIs and IPs, were noted. Pregnant women who are genotyped resistant to viruses at the start of prophylactic treatment can significantly lower the amount of vertical transmission in Brazil.

EP100

Using Nominal Group Technique to inform decentralization of HIV care toward treatment as prevention efforts in Peru

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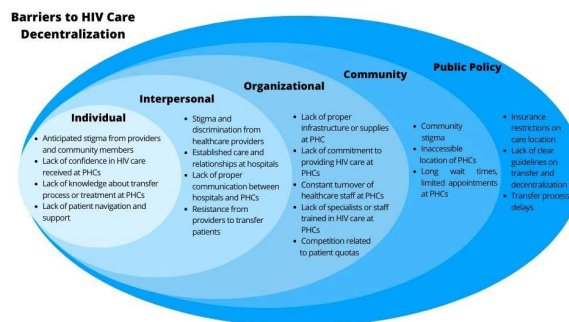
Background: The decentralization of HIV services is an evidence-based practice recommended by the World Health Organization to expand healthcare access and availability by shifting the majority of care from specialty to primary health centers (PHCs), thus helping to improve the cascade of care and achieve treatment as prevention.

Our study objective was to assess the perspectives of providers and people living with HIV (PWH) regarding HIV care decentralization and to identify barriers and facilitators to inform ongoing decentralization efforts.

Methods: Between January and March 2024, we used Nominal Group Technique (NGT), a mixed-methods research strategy, to identify barriers and potential solutions to the decentralization of HIV services among two groups of patients and four groups of providers in Lima. NGTs consist of an open question followed by individual round-robin feedback from each participant with the ul-

timate goal of yielding information saturation and voting on the ideas that are considered of highest importance.

Results: In both NGTs with patients, the barrier of highest importance was community stigma and fear of exposure as having HIV related to a lack of patient confidentiality at PHCs. Providers were more split, with two NGTs considering a lack of proper infrastructure, laboratory equipment, and permanent human resources at PHCs as the highest concern. The other two provider NGTs considered stigma and discrimination from healthcare staff at PHCs and a lack of patient confidentiality at PHCs as the most important barriers. Overall, all groups highlighted a general lack of confidence in the care received at the primary level.



Conclusions: While the Peruvian Ministry of Health has prioritized decentralization, achieving this goal remains a challenging process. Issues of anticipated stigma and discrimination are highlighted as key barriers to decentralization by both providers and PWH. Addressing stigma and discrimination at the community level will help to address engagement in the cascade of care.

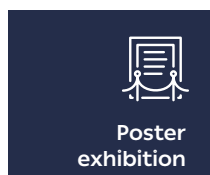
EP101

Engaging key populations in PrEP program in Kazakhstan: increasing uptake and retention

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Background: Kazakhstan started pre-exposure prophylaxis (PrEP) program in August 2021. As the country's HIV epidemic is concentrated among key populations, the program targets gay, bisexual and other men who have sex with men (GBMSM), transgender persons (TG), people who use drugs (PWUD) and sex workers (SW). However, as Kazakhstan has approved oral PrEP for distribution only at state-run AIDS Centers, engagement of highly stigmatized populations, such as GBMSM, TG, PWUD, and SW presented a significant challenge. In 2021-2023, our Amanbol PrEP project, implemented demand creation (DC) campaign and training activities with 6 regional AIDS Centers and 6 NGOs in Kazakhstan to increase uptake and retention among key populations.



Methods: Our DC strategies included: (1) online postings in GBMSM-focused social media (i.e., VKontakte, Instagram, Facebook, Tiktok) and online dating/hook-up apps (i.e., Hornet, Grindr) with the direct link to the project's Amanbol.kz (for GBMSM) and HIV.kz (for other key populations) websites with PrEP-related information; 2) online counseling (chatbot, phone calls and text messages with peer educators). To increase retention in PrEP program, we conducted trainings and monitoring visits to the regional AIDS Centers and NGO staff on adjusting PrEP clinical protocols, eliminating facility-level structural barriers for patients, ethics of working with key populations, and building effective partnerships with NGOs.

Results: From December 2021 till 2023, in 6 Amanbol PrEP regions compared to all country, engagement of GBMSM has increased from 63/174 (32%) to 984/1746 (56%); TG - from 0/0 (0%) to 11/24 (46%); SW - from 1/3 (33%) to 502/1192(42%), and PWUD - from 0/1(0%) to 948/2023 (47%). The retention rates (defined as percentage of clients remaining in PrEP program by the end of the year among total enrolled) in project regions as of December 2023 compared to other regions were: for GBMSM - 66% vs. 63%; TG - 82% vs 76%; SW - 86% vs 63%, and PWUD - 87% vs 70%.

Conclusions: Implementation strategies, including online DC using various social marketing tools showed promise in increasing uptake of PrEP among key populations in Kazakhstan. Service provider trainings and monitoring visits can be effective in building a client-centered collaborative models resulting in improving PrEP retention rates for key populations.

EP102

Latent classes of factors affecting uptake of HIV and SRH services among Female Sex Workers in rural KwaZulu-Natal, South Africa

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Background: Female sex workers (FSW) are at risk of acquiring HIV and sexually transmitted infections (STIs) in South Africa. FSW programmes are typically concentrated in urban settings. We investigated factors associated with the uptake of sexual and reproductive health (SRH) and HIV services among FSWs in rural KwaZulu-Natal (KZN), South Africa.

Methods: From November 2021 to June 2022, we surveyed 201 FSWs using respondent-driven sampling (RDS). We collected data on socio-demographics, psychosocial aspects (e.g., stigma assessed with a modified HASI-P tool), and sexual behaviours and collected dry blood spots for HIV testing, and self-taken vaginal swabs to test for chlamydia, gonorrhoea, and trichomonas. Uptake was defined as self-reported linkage to HIV sero-neutral-friendly SRH/HIV services provided during the study.

We investigated the relationship between various factors (food insecurity, violence, alcohol use, etc.) and SRH services uptake using a latent class analysis approach with two latent classes.

Results: FSWs had a median age of 31 and 66% reported food insecurity. Most (90%) accessed SRH/HIV services and experienced high rates of violence (18%), alcohol use (85%), and condomless sex in the past 12 months (86%). Internalised (22%) and externalised (16%) stigma were common, with HIV and STI prevalence at 65% and 34%, respectively. In LCA, 82.2% (n = 165) and 17.8% (n = 36) of the FSWs were predicted to be in Class 1 and Class 2, respectively and these classes exhibited different behavioural patterns regarding service uptake.

For instance, Class 1 had higher probability of alcohol use (85.5%), condomless sex (83.8%), and living with HIV (64.3%) but lower stigma (externalised: 1.9%, internalised: 5.6%), violence (12.9%), and STI prevalence (31.6%).

Class 2 had lower HIV prevalence (49.5%) but higher stigma (internal: 100%, external: 80.6%), violence (52.2%), and STI rates (46.8%), along with more condomless sex (93.5%).

Conclusions: The uptake of HIV sero-neutral-friendly services was high when offered to FSWs in this rural setting. However, there was a subgroup of FSWs who experienced a higher level of stigma, violence, sexual risk, and STIs resulting in lower uptake of SRH and HIV services, highlighting the need for differentiated and tailored services which include violence prevention for FSWs in rural settings.

EP103

Strengthening HIV and cervical cancer prevention through community engagement in Tanzania: Community-Led Monitoring (CLM) as mechanism to understand gender inequality and address barriers that women face in accessing comprehensive healthcare

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Background: Worldwide, women living with HIV are six times more likely to develop cervical cancer than women who are not living with HIV. In Tanzania, HIV and cervical cancer disproportionately affect women due to the lack of access to screening and treatment. We outline the findings from a CLM initiative conducted in Bahi and Kongwa

districts, focused on cervical cancer prevention, screening and treatment services provided within the Global Fund programmes for WLHIV. This women-led process aimed to highlight how community engagement participates in shaping effective prevention strategies.

Methods: We implemented our CLM and feedback Accountability Toolkit in Tanzania in 7 stages:

1. Reflection and Engagement Assessment;
2. Inception and Planning;
3. Workshop Training;
4. CLM Implementation;
5. Data Analysis;
6. Findings into advocacy;
7. Outcome sharing and continuous monitoring.

Data collection included: KIIs (N=188) with 59% of WLHIV, FGDs (N=5) comprising 12 members each, and IDIs (N=4) with community advocates and healthcare providers.

Data analysis on the availability, accessibility, affordability, acceptability, and quality of cervical cancer services provided within Global Fund programmes, was conducted; exploring 4 approaches to measuring results: Formal-quantitative, Participatory-quantitative, Formal-qualitative, and Participatory-qualitative.

Results: 16% of women were found with different stages of cervical cancer, 80% were women living with HIV. Of the 188, only 18.1% confirmed using contraceptives and seeking family planning services at healthcare facilities, underlying high risk of transmission of HIV and other STIs. 12.2% of women who tested VIA positive in screenings experienced Gender-Based Violence, resulting in immediate divorce, emotional distress, and physical abuse.

Only 36.3% of these cases received support. Among the major barriers in accessing healthcare, distance from healthcare facilities was predominant. Shortage of acetic acid and lack of skilled staff to professionally operate equipment, were among the most prevalent impediments to quality services.

Conclusions: CLM underscores the role of community engagement in comprehensive HIV and cervical cancer services. While community-led work has effectively raised awareness and addressed stigma, the persistent challenge of GBV, discrimination, and lack of skilled professionals and supplies; highlight the urgent need for collaborative actions between the government, CSOs, healthcare providers, and communities to ensure comprehensive and effective HIV responses.

EP104

Modeling the probability of vaginal HIV infection: integrating viral mass transport theory, viral load, viral infection dynamics, and menstrual cycle phase

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Background: Risk of HIV infection during vaginal exposure depends on female and male-derived interacting factors, including viral load, kinetics of viral mass transport, dynamics of infection at target sites, and physiological factors modulated by the menstrual cycle. Here we present a new deterministic mathematical model incorporating these four key factors to predict probability of HIV infection (POI). We focus on roles of viral load and cycle phase as a first pass implementation of the model.

Methods: Deterministic mass transport and viral dynamics theories were integrated in a system of equations characterizing spatiotemporal dynamics of infection within the female tract and bloodstream. Log-normal parameter distributions characterized population-wide physiological and infection-dynamics factors - viral load, epithelial thickness, vaginal fluid volume, and initial CD4+ T cell density in vaginal submucosa - distinguishing luteal, follicular and midcycle phases. 100,000 computational simulations sampled randomly from parameter distributions characterizing population variability. POI was based on computed viral load in blood above the limit of detection of modern diagnostics, 18 days post-exposure.

Results: POI was highest during the luteal phase, due primarily to higher densities of infectible CD4+ T cells in the vaginal submucosa (0.6% POI in luteal phase; ~3x > mid-cycle or follicular phases, $P < 0.001$). There was a positive correlation between viral load and POI across phases, but not a significant interaction between load and phase. Infected cell-cell interactions were the dominant mode of infection propagation, (~70% of all infections) regardless of phase.

Conclusions: Our model is a computational engine for further exploring acute HIV infection at different sites of propagation (e.g. vaginal submucosa, bloodstream) in relation to multiple causative factors. We enhanced prior modeling work by coupling viral transport to viral infection dynamics, in the context of varying inseminated viral load and host physiology. Our model correctly predicts positive correlation between POI and viral load, and heightened POI during the luteal phase.

Using this model - that predicts clinically-relevant relationships - we can next extend to antiretroviral (ARV) kinetics, to elucidate relationships between POI and ARV characteristics (e.g. site of administration, delivery vehicle characteristics, mechanism of action, API potency, etc.), in relation to host factors (NIH AI150358).



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EP105

“Turning the tide”! Using enhanced peer model for HIV testing and linkage to care among key and vulnerable populations in Tanzania

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Background: The gains made in Tanzania against HIV are a major public health achievement. Despite the gains made, there are still gaps including inequitable access low coverage, and sub-optimal HIV testing services among key and vulnerable populations (KVP). Vulnerability to and risk of HIV acquisition vary between populations and places, as does people’s access to HIV prevention and treatment services. Implementing diverse and targeted interventions for KVPs remains a good strategy to ensure the tide is being changed. Using a peer model is key to ensuring no one is left behind and ownership will promote sustainability.

Methods: Amref, through the Global Fund Support, is currently implemented in 9 regions and 32 councils with a focus on key and vulnerable populations. We have recruited 250 peers and 350 counselors to join our program. They conduct three outreach services every week at identified hotspots for HIV testing, refilling ART, and PrEP drugs using healthcare providers and peers. We are utilizing the peer model, which has proved to be an incredibly successful strategy for locating individuals at the highest risk of contracting HIV and bringing them in for testing, counseling, and referral services.

Results: From January 2023 to December 2023, we tested for HIV with a total of FSW 31,736, MSM 9830, and PWIDs 3599. Of this positivity rate were FSWs- 2,140 (7%), MSM 687 (7%), and PWIDs 364 (10.4%). The enrollment to care was 94% to FSW and 100% initiated on ART, while for both MSM and PWIDs enrolment to care was 97% and initiation on ART was 100%. Using peer ambassadors, we distributed 1,955,332 condoms as part of prevention packages. Of these, 75% were distributed to FSW, 19% to MSM, and 6% to PWIDs. Total GBV cases reported 3,589 and total GBV cases referred for services 1,502(42%) through peer referral platforms.

Conclusions: Community-based outreach services that utilize peers have proven to be an effective model for reaching key populations (KPs) in Tanzania. This approach should be expanded to cover all identified hotspots, utilizing both peers and healthcare workers located within these hotspots, to improve KVPs’ engagement and connectivity to health and other social services.

EP106

Experimental medicine HIV vaccine trials in Africa: advocates speak up

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Background: Community and stakeholder engagement is integral to ethical clinical research. By engaging with advocates and community representatives and on research concepts and planned studies, researchers can gain important insights on acceptable trial conduct, participant recruitment, and product design, which can lead to smoother trial implementation.

Following disappointing results from multiple HIV vaccine efficacy trials during 2021–2023, the field has undergone a profound shift: from efficacy trials recruiting thousands of participants at elevated risk of HIV acquisition, to Experimental Medicine (ExMed or Discovery Medicine) trials—short clinical studies involving just handfuls of participants at very low risk of HIV acquisition. ExMed trials seek to advance scientific knowledge, rather than progress experimental products towards licensure.

The Coalition to Accelerate & Support Prevention Research (CASPR) has created spaces for researchers and stakeholders to learn about and engage on the ExMed trials in the African context.

Methods: We built research literacy and gathered advocates’ and communities’ views, questions and recommendations on ExMed trials in Africa, through three in-person meetings (June, October, and December 2023); and three virtual sessions (May 2023, March 2024, April 2024). Of the 70 advocates reached, most were cis-gender women (80%) and men from Kenya, South Africa, Uganda, Zambia, and Zimbabwe, around half among them women living with HIV.

Results: Advocates recognized that Experimental Medicine trials were critical to HIV vaccine R&D. Their questions, concerns and recommendations include the following:

- Engage communities in ExMed trials, and integrate their voice in the research agenda.
- Break down the science and jargon. The phrase “Experimental Medicine’ was thought to be problematic, and ‘Discovery Medicine’ more acceptable.
- Mitigate potential risks to participants associated with the short timeframes of ExMed trials, novel investigational products and approaches, and invasive and intensive sampling.
- Clarify the risk-benefit analysis for ExMed research to participants and communities.
- Conduct ExMed trials in multiple sites globally.
- Reimburse ExMed trial participants in line with the demands of studies.
- Adapt and apply Good Participatory Practice (GPP) guidelines to ExMed trials.

Conclusions: The inputs of advocates and community stakeholders can help researchers design ExMed trials that have broader acceptance in Africa, and thereby contribute to HIV vaccine R&D.

EP107

Adolescents wellness visits to increase HIV testing: preliminary results from of a cluster RCT in Tanzania

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Background: Adolescents in low-resource settings have less timely access to HIV treatment services than adults and need novel HIV testing strategies. The VITAA trial in Tanzania is evaluating the impact of new school-facilitated and clinic-based Adolescent Wellness Visits (AWV) on future health service use among adolescents, including HIV testing and counseling (HTC). The primary outcome for this ongoing cluster RCT is HTC uptake 2.5 years post-baseline.

This presentation describes HTC uptake at baseline during the AWV and during follow-up, and identifies factors associated with HTC uptake during the AWVs.

Methods: Twenty government primary schools were randomized to intervention or control. Entire Standard 7 classrooms (mean age 13.4, range 11-17) at 10 intervention schools were eligible to participate in AWVs at nearby health facilities in Kinondoni and Bagamoyo districts, Tanzania. Intervention arm participants were escorted in groups by teachers to clinics where they received screenings for nutrition, vision, dental, and mental health concerns plus optional reproductive health and HTC services provided by trained clinicians. Survey data were collected at baseline, 12-months, and 18-months (ongoing). Descriptive and bivariate analyses were performed.

Results: The VITAA cohort includes 1095 participants (52% girls, 48% boys); 5.7% had ever tested for HIV pre-baseline (6 living with HIV, 1 newly identified during AWV). 509 of 1,095 adolescents are enrolled in the intervention arm and completed AWVs. Of those, 172 (34%; range 4%-88% by school) requested and received an HIV test.

Correlates of HIV testing uptake during the AWVs included being more likely to be aware that their peers were also testing for HIV and having lower perceived HIV risk. 95% of study participants were retained through 12 months. HTC uptake, exclusive of the AWV-associated test, was 7.6% (6.6% among boys, 8.6% among girls) at 12-month follow-up. 18-month survey data will be presented in October 2024.

Conclusions: This study demonstrates high uptake of HIV testing when paired with routine health screenings and normalized by school cohort involvement. However, HTC uptake appears to vary significantly by school, possibly driven, in part, by peer influence. Research to provide evidence regarding the impact of AWVs on future HTC uptake is ongoing.

EP108

Sero-conversion rates and time intervals post-PrEP exposure among newly diagnosed HIV individuals in Malawi: insights from a National descriptive study

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Background: HIV Testing Services (HTS) are an important gateway for prevention interventions, including the provision of PrEP, which aims to reduce new HIV infections. However, this reduction, in the context of recent PrEP exposure, represents a clinical challenge because the effectiveness of PrEP depends on proper adherence. Although the program has an established PrEP intervention, no study on the rates of new HIV diagnoses after recent PrEP exposure and the time interval has been done.

Thanks to new testing guidelines and the availability of electronic individual-level data from scannable paper registers via ScanForm technology, the sero-conversion analysis is possible.

Methods: This national descriptive study analyzed PrEP usage among adults newly diagnosed HIV individuals in Malawi from November 2022 to March 2024. With ScanForm, data is collected by taking a smartphone photo of each completed HTS register page and AI digitizes all handwritten information, in seconds. Data on oral PrEP use and time since last use, coupled with demographics and HIV risk categories was analyzed with STATA version 17.

Results: Out of 2.2 million HIV tests conducted, 2.14% (61,020) reported prior PrEP usage. Of these clients, 0.58% (393 / 61,020) seroconverted and were diagnosed with HIV. Females accounted for 83% of these cases, including 5% pregnant and 3% breastfeeding individuals. Among males, 71% were uncircumcised. The median age at diagnosis was 27 years (IQR: 23-32 years).

Alarmingly, 63% (248 out of 393) identified ongoing HIV acquisition risk with 23% at high risk, highlighting the continued vulnerability among PrEP users. The median interval from the last PrEP intake to HIV diagnosis was 122 days



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(IQR: 30–365 days), with 11% (46 out of 393) taking PrEP less than a week before testing positive. The median time interval between the recent HIV test and the current test was 152 days (IQR :61-365).

Conclusions: The findings highlight gaps in Malawi's PrEP program adherence and recommends enhancing combined prevention efforts to reduce new infections among individuals already participating. It suggests the need for better monitoring of drug resistance as individuals move from PrEP to ART and updating care guidelines accordingly. Further research into the reasons for HIV diagnoses is essential.

EP109

Renal function monitoring difficulties in transgender women PrEP-users

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Background: There is a sparsity of real-world clinical data surrounding the monitoring of kidney function in gender diverse groups (GDGs) using Pre-Exposure Prophylaxis (PrEP) who are on gender affirming hormones (GAH). Where risk factors for renal disease are identified, the British HIV Association (BHIVA) advocates monitoring creatinine, eGFR, and urinalysis at baseline and subsequently every 6 months.

Given that hormone therapies can affect muscle mass, creatinine and eGFR, this proves challenging in monitoring GDGs.

Methods: This is a retrospective case note review from 4th January 2021 to 29th December 2022. The inclusion criteria were PrEP-users who identified as female. The relationship between PrEP usage, follow-up, and the effect on eGFR was explored in these population groups. A total of 716 women were included, of which 268 (37.4%) were cis-gender women, 438 were transgender women (61.2%) and 10 (1.4%) were non-binary.

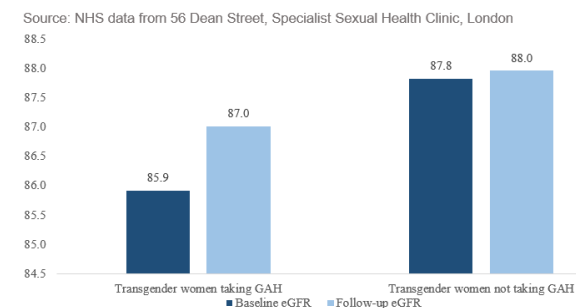


Figure. Comparison of eGFR trend over time.

Results: The baseline mean eGFR for transgender women prior to starting PrEP was 85.9ml/min/1.73m² for those on GAH and 87.8ml/min/1.73m² in those not taking GAH. The comparison mean eGFR at a follow up time interval of up to 1 year after starting PrEP in the same population

groups was 87.0ml/min/1.73m² and 88.0ml/min/1.73m² respectively. Overall, 123 transgender women were lost to follow up for various reasons.

Conclusions: The review found small increases in the mean eGFR over time. Patients lost to follow up can lead to attrition bias in the population sample. The retrospective nature could have introduced information bias from the lack of a robust systematic approach to recording the data on the electronic health system.

Additional research could investigate the relationship between the duration of GAH usage and eGFR change over time. Such insights could enhance the interpretation of eGFR values. Addressing this evidence gap is important to inform clinical guidance for this under-served population.

EP110

Bringing prevention to where the population is: extramural activities as a strategy to reduce access barriers to care and prevention of HIV, STIs and Aids in São Paulo, Brazil

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Background: In São Paulo, the HIV/Aids epidemic affects the population differently, with some parts having increased rates of acquisition of the virus, due to individual, social and programmatic barriers. Considering this reality, the city's STI/Aids Coordination (CIST/Aids) developed the *Se Liga!* and *PrEP na Rua* projects, to drive encouragement and technical-structural support for the extramural activities carried out by the Municipal Network Specialized in STI/Aids (RME). These projects aim to reach the most vulnerable groups, reduce access barriers to Rapid Tests (RT) for HIV and other STIs, as well as expand access to prevention strategies such as pre- (PrEP) and post-exposure (PEP) HIV prophylaxes.

Methods: Extramural activities offer testing and prevention, beyond the conventional space of healthcare units. They occur on different days/times, adapting to the target population of the location. Most of these places are recommended by reference people in the RME unit to reach the groups most vulnerable to STIs and Aids. The structures of the CIST/Aids locations or mobile units (mini-buses or trailers) are used, suitable for providing comprehensive care to the individual. As part of the *Se Liga!* project, HIV, syphilis, and hepatitis B and C testing is offered, along with registration, collection, reception and counseling. In the *PrEP na Rua* project, the services available are the same, in addition to point-of-care creatinine testing and distribution of PEP and PrEP.

Results: From August/2022 to March/2024, 199 *Se Liga!* and 613 *PrEP na Rua* extramural activities were registered, in places of leisure, transit, sex work and entertainment, social assistance institutions, among others. HIV RTs were

performed in all of them, accounting for 19,860 appointments, with 156 positive results. For syphilis, 16,259 RTs were performed, with 1,003 positive results, carried out in 696 activities. There was adherence to PrEP in 2,404 of the visits, including initiation and continuation of treatment. 239 PEP were distributed.

Conclusions: The extramural activities covered in this study are a key strategy for reaching the most vulnerable populations, offering preventive care and methods, controlling the HIV epidemic and eliminating horizontal transmissions of the virus.

EP111

Sex workers' leadership in addressing prep continuation barriers in Kilifi county – a case study of ICRH-Kenya's hotspot community group

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Background: Despite the proven efficacy of pre-exposure prophylaxis (PrEP) in reducing HIV transmission among high-risk individuals, low continuation rates remain a significant challenge. While PrEP holds immense potential in ending the HIV epidemic, its effectiveness hinges on successful integration with community-centered approaches. In Kilifi County, Kenya, PrEP continuation at the ICRHK Mtwapa Drop-In Centre (DICE) between October 2022 and June 2023 was alarmingly low, with only 17% of clients continuing at month 3 and a mere 4% at month 6.

This highlighted the need for innovative, community-driven interventions to overcome these barriers and ensure equitable access to PrEP for all sex workers.

Methods: Recognizing low PrEP continuation among sex workers at Mtwapa DICE, FSWs took charge by forming voluntary, hotspot-based community PrEP groups. Capped at 20 members, these groups met on shared refill dates, offering peer support, health education (focused on PrEP), comprehensive clinical services (STI treatment, TB screening, etc.), and tailored counseling. Absent members were encouraged to rejoin, and all received consistent advice and the next meeting venue, fostering peer-driven learning and sustained PrEP use. This proactive approach aimed to scale up and retain FSWs on PrEP, empowering them to lead the fight against HIV.

Results: Between July and December 2023, six hotspot-based FSW community PrEP groups blossomed, empowering 131 sex workers to overcome barriers and achieve remarkable PrEP continuation rates. With 89% and 76% continuation at months one and three, respectively, these groups showcase the power of peer support. Sex workers have become champions, raising awareness, reminding each other about refills, and demystifying myths surrounding PrEP and HIV. This community-driven initiative proves that empowering sex workers can lead to a sustainable fight against HIV.

Conclusions: Community play central role in HIV prevention and response is critical in ending HIV pandemic. They have solutions to address barriers in HIV prevention through the invaluable innovation, passion and insight which have proven pivotal in getting the world to the point where there is a clear path to end AIDS as a public health threat.

EP112

Evaluating post-exposure prophylaxis (PEP) uptake in newborns: a mixed-methods study on strengthening traditional birth attendants' engagement for perinatal HIV prevention in Bayelsa State, Nigeria

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Background: In Bayelsa State, Nigeria, a gap exists between where women receive Antiretroviral Therapy (ART) and Antenatal Care (ANC) services and where they give birth, often opting for Traditional Birth Attendants (TBAs). The "MAMA IJAW knows how" mentorship package engages TBAs in perinatal HIV prevention through one-week training and ongoing mentorship.

This study evaluates the effectiveness of this approach after one year of implementation in 2022. Previous data shows a 78% PEP uptake for newborns exposed to maternal HIV in Bayelsa State. This mixed-method study assesses the impact of enhancing TBAs' involvement on PEP uptake among newborns.

Methods: This mixed-methods study investigated Post-Exposure Prophylaxis (PEP) uptake and associated factors among newborns of women living with HIV who delivered at Traditional Birth Attendants (TBAs) in Bayelsa State, Nigeria. Spanning January 1 to December 31, 2022, all accredited healthcare settings, including ART-supported sites and TBAs in Bayelsa State, were included in the study. Data collection involved comprehensive extraction from the State-based Health Information Management System (HIMS) and facility records.

Additionally, a structured questionnaire survey captured both quantitative and qualitative data on PEP uptake rates, awareness, administration practices, and barriers among TBA-delivered women living with HIV. Quantitative data were analyzed using SPSS, while qualitative data underwent thematic analysis in ATLAS.ti. Ethical standards were strictly followed throughout the study.

Results: The study revealed a remarkable PEP uptake rate of 93% across Bayelsa State, Nigeria, with TBAs showing a 95% utilization rate. TBAs in the mentorship program contributed 90% of PEP utilization among TBA-delivered newborns.

Statistical analysis found a significant correlation ($p < 0.05$) between educational sessions at TBAs and maternal PEP uptake willingness. However, barriers to PEP uptake



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were identified, notably the availability of PEP within the 72-hour post-delivery window. This emphasizes the need for timely PEP access at TBAs for effective perinatal HIV prevention.

Conclusions: The findings underscore the critical role of TBAs in achieving high PEP uptake rates, emphasizing the importance of educational interventions. However, challenges remain in ensuring timely access to PEP.

Addressing these barriers is essential for effective prevention strategies. Research should explore sustainable solutions to enhance access and reduce HIV transmission rates further.

EP113

Depression and suicide in the Post COVID 19 era among adolescent girls living with HIV in refugee settlements in northern Uganda

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Background: Depression and HIV are among the leading causes of disability, morbidity, and mortality among adolescent girls in Africa, with varying prevalence across different populations. After the COVID-19 pandemic, there was an increase in the incidence and prevalence of both depression and HIV. However, there is paucity of research among priority groups in unique settings like adolescent girls living with HIV in refugee settlements, where access to HIV services and mental health services including drugs, psychosocial support and psychiatric consultation is scarce.

Methods: We conducted a cross sectional descriptive study on conveniently sampled adolescent girls living with HIV from four selected refugee settlements in Obongi and Yumbe districts, Uganda, between March to May 2023. Multi-stage sampling, and cluster sampling techniques were used. Prevalence of depression was assessed using the patient health questionnaire - 9 (PHQ-9) modified for adolescents, followed by a P4 assessment tool for suicidal risks. We performed modified Poisson regression analysis for predictors of depression.

Results: We included 385 participants with a mean age of 17 (IQR: 15-18) years. The prevalence of depression was 15.1% (n=58, 95% CI: 11.6 – 19.0). Overall, 8.6% (n=33) participants had recent suicidal thoughts (within 1 month) and 2.3% (n=9) attempted suicide. Pregnancy (aOR: 2.4, 95% CI: 1.00 – 5.94, P = 0.049), sexual abuse (aOR: 2.1, 95% CI: 1.19 – 3.76, P = 0.011), and physical abuse (aOR: 1.7, 95% CI: 1.01 – 2.74, P = 0.044) were independently associated with depression.

Conclusions: We found out that 1 in 6 adolescents living with HIV in refugee settlements of northern Uganda suffered from depression in the post COVID 19 period, particularly among those who experienced adolescent pregnancy and abuses. Incorporating mental health care in

the existing HIV care settings and social structures within the refugee settlements, exploring legal options against perpetrators of sexual abuse and encouraging education will go a long way in dealing with challenges related to depression, reducing morbidity and suicide risks in this vulnerable population.

EP114

Determinants, friendship and influential networks of Black and Latina transgender women's engagement with PrEP bundled with gender-affirming hormone therapy

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Background: Structural racism, transmisogyny, and xenophobia compound Black and Latina transgender women's (BLTW) vulnerability to HIV. BLTW have the highest HIV rates among transgender women (Black: 62%, Latina: 35%, white: 17%).

The purpose of this study is to identify the barriers and facilitators to engagement in PrEP bundled with gender-affirming hormone therapy (PrEP-GAT) services and the use of friendship and influential social networks (SN) of BLTW to promote PrEP-GAT.

Methods: BLTW were recruited through the University of Miami's RAPID Clinic GenWell Program, which provides PrEP-GAT. Study components are qualitative and SN. Qualitative component: Content analysis was conducted on 20 in-depth interviews with BLTW focused on barriers and facilitators to PrEP-GAT services using Consolidated Framework for Implementation Research (CFIR) constructs. SN component: 27 SN-based interviews identified a) influential characteristics, and; b) friendship dynamics that could promote PrEP-GAT.

Analysis included multilevel logistic regression using R and network visualizations using UCINET.

Results: Barriers and facilitators to PrEP-GAT for BLTW mirror those in the literature. SN component.

A) Influential SN: Most alters were friends (70%) or family (15%). Egos perceived high emotional attachment and engaged in frequent contact (79% indicated monthly to daily contact) with their influential alters. Forty-four percent of egos reported past conversations about PrEP-GAT with their influential alters, yet 59% of them disclosed their PrEP-GAT status with them. Multilevel models: No ego-alter level characteristics that were related to ego disclosure of PrEP-GAT status.

B) Friendship SN: most participants used GAT (75%), and more than half reported lifetime PrEP use (56%). Bivariate analysis: having a Latinx friend, a friend who shared GAT

status, and higher emotional closeness were associated with future conversations about PrEP-GAT ($p < 0.05$). Multilevel model: emotional closeness was associated with future conversations about PrEP-GAT ($p = 0.02$).

Conclusions: Mental health, legal, employment and housing services are needed to meet BLTW access to PrEP. GAT is a life-affirming service that can increase PrEP uptake in BLTW. SN approaches can identify key individuals in BLTW friendship and influential networks to promote and disseminate information about PrEP-GAT.

Future research will determine whether bundled PrEP-GAT, social network support, and telehealth effectively increase BLTW's engagement in PrEP-GAT.

EP115

Inflammatory profiles of vaginal *Gardnerella vaginalis* isolates from South African women with and without bacterial vaginosis

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Background: Bacterial vaginosis (BV) is highly prevalent amongst women residing in sub-Saharan Africa, where HIV is also widespread. BV, characterised by the overgrowth of non-optimal vaginal anaerobic bacteria, most commonly *Gardnerella vaginalis*, is associated with genital inflammation which facilitates HIV acquisition. However, *G. vaginalis* is also found in healthy women with low levels of inflammation, suggesting strain-level differences that may influence inflammatory responses. Hence, this study aims to characterize vaginal *G. vaginalis* isolates from South African women to elucidate their role in inflammation.

Methods: Cervicovaginal fluid samples from 10 BV-negative and 10 BV-positive South African women (aged 16 – 25) were cultured on Columbia Blood agar to isolate single strains of *G. vaginalis*, followed by species-level identification via 16S rRNA Sanger sequencing. Isolates were then co-cultured with vaginal epithelial VK2/E6E7 cells, and the concentrations of inflammatory cytokines previously associated with HIV risk were measured via Luminex assay. The protein profiles of the isolates were also analysed via liquid chromatography tandem mass spectrometry.

Results: Thirty-nine isolates were acquired from all women, including $n = 15$ *G. vaginalis* and other bacterial taxa. Three and four *G. vaginalis* isolates from different BV-negative and BV-positive women, respectively, were selected for inflammatory profile assessment.

Significant increases in interleukin (IL)-1 β , IL-6, IL-8, and chemokine ligand (CCL)2, CCL4 and CCL5 were induced by isolates from BV-positive women compared to BV-negative women ($p < 0.05$).

Proteomics analyses detected 2,139 proteins and although 125 proteins were significantly differentially abundant between isolates from BV-negative versus BV-positive women, only two remained significant after adjusting for multiple comparisons. This included chaperone protein ClpB and peptidase.

Conclusions: *G. vaginalis* isolates from BV-positive women elicited higher levels of inflammatory cytokines compared to those from BV-negative women. This suggests that strain-level differences may play an important role in genital inflammation and resultant HIV acquisition risk. Few proteins differed significantly between isolates from BV-negative versus BV-positive women, largely due to the small sample size and high protein variance between individual strains.

Hence, the genomic profiles of additional *G. vaginalis* isolates are currently investigated to determine genomic differences that may influence genital inflammation between isolates.

EP116

Community driven integrated service outreach leads to increased HIV testing among unreached transgender, PWID and Bridge populations: results from Global Fund-supported One Stop Center project in India

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Background: Though overall adult HIV prevalence remains low in India, as per data from HSS 2021, HIV prevalence was estimated to be at 3.78% among TGs, 9.03% among PIDUs and 1% among Long distance truckers (LDT). Complementing Govt. of India's effort to end AIDS by 2030, Plan India is implementing One Stop Center (OSC) project in 25 Indian states through community led Innovative strategy of One Stop Centre project (OSC) funded by The Global Fund.



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Methods: The project has three strategic objectives:

1. To reach out to and identify new & uncovered Key & Bridge Population through 74 OSC,
 2. Creating enabling environment to the community,
 3. Empowerment of the communities by generating awareness and engaging in various skill development.
- Analysis carried out on Ninety thousand registered KP during October 22 to December 23.

Results: Community based testing led to 75 thousand previously unreached KP received HIV testing, with 1,500 clients identified to be HIV positive. While HIV positivity remained very high 3.75% and 2.40% for PWID and TG respectively, the same remained 0.3% for the BP population. 91% of the identified clients were linked to ART and followed up for adherence.

Most (98%) of the registered client received TB 4s screening. Around 40% of total registered client received STI screening services, Viral hepatitis screening was accessed by 8% of registered client.

A bouquet of value-added services was provided i.e. 43% of the clients received OST services, abscess management, general Health check-ups including Blood Pressure & Blood Sugar etc., 60% of the clients received counselling on ART adherence, prevention & risk reduction, Gender transition (including HRT & SRS), Beauty Management & Self-Care, SRH & GBV and 21% clients received awareness on legal aid, TG Shelter Homes, Drug De-Addiction and rehabilitation, Mental Health, Social protection, welfare scheme, livelihood.

Conclusions: Integration of services is a vital strategy to respond to the unmet need service needs for transgenders, PWID, Truckers and migrants. Provision of value-added services at OSC has attracted KPs to the centre otherwise remained hidden.

Plan India's OSC project demonstrates a one stop solution for medical and services beyond for the communities most vulnerable.

EP117

Beyond viral load: unraveling social and behavioral dynamics in HIV care

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Background: This study delves into the intricate social and behavioral aspects of HIV and living with HIV, with a specific focus on the present experiences of individuals in vulnerable populations within specific contexts.

We explore community mobilization, demand creation, harm reduction strategies, intersectional identities, interventions to combat stigma and discrimination, and the transformative impact of the U=U paradigm (Undetectable = Untransmittable).

By acknowledging and addressing the unique challenges faced by diverse populations, we aim to foster a more inclusive and effective approach to HIV care.

Methods: Employing a participatory research framework, this study integrates qualitative and quantitative methodologies. In-depth interviews, focus group discussions, and surveys capture the nuanced experiences of people living with HIV within various contexts. Community mobilization initiatives and harm reduction strategies are assessed through a community-based participatory research (CBPR) approach. Intersectionality is explored through a lens that recognizes and understands the intersecting social identities that shape individual experiences. The U=U paradigm is examined in the context of its impact on stigma reduction and community empowerment.

Results: Our findings illuminate the complex social and behavioral dynamics at play in the HIV landscape. By understanding the present experiences of people living with HIV, we identify context-specific interventions to enhance community mobilization and demand creation. Harm reduction strategies are evaluated for their effectiveness in mitigating risks. Intersectional identities are explored, providing insights into the unique challenges faced by individuals with multiple marginalized identities.

The study also sheds light on the transformative potential of the U=U paradigm in reducing stigma and discrimination.

Conclusions: This study contributes to a holistic understanding of HIV by going beyond viral load metrics. It advocates for tailored interventions that address the social and behavioral dimensions of HIV, recognizing the diversity of experiences within vulnerable populations.

By amplifying community voices, fostering inclusivity, and embracing the U=U paradigm, we aspire to reshape the narrative around HIV, reduce stigma, and pave the way for more empathetic and effective approaches to HIV care.

EP118

Understanding inequities in PrEP uptake and persistence among high risk MSM in Lima, Peru

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Background: While PrEP is approved for use in Peru, it has only recently been integrated into the national health system despite consistently high HIV incidence among key populations. To information national implementation, we investigate PrEP uptake, adherence, and discontinuation among sexually active HIV-negative MSM in Lima, Peru.

Methods: Between June 2022–January 2023, 1,397 MSM were screened for an STI management trial, all of whom reported condomless anal sex with >1 partner in the past 3 months. Participants were tested for HIV and bacterial STIs and completed questionnaires on demographics, sexual behaviours, and engagement with HIV prevention and treatment.

Descriptive statistics characterize PrEP use and chi-squared tests were used to evaluate associations between participant characteristics and lifetime PrEP use.

Results: Among HIV-negative MSM (N= 720; median age 29 years [IQR: 23-36]), 61% identified as gay and 35% as bisexual. Participants reported condomless anal sex with a median number of 5 casual partners in the past 3 months (IQR 2-12) and 22% reported transactional sex (past 6 months).

Overall, 86% (n=619) were previously tested for HIV, of whom 8% (n=61) ever used PrEP. The most common reasons for taking PrEP were to reduce the risk of HIV (70%), because it had been offered during a study (38%) and to have sex without condoms (36%). Of the 61 MSM who had ever used PrEP, only 14 (23%) were still taking PrEP while 47 (77%) had discontinued PrEP use. The most common reason for PrEP discontinuation (47%, n=22) was the end of the research study that was providing PrEP.

Among participants still using PrEP, all reported daily dosing and all reported adequate adherence (5 or more pills per week). Participants who identified as gay (p<0.01), older (p<0.01), university-educated (p<0.01), and recently used drugs (p<0.01) were all significantly more likely to have used PrEP.

Conclusions: PrEP use was rare among Peruvian MSM at risk for HIV acquisition, with PrEP users more likely to be older, identify as gay instead of bisexual, have a university education, and recently used drugs. Stark gaps in the PrEP continuum must be addressed during national implementation through targeted strategies to ensure consistent access.

EP119

High levels of stigma on immunity and virological control in people living with HIV in antiretroviral therapy

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Background: HIV-related stigma is one of the greatest challenges patients must overcome. The present study aimed to show external (disclosure concerns and concern with public attitudes) and internal (stabilished and negative self-image) stigmas influences directly in virological control and the immunological state of people living with HIV (PLWH).

Methods: We conducted a cross-sectional study consisted in a self-administered survey to PLWH receiving antiretroviral therapy (ART) in a Peruvian hospital during March and May 2017. Survey was composed by different scales evaluating depression, anxiety, quality of life, adherence to treatment, cognitive state and stigma. Variables were assessed by multivariate cox regression model adjusted to main statistics variables according with the level of stigma.

Results: From a total of 407 PLWH on ART, the median age was 39 (RIQ 25-75: 32-47 years-old); 332 (81.6%) were male; 135 (33.3%) MSM and 36 (8.9%) bisexuals. The ultimate CD4+ cell count median level was 429.5 (RIQ 25-75: 297.5-603.0); 11.8% have CD4 cell count ≤ 200 cell/mm³.

Stigma was evidenced in 376/407 (92.38%) patients: 112 (27.5%) with mild degree, 165 (40.5%) with moderate degree, and 99 (26.32%) with severe degree. In types of stigmas, 98 (24.1%) presented established stigma; 267 (65.6%) presented disclosure concerns; 96 (23.6%) presented negative self-image and 221 (54.3%) presented concern with public attitudes toward people with HIV. No virological control showed prevalence ratio of 0.37 (0.14 - 0.96; IC 95% p 0.04) in association of negative self-image of stigma; and last CD4+ cell count <200 showed prevalence ratio of 2.27 (1.17 - 6.56; IC 95% p 0.02) in association of a stabilshed stigma.

Conclusions: Our study showed high stigma levels in PLWH. Patients with a CD4 count less than 200 cells/ml were related with more than twice the risk of having established stigma; and no virological control was related with 70% less risk of have negative self-image stigma.



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This study exhibits that even though have good virological control, there is always a risk for internal stigma, and immunological compromise increase this risk with established stigma, it must be correctly assessed and treated in the continuum of HIV attention.

EP120

Analyzing spatial-temporal trends of HIV mortality across 32 Mexican states from 1990 to 2019

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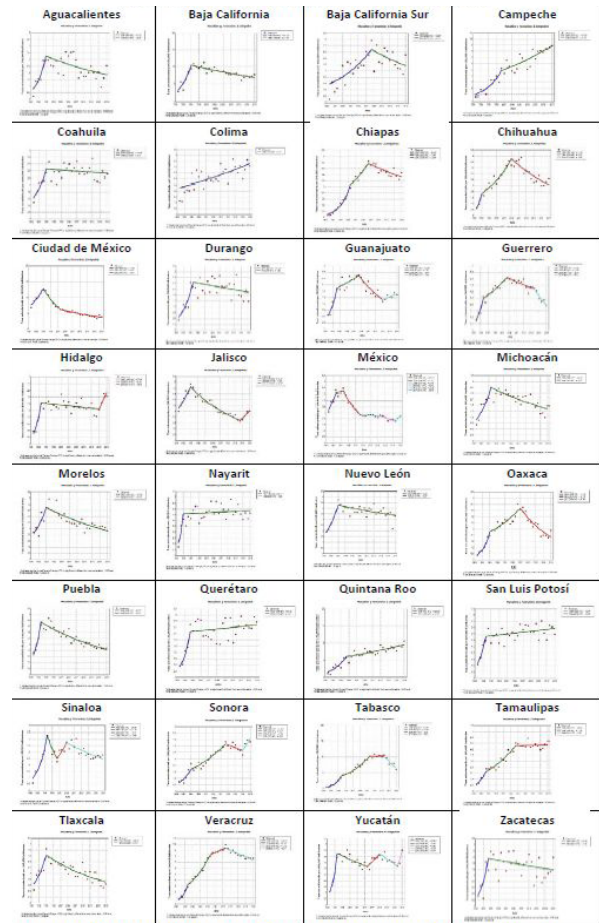
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Background: More than 150,000 people have died from HIV/AIDS in Mexico. Despite a 22% decline in HIV mortality from 2008 to 2017, recent data signals a concerning resurgence in mortality rates. This study aims to analyze the evolving trends in HIV mortality across the 32 Mexican States.

Methods: Age Standardized Death Rates (ASDR) per 100,000 population were calculated for all 32 Mexican States, utilizing official mortality records from INEGI and population estimates from CONAPO. JoinPoint regression analysis software was employed to scrutinize mortality trends.

Results: The latest trend reveals an increase in HIV mortality in 13 out of 32 Mexican States (40%), with Annual Percent Change (APC) ranging from 0.1 to 16.1. In contrast, the APC decreased in 19 States (60%), ranging from -0.4 to -9.8. Yucatán experienced the most significant increase (APC=16.1 from 2017 to 2019), while Guerrero witnessed the most substantial decrease (APC=-9.8 from 2004 to 2019) (see Figure 1).

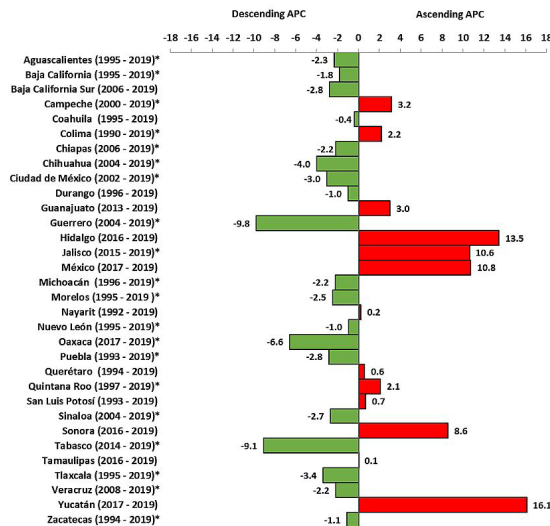
ASDR gap between Tabasco and Zacatecas was stark, standing at 7.6-fold (see Figure 2).



* The estimated annual percent change (APC) is significantly different from zero at alpha = 0.05

Figure 2. HIV/AIDS mortality by Mexican States. Mexico, 1990 - 2019.

Conclusions: Despite an overall reduction in HIV/AIDS mortality across most Mexican States, a concerning upward trend persists in 40% of them. Bridging the gaps in timely HIV diagnosis among key populations is imperative, coupled with enhanced provision of antiretroviral drugs and monitoring of persons with HIV. In a country with free and universal access to HAART, the increase in HIV/AIDS mortality is deemed unacceptable.



* The estimated annual percent change (APC) is significantly different from zero at alpha = 0.05

Figure 1. Last APC segment of HIV/AIDS mortality by Mexican States. Mexico, 1990-2019.

Among the 32 Mexican States, Tabasco recorded the highest ASDR from 2010-2019 (9.1/100,000), whereas the lowest mortality was observed in Zacatecas (1.2/100,000). The

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Deeper virological characterization of people with persistently undetermined HIV serology to detect possible cases of extreme control of HIV-infection

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Background: There exist very few cases, albeit consistently reported, of people with persistently undetermined HIV-serology (UHS). Although most of them are considered false-positive results, some of them could represent cases of extreme control of HIV-infections. Advances in molecular techniques provide new opportunities to perform a deeper characterization of these individuals.

Methods: Five individuals with UHS (more than one reactive ELISA over 6 months + undetectable viral load (VL) + indeterminate or negative WB; in absence of cART/PrEP/PEP) were enrolled. HIV-VL from centrifuged-plasma (15-20mL, 100,000xg 2h), total HIV-DNA from peripheral CD4 T-cells (qPCR) and HIV-specific T-cell response were evaluated and compared with samples from elite controllers (EC, undetectable VL without cART), viremic controllers (VC, VL<1000 copies/mL without cART) and individuals under successful long-term cART (>8 years).

Results: Participant characteristics are depicted in Table 1.

Group	CD4/CD8 (median, IQR)	CD4 counts (median, IQR) cells/uL	HIV-VL (median, IQR) copies/mL plasma	HIV-VL (median, IQR) copies/mL centrifuged plasma	Total HIV-DNA (median, IQR) copies/1M CD4+ T-cells
Undetermined HIV serology (UHS, n=5)	1.17 (0.92-1.56)	1008 (798-1044)	Target not detected (TND)	TND	0.056 (0-0.098)
Elite controllers (EC, n=7)	1.55 (1.31-1.71)	1200 (710-1772)	TND	Not performed	2.80 (1.03-13.81)
Viremic controllers (VC, n=3)	0.64 (0.59-0.69)	771 (492-802)	179 (76-738)	Not performed	1.26 (0.37-2.09)
Long-term ART (n=9)	1.19 (1.06-1.40)	732 (508-1060)	TND	Not performed	156.7 (61.65-1374)

Table 1. Characteristics of the different populations analyzed.

Three of the five UHS presented very low levels of total HIV-DNA, while no HIV-DNA was found in the other two. Significant differences regarding total HIV-DNA were observed when compared to VC (p=0.036) and long-term ART (p=0.008) groups, but not versus EC (p=0.09). HIV-RNA was not detected in any of the five individuals after

plasma ultracentrifugation. The median CD4/CD8 ratio was higher in UHS than in VC-group (p=0.012); while no differences in CD4 absolute counts were found between groups. HIV-specific T-cell responses were detected in two UHS-individuals; both of them presented HIV-DNA copies.

Conclusions: Natural cases of HIV remission have been reported among exceptional elite controllers. Here, we describe individuals with an incomplete serological response but with detectable viral DNA.

These findings raise the hypothesis of a possible extreme control of HIV-infection, compared to the previously reported. Deeper analysis of a higher number of individuals with persistent UHS could shed light about the possibility of a potential novel viral control mechanism.

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All in this together: leveraging private sector resources to increase the uptake of HIV services among young people in Zambia

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Background: According to the 2018 Zambia Demographic and Health Survey; 59% of girls and 46% of boys aged 15-19, and 91% of women and 77% of men aged 20-24 years, reported to have ever tested for HIV. To improve the uptake of HIV testing and other HIV services for young people, a multi-sectoral approach is required, with collaboration of the public and private sector. In 2023, USAID DISCOVER-Health, implemented by JSI, partnered with Trade Kings Group, a conglomerate of Zambian household goods manufacturing companies with strong name recognition to work together in increasing awareness of HIV services, and ultimately improving uptake for young people.

Methods: The project and Trade Kings Group partnered to bring together their collective expertise and reach in accessing young people through four large-scale in-person events. Organised by Trade Kings Group, the events involve their product promotion and social responsibility programs, live music, celebrity guests, and interactive games.

The project provided key health messages for these events, as well as booths for young people to receive health advice and services on-site, including HIV testing services (HTS), pre-exposure prophylaxis (PrEP), antiretroviral therapy (ART) and distribution of condoms and information, education and communication (IEC) materials.



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Results: At four supported events in Chibombo and Ndo-la districts, between July 2023 - March 2024, the project reached 871 people (365 females and 506 males) with HTS, linked 273 people to oral PrEP, 31 to injectable PrEP, and 6 to ART; plus distributed 6,194 condoms and 1,420 IEC materials on HIV treatment and prevention options. With outreach to men lagging behind women in knowing their HIV status and on ART in Zambia, this partnership also proved an effective way to reach this demographic.

Conclusions: This public-private partnership demonstrates that private sector resources can be successfully leveraged to increase access to HIV services for young people, in Zambia. Through this partnership, Trade Kings Group, lives up to its mantra of "improving lives", and is supporting the project's health service demand creation efforts. The project will scale up public-private partnerships to enable more young people to access HIV services.

EP123

Using peer to peer approach to improve voluntary medical male circumcision among a traditionally non-circumcising nomadic population in North-Eastern Uganda, a cross-sectional study

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Background: Voluntary Medical Male Circumcision (VMMC) reduces the HIV transmission rate by up to 60%. However, uptake in Uganda is still low at 57.5%, and much lower in Karamoja region at 20.6%. This is due to accessibility, insecurity, and cultural beliefs.

This study shows peer-to-peer mobilization strategy and associated factors on VMMC uptake in the Karamoja region, Northeastern Uganda.

Methods: This retrospective cross-sectional study was conducted at 2 pilot public health facilities in the Karamoja region offering surgical VMMC in northeastern Uganda. Routine program data on the Sociodemographic and clinical characteristics of all the volunteers circumcised between October 2021 and June 2023 was collected using an Excel-based tool from safe male circumcision client cards. Data was cleaned in Excel and entered in STATA version 15.0 for analysis.

The primary outcome was demand creation strategies that included a peer-to-peer approach, a community health worker model, and radio/TV. Data was summarized into percentages and frequencies to determine VMMC uptake in each strategy and a Multinomial logistic regression was fitted to identify the factors associated with VMMC demand creation strategies. A P-value of less than 0.05 was considered significant.

Results: Between October 2021-June 2023, a total of 3,561 volunteers were circumcised, of these 96.29% (n=3429) were aged 15-29, 90.34% (n=3217) had never married, and 92.29% (n=3,293) were HIV negative. The peer-to-peer approach contributed 86.27% (n=3078) of the volunteers cir-

cumcised whereas 13.54% (n=483) were through community health workers. Among the peer-to-peer approach, sexually active participants (95% Confidence Interval (CI): adjusted relative risk ratio (aRRR)=3.67, 2.84-4.48, P=0.001), the unemployed (aRRR=2.62, 95% CI: 0.97-7.10, P=0.045), participants whose level of education was primary (aRRR =2.2, 95% CI: 1.57-3.57, P=0.001) and secondary (aRRR = 2.4, 95% CI: 0.44-0.70, P=0.001) had a higher uptake of VMMC. An increase in age was associated with an increase in VMMC uptake (aRRR =1.04, 95% CI: 0.10-0.18, P=0.018).

Conclusions: Engaging circumcised participants to inform and mobilize their peers was associated with a higher uptake of VMMC. This approach proves to be instrumental in regions where strong beliefs against circumcision exist, as it could address barriers and promote the adoption of this preventive measure.

EP124

Fostering young people living with HIV

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Background: The collaborative effort between UNICEF, NACOPHA, and NYP+ resulted in the implementation of the project titled "Fostering young people living with HIV" in the Southern Highland Zone Region, covering Mbeya, Iringa, Njombe, and Songwe. The overarching goal was to address the specific needs of 20,000 Young People Living with HIV (YPLHIV) in these regions.

The project aimed to enroll them into the NYP+ National Database, establish empowerment groups, and identify cases related to Gender-Based Violence (GBV) and mental health.

The primary objectives were set to reach and enroll 20,000 YPLHIV into the NYP+ National Database and to establish Empowerment groups. Additionally, the project aimed to identify and address cases of GBV and mental health issues among the targeted population.

Methods: Commencing in June 2021 and concluding in March 2023, the project involved the training of 105 YPLHIV Cluster leaders. These leaders, functioning as branches of NYP+, operated at the District Level, responsible for enrolling other YPLHIV into the national database, forming Empowerment groups, and addressing GBV and mental health cases in their respective districts. Leveraging the ease of communication among youth, the strategy capitalized on peer-to-peer outreach to enhance enrollment and group establishment.

Results: The project surpassed its targets, identifying and enrolling a total of 20,762 YPLHIV into the NYP+ National Database across Mbeya (6412), Iringa (4302), Njombe (6321), and Songwe (3725).

Furthermore, 101 empowerment groups were successfully formed, with 15 of them receiving government loans. A total of 153 GBV/PSEA cases and 281 mental health cases were screened and reported, showcasing the project's effectiveness in addressing critical issues.

Conclusions: Despite achieving commendable results, challenges such as geographical distance and limited technology literacy among YPLHIV were encountered. Future initiatives could explore innovative solutions to overcome these barriers, ensuring more comprehensive coverage and impact. The successful outcomes, however, underscore the potential for collaborative efforts in addressing the multifaceted needs of YPLHIV in resource-constrained settings.

EP125

Statewide HIV surveillance system with sequencing-based quantitative recency assay reveals testing behavior and measures incidence in the Southern United States

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Background: HIV remains as a major public health threat in the Southern United States. Knowing the true incidence of HIV infections is pivotal to the Ending the Epidemic initiative. We used data from the North Carolina public health surveillance system joined with data from a multiplexed MPID-NGS assay to understand HIV incidence in NC starting in 2018. This assay leverages the temporally increasing diversity in the viral population to predict days post infection (DPI) at diagnosis for each individual up to 2 years (quantitative recency assay).

Methods: Serum samples from individuals with a new HIV diagnosis (sample collected within 30 days of diagnosis) from the NC State Lab of Public Health (NCSLPH) were sequenced. DPI up to two years were predicted based on viral diversity in regions of the viral *pol* and *env* genes. Within each calendar year we evaluated the distribution of DPI. Transmission events were calculated based on summing infection dates within each calendar year with a look-back period of two years. We used the percent of all NC cases diagnosed via the NCSLPH to adjust the total incidence figure to reflect all NC HIV diagnoses.

Results: From 2018 to 2022, a total of 1,012 persons newly diagnosed with HIV were successfully interpreted by this assay, representing 16% of all new diagnoses in NC in the same period. Overall, 29.6% people were diagnosed within 6 months of acquiring HIV, 21% between 6 months to 1 year, 29.4% between years 1 and 2, and 21% beyond 2 years of infection. In 2020, more PLWH were diagnosed at early stage of infection (34.8% within 6 months), while in 2021, there were more PLWH diagnosed at chronic infection (26.3% after 2 years), consistent with changes in testing behavior during the SARS-CoV-2 pandemic. Incidence was estimated as 15, 13.7 and 14.6 per 100,000 population (13 and older) for 2018 to 2020, respectively.

Conclusions: This sequence-based quantitative recency assay enables inferences in testing behavior by informing the time between infection and diagnosis. Furthermore, we developed an approach to estimate the incidence by identifying the number of transmission events within a given period.

EP126

Trends in the HIV epidemic among whites, blacks and brown race people in the state of Sao Paulo

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Background: Racial inequalities are a result of the living and working situation of populations and public health policies. To analyze trends in detection rates (DR) of HIV+ cases in Sao Paulo, according to skin color, regarding to the period of time from 2014 to 2022.

Methods: Trend study using polynomial regression models developed with newly reported HIV+ cases (NRHIV) compared by black, brown and white skin color and diagnosis period. DR were estimated using the number of NRHIV as the numerator and the denominator as the respective population base of the race. The annual DR of HIV+ cases, in each category, was considered as the dependent variable (Y), and the independent variable (X) was time, represented by the respective calendar years. The goodness of fit via r^2 and $p < 0.05$ were used to determine which models and data were most appropriate. Sources of information Data were: Abrinq Foundation population projection and Notifiable Diseases Database-AIDS.

Results: In the period from 2014 to 2022, 75,020 NRHIV were analyzed. Between 2014-2018 there were 45,747 NRHIV. DR among black people was significantly higher compared to browns and white people. For black, brown and white people the DR increased with 2nd order modeling [$Y = -1x^2 + 7x + 26; r^2 = 0.93; p = 0.001$], [$Y = -0.5x^2 + 3.5x + 17; r^2 = 0.90; p = 0.005$] and [$Y = -0.5x^2 + 3x + 13; r^2 = 0.99; p < 0.001$], respectively. Between 2018-2022 there were 38,359 NRHIV with a downward trend until 2020 and subsequent growth in DR among



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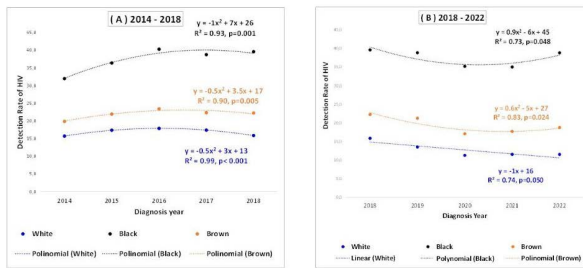


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blacks and browns with 2nd order modeling [$Y=0.9x^2-6x+45$; $r^2=0.73$; $p=0.048$], [$Y=0.6x^2-5x+27$; $r^2=0.83$; $p=0.024$], respectively, and among white people there was a trend with a decreasing linear model [$Y=-1x+16$; $r^2=0.74$; $p=0.050$].



Source: Siman - Epidemiological Surveillance - IST/Aids-SP State Program (VE-PEIST/Aids-SP)
Note: * Used population projection from Abertq Foundation.

Figure 1. Trends of Detection Rate* of reported cases of HIV infection aged 13 or over (per 100,000 inhabitants), according to race/color and year of diagnosis, state of Sao Paulo, (A) 2014 to 2018 and (B) 2018 to 2022*.

Conclusions: HIV DRs among black and brown people were significantly higher than among whites, from 2014 to 2022. Between 2018 and 2022, a downward trend in HIV+ DRs was observed only among white people. These differences are probably due, in part, to the difficulty in accessing health services, expressing the weight of racial inequalities in Brazil.

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Development of USAID's biomedical HIV prevention product research and development framework to prioritize USAID's microbicide portfolio for PEPFAR programs

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Background: Public sector funding for biomedical HIV prevention product research and development (R&D) is limited and stretched to meet a wide range of critical needs. To better inform how R&D products are prioritized, the United States Agency for International Development (USAID) identified the need for a technical framework to systematically assess the value-add of HIV prevention products in development and their potential for stringent regulatory approval and successful implementation in PEPFAR programs.

Methods: USAID contracted the Boston Consulting Group to develop a set of objective criteria to assess USAID's biomedical R&D portfolio of products against USAID's priorities. To develop this prioritization framework, over 30 experts in product development from international agencies, donors, academic and research centers, and the private sector participated in key informant interviews. Additionally, eight unique prioritization models imple-

mented by biopharma and global health funders were reviewed and adapted to develop the USAID Biomedical HIV Prevention Product R&D Framework (Framework).

Results: To meet USAID's priorities, six areas were included in the Framework to determine a product's value-add to the HIV prevention field and likelihood of successful implementation in PEPFAR programs. These priority areas include safety, efficacy, user acceptability, probability of technical and regulatory success, ease of introduction and scale-up, and health impact. Each product is evaluated against a set of product-development-stage-appropriate indicators, to objectively inform USAID's investment decisions for the R&D portfolio.

Conclusions: The USAID Biomedical HIV Prevention Product R&D Framework is a novel portfolio prioritization tool to systematically evaluate products for their potential to meet PEPFAR programmatic needs. The Framework enables rapid decision-making when products do not meet standards for PEPFAR programs. As such, the Framework optimizes USAID's portfolio and allows funding to be redirected to accelerate R&D of more promising HIV prevention products: Based on assessments that determined that five of the candidate products had relatively low acceptability potential, significant barriers to introduction and access and a low probability of reaching technical and regulatory success, USAID funding was discontinued for these products and reallocated towards other early-stage products with clear advantages over current and soon-to-market technologies.

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"DPP is good because you will be taking it as one pill" Attitudes and experiences with the dual prevention pill (DPP) among adolescent girls and young women in Harare, Zimbabwe

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Background: Oral pre-exposure prophylaxis (PrEP) is an effective HIV prevention method, however, uptake and use by adolescent girls and young women (AGYW) has been inconsistent. A dual prevention pill (DPP) combining PrEP with oral contraception (OC) for HIV and pregnancy prevention could increase PrEP use. We explored preference for, acceptability of, and adherence to an over-encapsulated DPP as a proxy for the co-formulated tablet currently in development.

Methods: We enrolled 30 16-24 y/o OC-users in a 6-month crossover study in Harare (Nov 2022-Sep 2023). Participants used the DPP capsule and 2 separate pills (PrEP, OC) for three 28-day cycles each.

We conducted in-depth interviews (IDIs) at study exit using a semi-structured guide. Topics included experience with study product use, social support for study participation, and recommendations for future DPP introduction. Interviews were conducted in the vernacular language, Shona, transcribed and translated into English, and analyzed using a rapid analysis framework.

Results: We conducted 27 IDIs with 26 participants who completed the study and 1 who discontinued early due to pregnancy. Most participants preferred the DPP versus two separate pills for the convenience of providing dual protection from a single pill and ease of remembering to take one pill. Some also felt encapsulation helped avoid the unpleasant taste/smell of PrEP. Major concerns about the DPP were its large size compared to PrEP and COCs, which were easier to swallow and had less cumbersome packaging. Most participants disclosed product use to partners, family members and other key influencers, which helped them feel supported and encouraged to adhere to study procedures. Overall, participants relied on alarm reminders and their own memory to take the DPP and PrEP/COC as prescribed. The DPP size and packaging were mentioned as key attributes for improvement.

Conclusions: The DPP could be useful for many AGYW seeking dual protection against HIV and unintended pregnancy. However, not all participants preferred the DPP, highlighting the importance of options for HIV and pregnancy prevention. Larger studies of the actual co-formulated DPP among women of all age groups will be needed to determine how to best support women in initiating and sustaining DPP use.

EP129

Oral HIV pre-exposure prophylaxis (PrEP) cascade among men who have sex with men (MSM) and transgender women (TGW) in the Dominican Republic: factors associated to a limited scalability

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Background: The introduction of HIV Pre-exposure Prophylaxis (PrEP) in the Dominican Republic (DR) is pivotal for combating HIV transmission, offering a proactive strategy, particularly in high-risk populations. Amidst persistent challenges in HIV prevention, PrEP's efficacy in reducing transmission risk is indispensable. This study aims to comprehend the obstacles and barriers across the PrEP care cascade in the DR.

Methods: A cross-sectional descriptive national study focused on self-identified men who have sex with men (MSM) in five DR provinces. Socio-demographic and behavioral surveys, along with HIV/STI samples, were obtained using snowball sampling and Respondent-driven sampling. Data were weighted using the successive sampling estimator and analyzed in STATA. Informed consent was obtained and approved by the national review board.

Results: Out of 2,183 participants, the majority were >25 years old (66%), 46% completed high school, and 90% were formally employed. First sexual relationships with men occurred between 17-20 years old, with 85% also reporting sex with women. Condom use with males was reported at 44%, and HIV and syphilis seroprevalence were 7.5% and 15%, respectively. Despite free availability, only 15% of MSM were aware of PrEP as a preventive tool, and merely 4% had ever taken it. TGW showed higher knowledge of PrEP programs (41%), but their usage in the last 6 months was lower compared to MSM.

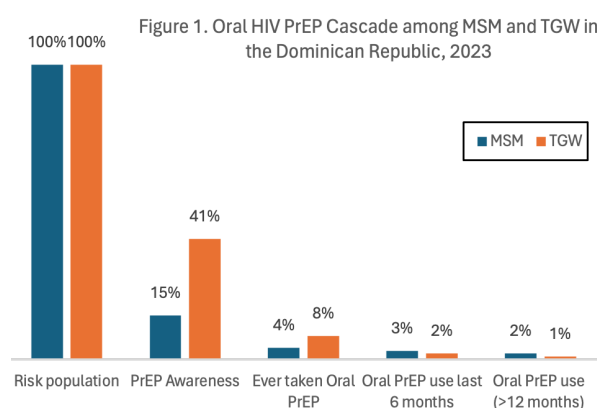
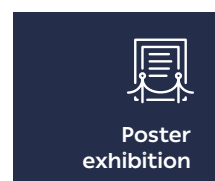
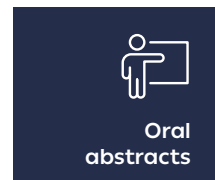


Figure 1. Oral HIV PrEP cascade among MSM and TGW in the Dominican Republic, 2023.

Conclusions: Emphasizing the importance of PrEP underscores a commitment to comprehensive preventive measures, fostering a significant stride toward achieving sustainable control of HIV transmission in the Dominican Republic. To make Pre-exposure Prophylaxis (PrEP) an effective preventive tool in the Dominican Republic, several challenges must be overcome. Access barriers, including limited awareness and availability, hinder PrEP uptake, especially among TGW. Stigma surrounding HIV and misconceptions about PrEP has not been addressed as a potential factor contributing to hesitancy among potential users.





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EP130

Pharmaceutical guideline for prescribing pre-exposure prophylaxis (PrEP) to prevent HIV: reducing barriers and expanding free access to PrEP in the municipality of Florianópolis, Santa Catarina, Brazil

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Background: The human immunodeficiency virus (HIV) epidemic in Brazil is concentrated in key populations. Data from UNAIDS 2022 shows that gays or men who have sex with other men (MSM), transgender women, cis women sex workers and people who use injectable drugs are the most vulnerable to HIV acquisition.

In 2022, there were 43.403 new HIV diagnoses in Brazil and 10.417 deaths by AIDS. Pre-exposure prophylaxis (PrEP) to prevent HIV has recently emerged as an effective pharmacological strategy in HIV prevention, but has not yet effectively reached the most important populations in Brazil. In Florianópolis, an island with 537.213 habitants in Santa Catarina (Brazil), in 2023, were 2.398 people using PrEP and only 1,9% of these were trans women. Also, 84% of the total prescriptions were made by physicians.

Key populations still face several different barriers in accessing medical appointments for PrEP prescriptions, both in the primary care and in the private health system, which has a high cost for physician consultations.

Methods: This study is an experience report on the construction of an free municipal guideline for prescribing PrEP to prevent HIV by pharmacists, in the public health system in the municipality of Florianópolis, with the aim of expanding the population's access to PrEP through independently prescribing PrEP in pharmaceutical consultations, in order to more effectively reach key populations vulnerable to HIV acquisition.

Results: The Pharmaceutical Guideline for Prescribing Pre-exposure Prophylaxis (PrEP) to prevent HIV (2024) was published with nine chapters that detail evidence-based recommendations for the prescription and follow-up of PrEP, also including screening, test and treatment of other sexually transmitted infections.

Conclusions: The expansion of free access to PrEP, through the qualification of its prescription by pharmacists in the public health system, who are often the gateway to the health system and professionals whom the population trusts the most, demonstrates an important advance in combating access barriers that key populations encounter in relation to PrEP, such as difficulty in scheduling appointments, lack of physicians and geographic barriers.

EP131

Fostering indigenous capacity and regional leadership in accelerating HIV prevention research – an integrative approach through south-south collaboration

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Background: HIV remains a global health challenge where India and Africa disproportionately share more than two-third of global disease burden. This calls for strategic centered efforts in HIV prevention research and development (R&D), rather than siloed activities, towards accelerating the pathway for scientifically robust, scalable and regionally relevant product development. The south-south collaboration emerges of utmost essence to fast-track HIV prevention research leveraging on complementary expertise and cross-learning across regions.

Methods: In 2023, a group of researchers (n=43) from academia, community-based organizations and clinical centers from India and 5 African countries were engaged in a survey to gather insights on the value of south-south collaboration in promoting regional research priorities, strengthening capacity across regions and devising a strategy for integrative research implementation. The data was analyzed using descriptive and parametric statistics.

Results: Survey response highlighted the following:

Most important virtue of South-South Collaboration: 44% respondents ranked *individual and institutional research capacity building*, 42% ranked *regionally relevant HIV prevention research prioritization* and 40% ranked *promoting complementary knowledge and tech transfer across region* as most important virtue.

Most prominent outcome expected: *Expansion of stakeholder network for HIV prevention research across region* was considered as most prominent outcome (46%) followed by *skill building of young researchers under senior expert mentorship* (26%), *opportunity for independent leadership in HIV prevention R&D* (23%) and *career development through medium-term financial sustainability* (5%).

The above findings informed conceptualization of an investigator initiated collaborative research initiative across India and Africa which was launched under partnership of Indian Council of Medical Research and IAVI to promote South-South collaboration.

4 joint research projects engaging 10 Indian and 4 African institutes, addressing regionally relevant research priorities such as T-cell diversity informing HIV vaccine development, suitability of broadly neutralizing antibodies against circulating HIV-1 strains, alternate animal models for HIV prevention research and comparative acceptability of prevention products were supported.

Conclusions: South-South collaboration for HIV prevention research creates an enabling ecosystem for mutually relevant science through a collective commitment towards fostering partnerships, improving knowledge-sharing platforms, and incorporating community voice in HIV R&D prioritization along with indigenous capacity building promoting next-generation leadership in HIV research.

EP132

HIV AIDS Program review Indonesia 2022: harm reduction component

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Background: At the end of 2022, the HIV/AIDS Program in Indonesia organized a program review involving stakeholders from government and non-government sectors. The aim of this activity was to:

1. Evaluate the extent to which recommendations from previous reviews were incorporated into program strategies,
2. Identify gaps in program implementation, and;
3. Develop recommendations for program improvement.

Methods: The harm reduction component program review was conducted from November to December 2022. Literature review was conducted.

Additionally, five in-depth interviews were conducted with representatives from Civil Society Organizations (CSOs) and key populations, and 2 FGDs were held with the support group component of the harm reduction program. Secondary data analysis was performed by comparing recommendations with program outcomes.

Primary data analysis involved categorizing data according to predefined themes using the study objectives.

Results: Several findings from the review process were noted:

1. Reports from program implementers in many cities indicate that since the disappearance of pure heroin in 2015, the number of injecting drug users has significantly decreased, and the variety of injected substances has increased.
2. Study evidence shows that the prevalence of Amphetamine-Type Stimulants (ATS) users has reached 3%. With an estimated 900,000 to 1.1 million ATS users. ATS users should be the primary target group for harm reduction interventions.
3. The distribution of sterile injection equipment appears to be very low. The situations include: The provided needle types do not meet user needs, inadequate logistics, and security issues for service providers and beneficiaries in implementing harm reduction programs are examples of ongoing issues.
4. The study indicates a high need to revive the function of the harm reduction working group to ensure coordination and interconnection with other programs and sector.

Conclusions: This study highlights the importance of the government's role in providing support in the form of policies and supportive regulations agreed upon by various sectors to achieve high-quality programs.

The global trend shift and the drug use situation in Indonesia underscore the importance for the government to take a stance on including ATS users as a key population in ongoing programs.

EP133

Which girls have been reached? A new method to operationalizing the DREAMS AGYW_PREV indicator to assess program reach and unmet need

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Background: The PEPFAR DREAMS program aims to reduce the risk of acquiring HIV among HIV vulnerable adolescent girls/young women (AGYW). All DREAMS countries should analyze DREAMS saturation – the percentage of HIV vulnerable AGYW who have received age-specific DREAMS services – annually to inform programming and planning processes.

However, the indicator used to track DREAMS program completion (AGYW_PREV) has limited ability to estimate saturation and was initiated five years after DREAMS program's inception. This gap has hindered DREAMS implementors' capacity to assess how many HIV vulnerable AGYW remain to be reached.

Methods: An intensive series of stakeholder engagement sessions were held with representatives from four DREAMS countries. Common reasons that limit the ability to operationalizing AGYW_PREV for DREAMS program tracking included restrictions in the indicator's archetype, limits of national data systems, and unique AGYW complexities. An algorithm was developed to adjust existing AGYW_PREV measures to derive saturation estimates for each DREAMS district and age cohort across all DREAMS countries using U.S. Census Bureau population estimates, WorldPop 100m² gridded population estimates, prevalence data from a range of sources and country-specific metrics around AGYW vulnerabilities and migration. These findings built the DREAMS Sat App, a R Shiny based user interface that allows countries to assess program reach and plan for the following fiscal year.

Results: Our method identified six modifiers that could be applied to AGYW_PREV estimates to increase utilization for a point-in-time saturation estimate by 5-year age-band cohort and district for all DREAMS OUs. These modifiers adapted flawed, aggregate measures into rea-



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sonable, standardized proxies to most/all country's base AGYW_PREV figures. Of the 15 DREAMS countries, nine used the DREAMS Saturation app to develop Fiscal Year 2024 DREAMS targets.

Conclusions: AGYW_PREV has limited ability to track the program's reach across time. Without the ability to assess past performance and unmet need, practitioners attempting to target programming for AGYW are working without adequate data on which to base decisions. This new method operationalizes the existing indicator, empowering country teams to fully realize the potential of their routinely collected AGYW_PREV data to better assess program reach and more intentionally set programmatic targets.

EP134

The reach, effectiveness, implementation, and maintenance of a New York City harm reduction program tailored for priority populations who use crystal meth, 2017-2022

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Background: Crystal methamphetamine (meth) use is increasing among MSM and transgender people in New York City (NYC) and is associated with increased risk of HIV transmission and poor care outcomes. Combining federal and local funding, the NYC Health Department created a harm reduction program to address participant needs around substance use, social support, and HIV prevention and care.

We describe its impact in terms of the populations reached, services delivered, and participant outcomes related to HIV transmission and meth use.

Methods: Eligible participants reported meth use (past 12 months), completed an assessment at enrollment, and received at least one service from January 2017-June 2022. Reassessments (delivered at least every 6 months) tracked longitudinal meth use outcomes. Analyses were stratified by race/ethnicity and sexual orientation/gender identity.

Results: Of 545 eligible, the program enrolled more PWH (53.6%) than non-PWH (46.4%) and more White MSM (34.2%) than Black (23.6%) or Latino MSM (30.5%). Among those enrolled ≥ 6 months (383), clients received a median of 21 services, the most common being individual counseling, health education, and benefits navigation. By the end of the study period, 6.7% (17/253) of non-PWH participants seroconverted. Of those who received ≥ 1 reassessment (165/545), only 44% continued to use meth at the time of their first reassessment.

Conclusions: This novel program reached priority populations at the center of NYC's syndemics of HIV and meth use. Although priority population participants reduced

meth use, all seroconversions of initially non-PWH clients occurred among priority populations, suggesting that greater engagement and support are needed to address enduring inequities.

EP135

The informal, non-prescribed use of antiretroviral medications for PrEP among a national US-based sample of men who have sex with men

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Background: Pre-exposure prophylaxis (PrEP) is a safe and effective method to prevent HIV infection. Sexually active men who have sex with men (MSM), and especially African American/Black MSM, have been identified as a population who may most benefit from PrEP. At the same time, some research has shown that MSM are engaging in informal, non-prescribed PrEP use.

This study examines behaviors and characteristics of informal PrEP use among a national sample of MSM to better understand this phenomenon and inform clinical practice.

Methods: Data are drawn from an anonymous online survey of MSM conducted in June 2023 (n=196). Eligibility criteria included being aged 18-55, identifying as LGBTQ+, having reported sex with men in the past 6 months, residing in the US, and use of smartphone enabled dating apps.

Results: Participants identified as white (63.8%), African American/Black (15.8%), Hispanic (13.3%), and other race/ethnicity (7.1%). Mean age was 33.4. Participants resided in 38 states in the Northeast (24.0%), South (37.2%), Midwest (18.9%), and West (19.9%) regions of the country. Nearly half (44.9%) resided in metropolitan cities. Informal PrEP use was reported by 11%.

Compared to those who have not, men reporting a history of informal PrEP use more frequently reported past year diagnosis of a sexually transmitted infection ($p<.001$), group sex ($p<.001$), sex in a gay sauna/bathhouse ($p=.002$), transactional sex ($p<.001$), ever receiving a PrEP prescription ($p=.004$), ease of finding diverted HIV antiretroviral medications on gay dating/sex apps ($p=.020$), and awareness of "on-demand" PrEP ($p=.012$); African American/Black race/ethnicity approached significance ($p=.098$).

Conclusions: This is the first apparent study to examine informal PrEP use among a national sample of MSM in the US. Although there were no geographic-based differences, findings suggest that men in the sample who reported informal PrEP use would appear to benefit from PrEP and that knowledge and acceptability are high. However, informal use may carry negative consequences if recommended dosing regimens are not followed or

if informally obtained HIV antiretroviral medications are not approved for PrEP. Additional research is needed to examine motivations for informal versus prescribed PrEP use (e.g., stigma, access), especially among African American/Black MSM.

EP136

Leveraging local leaders for successful COVID-19 vaccination uptake in Central Province, Zambia: a multi-sectoral approach

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Background: In April 2021, Zambia received its first batch of COVID-19 vaccines, following months of growing COVID-19 vaccination misinformation and resultant vaccine hesitancy.

Province	Month	Eligible for Vaccination	Fully Vaccinated	% Fully Vaccinated
Central Province	April 2022	1,060,213	164,200	15%

USAID DISCOVER-Health, implemented by JSI, employed a multi-sectoral response to engage leaders and help the Zambian government achieve its target of vaccinating 70% of the eligible population.

Methods: Over 10 days, the project engaged leaders across political, traditional, religious, civic, and professional spheres to champion COVID-19 vaccination. As part of the effort, members of the Provincial Administration Leadership went to all 10 districts in the province and spoke with members of District leadership to get their buy-in to support vaccine promotion. Collaborating with these respected leaders, the project trained them and empowered them with specially-developed information materials. These leaders were then able to share the benefits of vaccination, dispel misinformation, and cultivate vaccine acceptance in their extensive networks.

Results: By July 2022, Central Province achieved 76% vaccination coverage, with 808,529 individuals in the province fully vaccinated, increasing uptake by 61% in 3 months. This multi-sectoral model harnessed local leaders' credibility, reach, and influence, fundamentally altering the vaccination landscape.

Conclusions: The increase in COVID-19 vaccination coverage underscores the impact of strategic and collaborative engagement with influential leaders. It highlights the value of engaging leadership from multiple sectors to help move people from vaccine barriers to vaccine facilitators.

Central Province's strategy was replicated nationwide, and Zambia achieved the goal of fully vaccinating 70% of the eligible population by October 2022.

EP137

Sexual dysfunction in people living with HIV: integrative review

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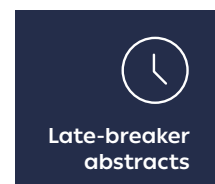
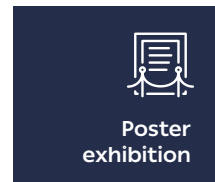
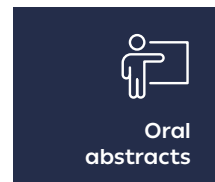
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Background: Antiretroviral therapy has increased the survival of People Living with HIV (PLHIV) and other aspects of this population's life have begun to be studied, such as sexual function. Thus, the study aims to identify the prevalence of sexual dysfunction in PLHIV and its related factors.

Methods: This is an integrative review carried out from October to December 2023, in the databases: MEDLINE, SCOPUS, CINAHL, Web of Science, LILACS, PsycINFO and Embase. The descriptors were used: "HIV", "HIV Infections", "Acquired Immunodeficiency Syndrome", "Sexual Dysfunction, Physiological", "Sexual Dysfunctions, Psychological". Complete articles were selected, available in Portuguese, English or Spanish, regardless of the year of publication. Letters to the editor, studies that did not address PLHIV, event summaries and repeated articles were excluded. 2.745 articles were found and 970 were excluded for being repeated. After reading the titles and abstracts, 1.692 works were excluded because they did not answer the guiding question or were unavailable, leaving 83. After reading in full, 25 articles were selected.

Results: In samples with men only, the prevalence of sexual dysfunction ranged from 49% to 80%, highlighting erectile dysfunction, reduced libido, sexual hypoactivity and premature ejaculation. The most common sexual dysfunction was erectile dysfunction, and was associated with depression, alcohol use, smoking and old age. In studies with women, the prevalence of sexual dysfunction ranged from 22.2% to 100%, women with HIV had more sexual dysfunctions when compared to women without HIV. The age of the participants ranged from 18 to 88 years old, the studies showed that sexual dysfunction was more common in single people and was mainly associated with depression, anxiety, hormonal changes, adverse events from antiretroviral drugs, social beliefs and body changes resulting from HIV, such as lipodystrophy.

Conclusions: High rates of sexual dysfunction have been observed in PLWH, especially in women. It is necessary to study the factors associated with sexual dysfunction in larger samples with longer follow-up periods, considering cultural and social variations, to support the development of strategies to improve the sexual function of this population.





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A model for strengthening gender transformative approaches in HIV advocacy campaigns

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Background: In 2022, approximately 1.3 million new HIV infections were reported globally, most in Eastern and Southern Africa, particularly among women, girls, and gender and sexual minorities¹. The Coalition to Accelerate and Support Prevention Research (CASPR) supports, expands, and advances advocacy to develop and deliver a robust pipeline of HIV prevention options, critical to which is gender equity. In June 2022, CASPR conducted a gender transformation workshop to enhance the Coalition's approach. While many tools exist to support gender transformation within HIV programming, they often fail to address the unique needs of diverse partners engaged in advocacy campaigns.

Methods: A literature review identified evidence-based tools for gender transformative approaches (GTA) in HIV. Elements of the tools were combined and adapted to develop a GTA assessment tool for CASPR. The tool guides respondents to assess activities based on gender transformation principles: human rights; power dynamics; gender norms; inclusion of sexual and gender diversities; empowerment of women and girls; and meaningful engagement of men and boys. Respondents then score and analyze activities along the gender continuum. The tool was piloted in May 2023, iterated, and distributed to all partners in October 2023.

Results: Six of thirteen partners completed the assessment, with five indicating their activities were gender responsive or transformative. All respondents outlined actionable steps for improvement, including collaborating with community male mobilizers; training program leads on GTA; and advocating for increased participation of informed young women in technical working groups. Results reflect that even in a Coalition focused on advancing prevention options for women and girls, there are opportunities to strengthen gender integration, and highlight the need for tailored tools to support advocacy efforts.

Conclusions: The findings suggest that the CASPR GTA assessment could serve other HIV advocates wanting to improve GTA within their organizations and projects. Its adaptability makes it suitable for a wide range of advocacy efforts, from community trainings to policy engagement, and small-scale campaigns to long-standing programs, distinguishing it from more narrowly focused tools. With continued use of the tool, recurring themes can be identified to enable ongoing monitoring of progress to demonstrate the impact of strengthening GTA over time.

EP139

Using HIV and hepatitis C molecular epidemiology to investigate assisted-partner services as an HIV testing and prevention strategy among people who inject drugs in Kenya

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Background: Sexual and injecting partners of people who inject drugs (PWID) may have elevated risk of HIV infection from sharing a transmission network. We estimated the degree of similarity between HIV and hepatitis C (HCV) sequences from PWID and their partners to assess whether partner-based recruitment identifies sexual or injecting partners within transmission networks.

Methods: We used assisted partner services to recruit sexual and injecting partners of PWID living with HIV in Kenya and offered them HIV and HCV testing. We evaluated the TN93 distances (an adjusted measure of sequence similarity) and the phylogenetic relationship of both HIV-1 and HCV sequences from partner pairs and tested for correlates of this distance.

Results: Of 135 unique pairs identified, 2 sexual, 2 injecting, and 3 sexual and injecting partner pairs had HIV sequences within a TN93 distance of 0.045, representing 16.7%, 1.8%, and 21.4% percent of sexual, injecting, and sexual and injecting partner pairs, respectively. All but one of these sequence pairs were nearest neighbors on a phylogeny. Of 18 partner pairs with HCV-4a sequences, 4 fell within a distance of 0.015. Sexual but not injecting partner pairs had HIV sequences with significantly smaller distances than non-partners, on average, while injecting partner pairs had significantly smaller HCV-4a patristic distances than non-partners. The difference in TN93 distance for sexual and injecting partner pairs was not significant; only the number of years since diagnosis and viral suppression level were associated with HIV TN93 distance among pairs.

Conclusions: Molecular evidence suggests assisted partner services partly reflects the HIV transmission network among sexual, but not injecting, partners of PWID. This may suggest lower recent parenteral HIV transmission. The relationship between the injecting partner recruitment and molecular networks is stronger for HCV than HIV and may reflect some recent parenteral HCV transmission.

Overall, these findings support the positive impact of harm-reduction programs like needle-syringe sites, but also the need for reducing sexual HIV transmission among PWID. More research is needed to understand recent trends in HCV transmission in the population, and education and services should continue to address the role of needle and equipment-sharing in HCV transmission.

EP140

Hidden solutions: uncovering unique sources of HIV treatment for key populations in Nigeria

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Background: The Integrated Biological and Behavioural Surveillance Survey (IBBSS) 2020 in Nigeria revealed that 3.4% of 1.9 million PLHIV are key populations, accounting for 32% of new cases. Access to HIV treatment remains a major barrier for key populations (KP) in Nigeria, consisting of female sex workers (FSW), men who have sex with men (MSM), transgender people (TGP), and people who inject drugs (PWID). Traditional healthcare systems frequently fail to reach these marginalized communities, resulting in discrepancies in treatment availability and outcomes.

However, inside these communities, there are hidden answers that provide alternative avenues to HIV treatment. This abstract investigates and identifies the preferred sources of HIV treatment used by key population in Nigeria.

Methods: Retrospective data from the 2020 IBBSS in 12 Nigerian states informed this study, encompassing Abia, Anambra, Akwa Ibom, Benue, Rivers, Lagos, Oyo, Nasarawa, Kano, Kaduna, Gombe, and Taraba. A descriptive cross-sectional approach was used to select the study participants: MSM (771), TG (991), FSW (2157), and PWID (869) across these states. Descriptive analysis uncovered the frequency and percentage of the unique sources of HIV treatment embraced by KP communities.

Results: This study illustrates the various sources of HIV treatment accessed by different key populations (KP) in Nigeria. Female Sex Workers (FSW) predominantly seek treatment from Pharmacy/Chemists (44.2%) and Private Hospitals (20.4%), with minimal reliance on friends/family members (2.6%) or NGOs (4.7%).

In contrast, People who Inject Drugs (PWID) access treatment through a mix of formal and informal channels, with significant proportions utilizing NGOs (17.95%) and

Pharmacy/Chemists (30.03%), alongside Public Hospitals (19.10%) and Traditional Healers (16.69%). Men who have Sex with Men (MSM) and Transgender People (TG) exhibit similar patterns, relying heavily on Pharmacy/Chemists and Private Hospitals, while also accessing treatment through NGOs and Public Hospitals.

Notably, Traditional Healers play a significant role in providing healthcare to PWID and TG, indicating the presence of alternative healthcare practices within these communities.

Conclusions: These findings underline the need for collaboration between formal healthcare systems, non-governmental organizations, and traditional healers in order to ensure comprehensive and inclusive HIV services or equitable access to HIV treatment for all KP communities in Nigeria.

EP141

Implementation strategies and recommendations to enhance Pre-Exposure Prophylaxis delivery for HIV prevention among adolescent girls engaged in transactional sex and use drugs in Uganda: a qualitative study

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Background: Adolescent girls engaged in transactional sex and drug use in Uganda are at increased risk of HIV transmission. Although PrEP has the potential to mitigate this risk, its scale-up and evidence on effective implementation strategies are still limited.

Methods: Between April 2018 and May 2019, we conducted cross-sectional semi-structured interviews to explore effective implementation strategies and recommendations for enhancing PrEP delivery with 18 Ugandan adolescent girls aged 15-24 years engaged in transactional sex/used drugs and 10 PrEP implementers (healthcare leaders and healthcare providers, policymakers, Peer leaders, community-based organization).

We analyzed data using a directed content analysis approach guided by Consolidated Framework for Implementation Research framework.

Results: Stakeholders deployed and recommended a variety of implementation strategies to enhance PrEP delivery among adolescent girls engaged in transactional sex. These included: Training key gatekeepers (e.g., identify/train PrEP focal persons at PrEP clinics, peer leaders); providing technical assistance (e.g., providing timely support supervision and hands-on mentorship to staff and



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peers involved in PrEP provision to discuss challenges and identify solutions); integrate PrEP with others services (e.g., offer PrEP with harm reduction, HIV testing, cancer screening, etc.); provide culturally sensitive/adolescent centered services (e.g. Identify, train and involve peers from the community of girls engaged in transactional sex in PrEP cascade of care delivery); develop community engagements (e.g., identify, equip and engage adolescents, peer leaders, parents, with information related to PrEP implementation), make changes within the health facility (e.g., designate time and specific adolescent friendly corner for PrEP provision).

These strategies influenced three domains of the CFIR framework including the inner setting (improved infrastructure and workflow), implementation climate (improved stakeholder engagement, reduced PrEP stigma and improved attitudes), and readiness for PrEP implementation (timely problem-solving).

Some barriers reported include inadequate government funding to support sustained PrEP implementation and a restrictive legal environment against adolescents engaged in transactional sex.

Conclusions: Our study underscores the need for context-specific implementation strategies to enhance PrEP uptake and effectiveness among adolescent girls engaged in transactional sex and drug use in Uganda. The stakeholder recommendations provide valuable insights for policymakers and practitioners striving to improve HIV prevention efforts in this vulnerable population.

EP142

HIV testing strategies: peer-led primary and secondary distribution of HIV self-testing kits among young people in rural South Africa

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Background: Promoting HIV testing as the gateway to treatment is well documented; however, less attention is given to testing as a gateway to HIV prevention, specifically to pre-exposure prophylaxis (PrEP). Young people in sub-Saharan Africa are at disproportionate risk of HIV and HIV Self-Testing (HIVST) is a promising strategy to improve testing and linkage to prevention and care for young people. We describe the primary and secondary distribution of HIVST among young people in rural Kwa-Zulu-Natal (KZN), South Africa.

Methods: Between August - December 2022, we pilot-tested the acceptability of distribution of HIVST to support PrEP uptake among young people aged 18-24 and their

sexual partners in the Africa Health Research Institute (AHRI) surveillance area in KZN. Young people were randomly sampled from the surveillance area, consented, and administered a questionnaire on demographic, sexual partner information, willingness to take HIVST kits for self (primary distribution) and partner (secondary distribution), and uptake of PrEP services.

We used logistic regression to determine the factors associated with primary and secondary distribution of HIVST kits, adjusting for age, sex, location and education.

Results: Among 165 sampled, 154 (93%) were enrolled, 51% were female, the median age was 21.5 years and 84 (55%) took HIVST kits for themselves or their partners. Of these, 60 (71%) reported tested themselves: 55 (92%) tested negative, of whom 3 (6%) initiated PrEP. 34 (40%) also distributed a kit to their partners of whom 20/34 (59%) were female. 31/34 (91%) reported that their partner used the kits: 23 (74%) reported their partner tested HIV-negative and 11 (48%) initiated PrEP. Males were more likely to report that their sexual partners initiated PrEP compared to females (8 (80%) vs 3 (23%) , p=0.012).

There was no association between age (aOR=1.00; 95%CI 0.78-1.27), higher education (aOR=2.15; 95%CI 0.84-5.57), multiple partnership (aOR=0.52; 95%CI 0.11-2.33), or inconsistent condom-use (aOR=1.11; 95% CI 0.34-3.42) and primary distribution of HIVST. Similarly, age, higher education multiple partnership and inconsistent condom-use were not associated with secondary distribution of HIVST.

Conclusions: Peer-led distribution of HIVST was high in this rural setting. While secondary distribution was relatively low, it did support partner HIV testing and PrEP uptake in this rural setting.

EP143

HPV vaccine acceptance and advocacy among a cohort of adolescents and young adults living with perinatally-acquired HIV in Kenya

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Background: Human papillomavirus (HPV) is a known cause of cervical cancer, particularly impacting people living with HIV (PLWH), and notably in sub-Saharan Africa which bears the greatest burden of cervical cancer. Despite the heightened risk, HPV vaccination uptake remains low, a consequence of inadequate awareness and poor access to vaccination services.

This study aimed to explore vaccine acceptance and advocacy among adolescents and young adults (AYA) living with HIV previously vaccinated with the HPV vaccine, shedding light on the potential for community-based interventions to improve vaccination rates in regions with significant cervical cancer burden.

Methods: Nine years after primary vaccination with the quadrivalent HPV vaccine, a cohort of 158 AYA living with HIV were evaluated for HPV vaccine effectiveness. At their study exit interview, they were asked questions to assess their likelihood of recommending HPV vaccination to family and friends, interest in future vaccine trials, and use of COVID-19 vaccine as indicators of vaccination acceptability. Descriptive analysis and log binomial model were used to evaluate factors associated with vaccination perceptions and willingness to recommend the HPV vaccine. Adjustment for potential confounding variables, including sex, age, education level, financial independence and sexual activity was conducted.

Results: Among 158 participants, 155 completed the survey. Eighty-two (52.9%) were women, aged 21-25 years; 84 (54.2%) completed secondary education level, 64 (41%) were financially independent and 116 (75%) reported no sexual debut. Approximately one-third (45/155) had recommended HPV vaccination to family members and friends, 74 (48%) had received COVID-19 vaccination and

144 (93%) were interested in future vaccine studies. In multivariable analysis, education level was a significant factor, participants with secondary school education had a lower likelihood of recommending the vaccine (adjusted prevalence ratio [aPR] = 0.45, 95% CI [0.26, 0.77]) compared to those with tertiary education.

Additionally, non-sexually active participants who had not initiated sexual activity were less likely to advocate for the HPV vaccine (aPR = 0.48, 95% CI [0.23, 1.00]).

Conclusions: Adolescents who received HPV vaccine can recommend vaccination to friends and family members. This provides a mechanism to increase community education and uptake of HPV vaccination in the general population.

EP144

PrEP pauses, restart, and inconsistent use: navigating PrEP adherence among Adolescent Girls and Young Women (AGYW) who initiated PrEP in an HIV prevention program in Kampala Uganda

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Background: Pre-exposure prophylaxis (PrEP) is highly efficacious in HIV prevention. However, for PrEP to prevent HIV infection, it requires high adherence. Understanding PrEP adherence patterns would inform HIV prevention message packaging. We aimed to examine the reasons for PrEP pause, restart and inconsistent use among adolescent girls and young women (AGYW) in an HIV prevention program in Kampala-Uganda.

Methods: Between January 2023 and March 2024, a qualitative study using 36 repeat interviews was carried out in Kampala, Uganda, involving 14-24-year-old purposively sampled HIV-negative AGYW at high risk of acquiring HIV. Data were transcribed and analyzed thematically.

Results: PrEP side effects were the major reason for missing pills and eventually PrEP pause. Secondly, mobility of AGYW caused missing PrEP doses and refills as some reported forgetting to move with their pills, pills they moved with getting finished before returning or having no knowledge of PrEP access points where they moved to. Changes in sexual behaviour like reducing the number of sexual partners or pausing sexual activities due to pregnancy or illness also led to PrEP pause.

Additionally, some reported pausing PrEP and using other HIV-prevention methods like condoms. For some, the prevailing or new health conditions that required long-term medication resulted in pausing PrEP. Financial constraints reportedly caused food challenges which affected adherence. Lastly, pill burden, forgetfulness and alcohol use also led to missing PrEP and eventually pausing.

The major reason for PrEP restart was high HIV risk awareness including having multiple sex partners of unknown status who they cannot ask for an HIV test and having sex



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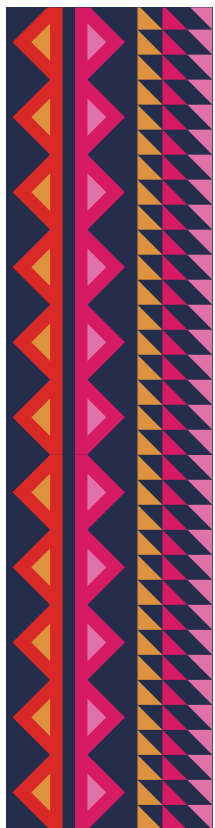
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while drunk. AGYW also reported that some clients did not like using condoms, and reported some clients tearing or removing condoms during sexual intercourse, such clients offered more money for (condomless) sex, which motivated restarting PrEP to get more money.

Lastly, future marriage prospects and hopes of getting into a long-term relationship motivated PrEP restart to remain HIV-negative.

Conclusions: The study highlights various reasons for PrEP pause, inconsistent usage and restart. It reveals risk mitigation as participants paused PrEP and used condoms. The findings highlight the necessity for tailored intervention messages to enhance PrEP uptake and adherence.

EP145

Uptake of care through accessible youth-friendly HIV status neutral services among adolescents and young adults in rural KwaZulu-Natal, South Africa

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Background: Adolescents and young adults (AYA) in South Africa have a high burden of HIV and sexually transmitted infections (STIs), but face barriers to access HIV and sexual reproductive health (SRH) services through primary care. We describe uptake of care through accessible HIV status-neutral services among AYA in rural KwaZulu-Natal(KZN).

Methods: We used data from a 2x2 factorial randomized controlled trial [NCT04532307] evaluating the effect of peer navigator support, with/without a comprehensive package of SRH services, on the prevalence of transmissible HIV. The trial was conducted March 2020-August 2022 among 1743 young people aged 16-29 years in KZN. All participants, irrespective of study arm, were referred to accessible, HIV status-neutral youth-friendly SRH services. At 12 months(endline) all participants were offered home-based self-collected testing for STIs (gonorrhoea, chlamydia and trichomonas) and rapid HIV-testing. We defined linkage to care as participant attendance at a study clinic during the 12month trial period. We conducted logistic regression for factors associated with linkage to care, adjusting for sociodemographic factors.

Results: Among 1300/1743 (75%) participants retained at endline, 53% were female, 37% aged 20-24years, 35% resided in peri-urban and 28% reported food insecurity. A third (33%) had more than one sexual partner in last 12months, 20% were living with HIV (PLWH) and 23% tested positive for STIs. Majority AYA (919/1300; 71%) linked to care: 394 (43%) were male, 734 were assessed for PrEP eligibility, 117/734(16%) were eligible and 110/734 (15%) started PrEP, with 19/51 (37%) started ART, and 121/525 (23%) received contraception. Being female (aOR 1.76 95%CI: 1.37,2.26), reporting food insecurity (aOR 1.39 95%CI: 1.04,1.83) and testing positive for an STI at endline (aOR 4.13 95%CI: 2.51,6.79) was associated with increased likelihood of linking to care. AYA from peri-urban (vs rural) areas (aOR 0.76 95%CI: 0.59,0.98) and PLWH (aOR 0.61 95%CI: 0.43,0.87) were less likely to link to care. Being older or having more than one sexual partner were not associated with linkage to care.

Conclusions: In this setting with a high burden of HIV and curable STIs, AYA, including men, accessed HIV serostatus-neutral youth-friendly services. There is need to enhance interventions to reach PLWH and AYA living in peri-urban settlements.

EP146

Improving HIV service delivery through community-led monitoring in Suriname

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Background: The Suriname CLM pilot (Jul 2023-Feb 2024) aimed to enhance HIV service quality and accessibility through community-led monitoring. Challenges in HIV response, including accessibility, quality, and accountability, drove the initiative, aligned with the 2021-2027 National HIV Strategic Plan and Global Fund guidance. The pilot, facilitated by CNFA, sought to address gaps identified in a 2018 assessment. It involved researching global CLM best practices, stakeholder consultations, and capacity-building. Ultimately, the pilot aimed to showcase CLM's value, develop national capacity, and potentially scale up community-led monitoring across health sectors for improved accountability and equity.

Methods: The methods involved desk review, stakeholder consultations to inform CLM design, developing structured questionnaires and consent procedures, training field officers, and deploying them to engage 468 HIV service users at two health facilities. Sessions conducted in local language enabled open feedback. Quantitative and qualitative data was gathered on topics like quality, accessibility, stigma. Informed consent allowed users to opt in/out. Data validation and triangulation strengthened evidence. Community-centered methods highlighted user experiences and priorities.

Results: While many users expressed satisfaction, issues emerged around quality of staff attitudes and infrastructure, accessibility barriers like costs, stigma around confidentiality, and medication availability gaps. Key priori-

ties highlighted were improving staff sensitivity training, upgrading infrastructure maintenance, strengthening privacy protections, enhancing medication coordination between prescription and pharmacy, removing user fees, and increasing transportation support. The results demonstrated CLM's value for uplifting community perspectives to shape equitable, people-centered improvements.

Conclusions: The Suriname CLM pilot (Jul 2023-Feb 2024) underscored the importance of community-led monitoring in shaping equitable HIV services. It centered user experiences, revealing gaps in quality and accessibility, necessitating improved feedback mechanisms. CLM generated qualitative and quantitative data complementing provider-centric metrics, with reliable data collection methods. Community leadership proved crucial, advocating for accountability and person-centered care. Recommendations include sustained community involvement, increased funding, data audits, centralized coordination, technical expertise enhancement, and exploring mHealth data collection. The pilot validated CLM's value, emphasizing its role in enhancing HIV service delivery and accountability in Suriname.

EP147

Recommendations made during Community consultations for analytical treatment interruption (ATI) HIV research studies in Southern Africa

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Background: There remain persistent challenges with ART initiation and adherence in Southern Africa, and ART is not curative. Broadly neutralizing antibodies (bnAbs) have the potential to fill gaps in prevention, treatment, and cure research. Before the implementation of a new bnAb ATI study, researchers from three research networks consulted community stakeholders to hear recommendations about how the study should be conducted.

Methods: A5416/HVTN 806/HPTN 108 will be implemented at 9 research sites in South Africa, Malawi, and Botswana. In June 2023, The HIV Vaccine Trials Network, HIV Prevention Trials Network, and AIDS Clinical Trials Group conducted an interactive one-day consultation in Johannesburg, South Africa with total of 35 stakeholders from the sites' communities.

Attendees included representatives from local ethics committees, community health clinics, traditional healers, governmental/non-governmental organizations, advocacy organizations and community advisory boards. The goals were to identify recommendations for study implementation. The consultation provided detailed explanations of intricate biomedical concepts (e.g., bnAbs,

ATI), and facilitated diverse dialogue by having attendees rotate through 6 breakout groups. Stakeholder questions/recommendations about study implementation were collected and reported back to the study team.

Results: This interactive process enabled stakeholders to express community-centered considerations based on lived experiences and knowledge of societal norms to provide recommendations regarding informing participants and their partners about PrEP and condom use during the ATI.

Recommendations included:

1. Provision of long-acting contraception to minimize pregnancy during the study;
2. Pre-screening questionnaire to assess willingness to use contraception while in the study;
3. Provision of materials in simple language for participants, their partners, and support systems that address stopping treatment (against standard of care guidance), contraception, pregnancy /breastfeeding, and;
4. Provision of ongoing psychosocial counselling to the participants and their partner(s) during study implementation.

Conclusions: The networks recognize that integrating community stakeholders in development and implementation of HIV prevention, treatment and cure research initiatives can increase community ownership. Stakeholder input represents a critical strategy for fostering partnerships to advance HIV research.

The study team has reviewed the recommendations received and sought additional funds for the study budget to implement them. Suggestions will also be incorporated into research staff training before study implementation.

EP148

Improving HIV case finding for key populations through the expanded peer outreach approach in Eastern Uganda

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Background: UNAIDS considers Men having sex with Men (MSM), Female Sex Workers (FSW) and their clients, transgender people, and people who inject drugs (PWID) as primary Key Population (KP) groups. These populations often suffer punitive laws, stigmatizing policies, violence, social, and economic marginalization, and criminalization. This leads to an increased risk of HIV exposure. In Uganda, KPs contribute about one in four new infections, with Female sex workers having 30 times higher risk of acquiring HIV



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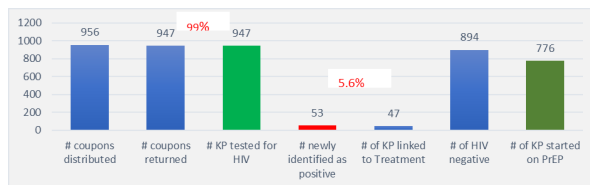
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than women in the general population. However, in the Eastern Uganda seropositivity survey, the finding highlighted fewer people having HIV among KPs at only 0.6% by the end of July to September 2022. This was associated with limited capacity to implement the EPOA approach and documentation gaps.

Methods: Methodology/description: To mitigate the above, LPHS-E, a USAID-funded program managed by Baylor Uganda contributed towards health systems strengthening through capacity building by identifying and orientating KP peers and counsellors on EPOA scope, service package, and approach. Existing known peer educators were enrolled as lead peers and assigned at the service point to recruit mobilizers per category. Peer mobilizers were assigned serialized coupons to distribute to their social networks targeting those who have not tested before with details of services provided, service location, and contact information. At the facility/service point, the KP Peer lead received and registered the peers returning with coupons offered education, counselling and linked them to appropriate service. Weekly analysis of coupons distributed and returns for payment. In addition, guided programming for new hotspots.

Results: During the period, Jan to March 2023, a total of 956 coupons were distributed and 99% (947) coupons were returned. 947 KPs were tested for HIV of whom 5.6% (53) were found to be positive. Of those newly identified positive, 41 were (FSW), six were Transgender (TG), four were men who have sex with men (MSM) and two were Persons Who Inject Drugs (PWIDs). 47 (87%) were enrolled on ART following national guidelines. 894 were identified as negative and 776 KPs were newly initiated on PrEP.

Overall HIV seropositivity improved from 0.6% in Oct-Dec 2022 (Quarter 1) to 3.3% by the end of Jan to March 2023.



Conclusions: The EPOA model has increased access to and uptake of services for hard-to-reach KPs. Directing resources where new HIV infections are more likely to emerge contributes to controlling the spread of the epidemic.

Responding to complex health needs of Most at Risk Populations in hidden networks requires a multi-sectoral approach. The government should conduct community awareness-raising and sensitization campaigns to reduce stigma and discrimination against KPs.

EP149

Interaction between vaginal microbiota composition, inflammation and *Chlamydia trachomatis* infection in the female reproductive tract

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Background: In the female reproductive tract (FRT), environmental factors, including the vaginal microbiota, play a significant role in modulating inflammation and susceptibility to sexually transmitted infections like *Chlamydia trachomatis* (CT). Specifically, a dysbiosis characterized by a decreased presence of *Lactobacillus* and an increased abundance of anaerobes such as *Gardnerella* or *Prevotella* is linked to heightened local inflammation and greater susceptibility to CT infection.

These environmental influences also vary with the menstrual cycle. Female cynomolgus macaques, which share similarities with women in terms of menstrual cycle, anatomy, immune cell population, and vaginal microbiota, were used to explore the interplay between these factors in the FRT.

Methods: The vaginal microbiota, local and systemic inflammation during different phases of the hormonal cycle were examined in 11 female cynomolgus macaques over three months. Additionally, the impact of different vaginal microbiota compositions (with or without *Lactobacillus* enrichment) on CT infection and inflammation was assessed in another set of twelve females exposed to repeated doses of CT. Analysis included profiling cytokines, assessing neutrophil phenotype and abundance, evaluating vaginal microbiota composition, measuring CT load and determining CT-specific IgG levels.

Results: Results indicated that cervicovaginal cytokine levels and bacterial abundances varied with the menstrual cycle, particularly noting a significant increase in cytokines and mature/activated neutrophils during menstruation. After CT exposure, both groups of females (with and without *Lactobacillus crispatus* enrichment) experienced temporary CT infections and developed CT-specific IgG antibodies.

Although *Lactobacillus crispatus* enrichment did not alter the susceptibility to CT infection, it was associated with higher levels of serum-specific anti-CT IgG and increased production of cervicovaginal cytokines compared to the untreated group. Both groups exhibited a higher abundance of mature peripheral blood neutrophils after CT exposure.

Conclusions: These results underscore the complex dynamics between the vaginal microbiota, hormonal cycle, inflammation, and susceptibility to STIs like CT. It highlights the potential of manipulating the vaginal microbiota to enhance immune responses against infections, contributing valuable insights toward developing strategies for STI prevention and improving reproductive health in women.

EP150

Testing the efficacy *Entre Herman@s*, an online intervention to increase PrEP use among Latinx sexual minority men

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Background: Families affect physical and mental health and can be leveraged in health interventions, but this resource has been overlooked for Latino sexual minority men (LSMM). LSMM report that social support from siblings is important and could influence their HIV risk behaviors. Yet siblings have not been engaged in HIV prevention strategies.

Together with St. John's Community Health, we used the Information-Motivation-Behavioral Skills model to create a sibling-based intervention, *Entre Herman@s*. It trains brothers and sisters of LSMM to promote PrEP. It has three modules: PrEP conversation (module 1), sibling motivational interviewing training (module 2), and follow-ups (module 3). In a pilot test, 70% of LSMM started using PrEP.

Methods: We conducted a randomized controlled trial to test the efficacy of *Entre Herman@s*. The three modules targeted all three IMB constructs (Figure 1).

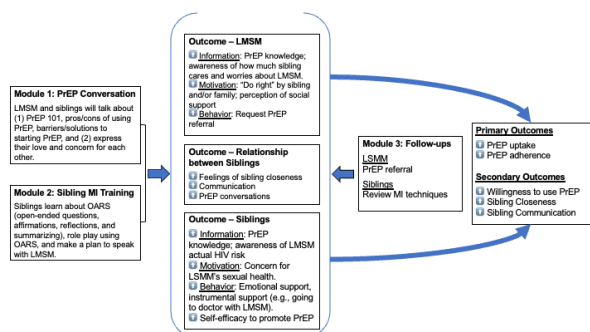


Figure 1.

Participants were randomized either to the intervention or attention control group (AC). The AC group consisted of the same three modules as the intervention, except

those participants talked about vaccines (COVID, MPOX, or Hepatitis A/B). We conducted follow-ups (30 days and 3 months) to determine whether LSMM were using PrEP.

Results: We enrolled 58 sibling pairs for a 12-week intervention. To date, we found that:

1. Of the 11 LSMM who completed the intervention so far, $n=6$ (55%) started using PrEP.
2. Of the 10 LSMM who completed the control group so far, $n=4$ (40%) chose to get a vaccine.
3. $n=30$ (52%) LSMM and $n=29$ (50%) siblings are 21-30 years old.
4. $n=28$ (48%) LSMM were born outside the United States.
5. $n=33$ (57%) siblings report being the sister.

Conclusions: Raw data suggests that the intervention results in greater behavior change than the control group. This implies that sibling-delivered PrEP promotion interventions may work for LSMM. We need to wait for more sibling pairs to complete the intervention to strengthen our findings.

EP151

Psychosocial interventions for GBMSM in rural areas to overcoming barriers to HIV testing and treatment

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Background: In Meru County, the implementation of the PEPFAR/USAID/CHAK/EMAC grant facilitated HIV/STI prevention, care, and treatment services for GBMSMs. However, a significant proportion of these services primarily reached young GBMSMs aged 18 to 35 years, leaving those aged above 35 years underserved.

Methods: To address the gap in HIV/STI service uptake among GBMSMs aged above 35 years, the program adopted a mental health intervention "Spaces of Grace". Twelve young GBMSMs were engaged to mobilize 75 older and hard-to-reach GBMSMs. The intervention provided safe spaces facilitated by psychologists where participants shared their experiences and challenges related to sexuality, HIV concerns, mental health punitive laws, and cultural norms.

Results: All 75 GBMSMs received mental health screenings, revealing high rates of depression, as 59 (79%) had depression signs, 9 (12%) Anxiety Disorder, 16 (21%) Substance use Disorder, 4 (3%) Bipolar and 3 (2%) PTSD.

61 (81%) acknowledged that community and internalised self-stigma as the main reason they would not seek HIV/STI services for fear of being identified, 7 (9%) were afraid of testing HIV positive while 7 (9%) held into myths & misconceptions on HIV/STI believing that having unprotected sex with Young MSMs was safer because being young one has fewer sexual encounters. 90% of those with depression reported less likelihood of self-see HIV/Mental health



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services. 56(74%) of the beneficiaries agreed to an HIV test emphasizing the importance of differentiated services to meet their needs.

Conclusions: The "Spaces of Grace" intervention provided valuable insights into the barriers faced by GBMSMs aged above 35 years in accessing HIV/STI services in rural areas. Addressing mental health issues and reducing internalized stigma are critical steps in improving service uptake among this population. Tailored interventions that acknowledge and address the unique challenges faced by older GBMSMs are essential for achieving comprehensive HIV/STI care in rural settings.

EP152

Navigating the complexity of PrEP Use among MSM in South Africa: towards tailored strategies for enhanced persistence

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Background: OUT LGBT Well-being's Engage Men's Health (EMH), a civil society-led programme funded by USAID/PEPFAR, has provided HIV prevention, care and treatment services to MSM in South Africa since 2019. WHO recommends multiple PrEP options including event-driven (ED) PrEP as part of combination prevention approaches. However, definitions and standard indicators to assess PrEP persistence have not been established. South African guidelines only indicate daily PrEP use, with those initiated due for follow-up visits at 1, 4 and 7-months post-initiation. EMH recognises that some MSM use ED PrEP, while others may initiate without intent to persist due to provider and/or peer pressure.

Methods: Of the 13,031 MSM who initiated PrEP with EMH since 2019, 44.6% did not return for any follow-up visits (55.4% crude PrEP persistence). In a sub-group of 2,268 MSM who initiated PrEP between October 2022 and April 2023, and who provided information on their PrEP intention (50%), 1,206 returned for at least one follow-up visit within 8-15 months (53.1% crude PrEP persistence).

Results: Of PrEP service-users with 1+ follow-ups, the majority (87%) indicated an intention for daily PrEP, 3% reported ED PrEP, and 9% indicated not knowing enough to specify their intention. Among those who returned and who indicated an intention for daily PrEP (n = 536), 420 (78%) returned for their 1-month follow-up visit, 181 (34%) returned for their 1-month and 4-month follow-up visits, while only 68 (13%) returned for their 1-month, 4-month and 7-month follow-up visits. There have been no seroconversions among the 1,206 PrEP service-users who returned for 1+ follow-up visits.

Conclusions: Patterns of PrEP use are complex and national guidelines do not account for these complexities. Allowing differentiated PrEP use can accelerate the de-medicalisation and destigmatisation of PrEP use. In the absence of rigorous case management, a return-

ing PrEP-user may be the best indication of where PrEP is needed and will be used. PrEP programs should assess service-users' PrEP intention at each visit, and support their persistence goals, including ED PrEP. South African PrEP guidelines, clinical tools and dispensing practices should be revised to accommodate real-world patterns of PrEP use.

EP153

The role of healthcare-related experiences in willingness and preference for long-acting injectable PrEP (LA-PrEP) among transfeminine persons in the US Transgender Women's Internet Survey and Testing (TWIST) study

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Background: Transgender women and transfeminine persons (TWTFP) experience disproportionately high HIV rates; negative healthcare experiences- including access barriers, stigma/discrimination; and low uptake of and adherence to HIV pre-exposure prophylaxis (PrEP). Long-acting injectable PrEP (LA-PrEP), FDA approved in 2021, holds the potential to expand PrEP coverage. We examined the role of past healthcare-related experiences on willingness and preference for LA-PrEP among a US nationwide sample of TWTFP.

Methods: Sexually active TWTFP age 15+ were recruited 6/2022-10/2023 via social media advertisements for a cross-sectional online sexual health survey. Analyses were restricted to TWTFP who did not report prior HIV diagnosis, had not taken any PrEP modality in the past year, and with non-missing key variables. Participants reported their willingness to use LA-PrEP and ranked preference of LA-PrEP versus on-demand and daily oral PrEP. Recent healthcare-related experiences (Table 1) were explored as correlates of willingness and preference to use LA-PrEP using multivariable Poisson regression with robust variance estimation, controlling for demographic and sexual risk variables.

Results: Among respondents who were willing to use any PrEP modality (48.6%; n=735/1513), 53.7% (n=395/735) were willing to use LA-PrEP, among whom 51.6% (n=204/395) preferred LA-PrEP to oral modalities or were only willing to use LA-PrEP.

Discussing sexual health with a healthcare provider (HCP) was associated with increased LA-PrEP willingness (adjusted prevalence ratio [aPR]=1.24; 95% confidence inter-

val [CI]=1.01-1.53; p=0.040) and hormone/blocker injection use was associated with LA-PrEP preference (aPR=1.35; 95% CI=1.00-1.81; p=0.049). (Table 1)

	Willing to Use LA-PrEP* (n=735)					Prefer LA-PrEP over daily oral or on-demand PrEP† (n=393)				
	n (col %)		Adjusted Regression Model‡			n (col %)		Adjusted Regression Model‡		
	Unwilling (n=30; 4.1%)	Willing (n=705; 95.9%)	aPR	95% CI	p-value	Prefer oral modality (n=191; 48.4%)	Prefer LA-PrEP (n=202; 51.6%)	aPR	95% CI	p-value
HCP talked about sex/sexual health, past 12 months	160 (47.1%)	234 (59.2%)	1.24	1.01-1.53	0.040	115 (60.2%)	119 (58.3%)	0.88	1.18	0.438
Hormone/blocker injection use, past 12 months	102 (30.0%)	136 (34.4%)	1.01	0.81-1.29	0.942	51 (26.7%)	68 (41.7%)	1.35	1.00-1.81	0.049
Hormone/blocker pill use, past 12 months	213 (60.2%)	247 (60.2%)	0.94	0.76-1.16	0.573	110 (57.4%)	137 (67.2%)	1.18	1.01-1.38	0.289
Bottom surgery, ever	39 (11.2%)	58 (14.2%)	1.04	0.80-1.41	0.797	36 (18.9%)	22 (10.9%)	0.71	0.44-1.13	0.151
Anticipated healthcare stigma, high vs. low	186 (55.3%)	206 (52.7%)	0.89	0.75-1.07	0.907	93 (51.3%)	110 (53.9%)	1.02	1.38-0.87	0.871
Any enacted healthcare stigma	96 (28.2%)	115 (29.1%)	0.99	0.79-1.25	0.909	52 (26.7%)	55 (26.7%)	0.87	1.21-0.417	0.417

* Among those willing to use any PrEP modality
 † Among those willing to use LA-PrEP
 ‡ Adjusted models controlled for all variables listed, as well as age, race/ethnicity, food insecurity, condomless anal sex, and sex exchange.

Table 1. Prevalence & associations between healthcare-related experiences and long-acting injectable PrEP (LA-PrEP) willingness and preference among transgender women in the US Transgender Women's Internet Survey (TWIST), 2022-23.

Conclusions: Many healthcare-related experiences, including stigma, were not associated with LA-PrEP willingness and preference. Approximately half of TWTFP expressed willingness to start LA-PrEP and greater willingness was associated with HCP sexual health discussions, suggesting the potential of LA-PrEP in combination with HCP action to expand PrEP coverage. TWTFP with gender-affirming care injection experiences may be well suited for LA-PrEP uptake.

EP154

Knowledge, attitudes, and perspectives of women who have migrated from Africa toward HIV pre-exposure prophylaxis (PrEP) in family planning centers in Paris, France

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Background: In France, women who have migrated from sub-Saharan Africa are disproportionately affected by HIV. Despite accounting for 20% of new HIV diagnoses in France, women from sub-Saharan Africa represent just 2% of pre-exposure prophylaxis (PrEP) users. This clear gap in HIV prevention in France must be addressed by understanding the experiences of women who have migrated from Africa and their knowledge and attitudes toward PrEP.

Methods: We conducted an exploratory qualitative study via focus groups and a brief demographic survey with women who had migrated from sub-Saharan Africa. Focus groups occurred from November 2023 to February 2024 within the Lariboisière family planning center (FPC) in

Paris, France. The social ecological model (SEM) informed the discussion guide, which explored women's PrEP experiences and various determinants on the individual, provider/system, and community level. Data were coded using Dedoose software.

Results: Five focus groups were conducted (N=19). The mean age of participants was 30.3 (IQR 28-37). Eight African countries were represented, and the average time in France since migration was 3.6 years. On the individual level, women reported challenges negotiating HIV prevention (multiple partners, condom use) and concerns about HIV and other sexually transmitted infections (STIs). The majority of women had never heard of PrEP and cited potential difficulties with adherence to daily pills and concerns about side effects. At the provider/system level, nearly all women reported positive experiences with the French healthcare system and a high level of trust with their providers, especially at the FPC. On the community level, there was a lack of accurate knowledge regarding HIV transmission. Women often stated pervasive misconceptions about HIV transmission that they attributed to culture-wide beliefs and stigma at the community level. Nonetheless, most women expressed positive attitudes toward PrEP and advocated for dissemination of PrEP information to their peers.

Conclusions: There was high PrEP interest among women after being informed about it. However, unawareness of PrEP was identified along with social and cultural factors that may hinder PrEP uptake. Culturally-sensitive interventions may address HIV prevention gaps. Future studies should implement and evaluate strategies to increase PrEP awareness and uptake among women from Africa in France.

EP155

Breakthrough mpox cases following NVA-BN vaccine

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Background: Since May 2022, 305 individuals were reported with mpox in Israel, during this period, 9,814 men were vaccinated, of those- 6,887 received a single dose and 2,927 received the second dose. MVA-BN vaccines are provided without cost in major clinics.

This cross-sectional study aimed to compare those who were diagnosed with mpox after they had been vaccinated with MVA-BN with those who had not been immunized.

Methods: The national registry of mpox in Israel was cross-checked with the national vaccine registry to identify those who were diagnosed after receiving the vaccine. Breakthrough infection was defined when clinical signs of mpox start more than 10 days after receiving the first dose of NVA-BN vaccine.





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Results: Vaccination status was recorded for 257 (84.1%) of all men diagnosed with mpox patients. Eleven received the vaccine less than 10 days before the first mpox symptoms were recorded, and they were excluded.

Altogether, 20 of 246 (8.8%) had a breakthrough infection. Those who had breakthrough diagnoses were more commonly older than those who were not vaccinated, with a greater number of cases who were older than 40 years, thus possibly vaccinated also against smallpox.

Regarding the clinical symptoms, those who were vaccinated were less likely to experience rash (75.5% vs. 97.0%, $p=0.02$), lymphadenopathy (35.5% vs. 49.1%, $p=0.03$), headache (15.0% vs. 41.2%, $p<0.0001$) and malaise (20.0% vs. 41.2%, $p=0.03$). No statistical differences were found between the two groups in the rate of HIV or syphilis infections, and anatomical sites of mpox infection.

Characteristics	Vaccinated with 1 or 2 doses N=20 (%)	Non vaccinated N=226 (%)	P
Age	39.2±6.3	33.6±9.0	
Central vs. periphery	19 (90.0)	167 (72.6)	0.07
HIV+	2 (10.0)	43 (18.2)	0.1
Syphilis	3 (15.0)	64 (25.0)	0.5
Rash	15 (75.0)	96 (97.0)	0.02
Rectal symptoms	7 (35.0)	29 (25.2)	0.003
lymphadenopathy	7 (35.0)	56 (48.1)	0.03
Headache	3 (15.0)	47 (41.2)	<0.001
Malaise	4 (20.0)	47 (41.2)	

Conclusions: The mpox breakthrough diagnoses rate after receiving at least a single dose of MVA-BN vaccine was 8.8%. Those who were vaccinated had a milder disease regardless of HIV. The relatively higher rate of breakthrough among older individuals is alarming and require further studies with a bigger cohort.

EP156

How do drug policies influence HIV prevention among people practicing chemsex and what protection strategies they use?

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Background: Chemsex is a practice associated with gay men and queer culture that involves the voluntary use of certain substances with the intention of facilitating, intensifying or prolonging sexual encounters. All people who use drugs, including those who practice chemsex, are affected by drug policies. In general, these policies stigmatize, criminalize, and punishes substance users. What's more, the intersection between drug use, coercive laws on substance possession and a repressive vision of sexuality results in the double stigmatization of people who practice chemsex, what can influence HIV prevention and how people implement prevention strategies.

The aim of this presentation is to describe and analyze perceptions surrounding the influence of drug policies on HIV prevention and protection strategies implemented by people who practice chemsex.

Methods: Based on Rapid Assessment Process, semi-structured interviews lasting approximately 90 minutes were conducted, involving 64 sexually and gender-diverse people practicing chemsex, living in Quebec province, Canada. Subsequently, a thematic analysis was performed.

Results: People who practice chemsex have reported feeling discouraged to talk about their substance use in sexual health services, partly because of the illegal status of certain substances. They also report feeling afraid asking for services from harm reduction services, for fear of being identified as drug users. The people we met also reported implementing several HIV and STIs prevention strategies, including the use of PrEP, frequent screening, learning with peers the techniques for use drugs effectively and safely, and informal communication networks between partners. These informal support networks were created due to the illegality of chemsex practice, to share information about substance use and sexuality, including harm reduction practices related to HIV prevention. Some participants suggested decriminalization of substance use as a harm reduction strategy that would reduce stigma and potentially increase access to prevention services.

Conclusions: Little is known about how decriminalization of substance possession could beneficiate HIV and STIs prevention among people involved in chemsex, because they rarely use harm reduction-based and other services for substance users. Support for activist organizations would facilitate the sharing of good harm reduction practices based on users' own experiences.

EP157

Maximizing partnership for sustainable livelihood geared towards resilience for orphans and vulnerable children within CoSMO (Consolidating Systems and Services for the Management of Orphans and Vulnerable Children in Cameroon) project

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Background: Partnership aids in increasing resources to maximize sustainable interventions for Orphans and Vulnerable Children (OVC), which has been a challenge for OVC programs in Cameroon since 2014. Launched in January 2023, the CoSMO (Consolidating Systems and Services for the Management of Orphans and Vulnerable Children in Cameroon) project funded by USAID/PEPFAR and implemented by the National Episcopal Conference of Cameroon (NECC) with the goal to enhance wellbeing for HIV/AIDS OVC households towards resilience, integrat-

ed advocacy and partnership in its strategy to expand sustainable livelihood service delivery to most economically vulnerable HIV positive households. This abstract illustrates progress made towards achieving this objective as a result of transformative partnerships.

Methods: Between January and September 2023, CoSMO implemented the following activities;

- Community-based assessments to map-out household economic vulnerabilities using standard project tools by trained case workers.
- Designed intervention plans in collaboration with households based on needs identified.
- Allocated funds to support/create livelihood activities.
- Organized micro-planning sessions with stakeholders to leverage additional support.
- Liaised and referred households to partners based on expertise.
- Followed-up implementation of activity for quality and completion.
- Monitor households' post-intervention to evaluate resilience.

Results: From 16,141 HIV/AIDS affected households assessed, 80% were in need in 3 major livelihood areas. 63% were served using project funds. Collaboration with 12 stakeholders served an additional 7% of households not served by CoSMO (Figure 1).

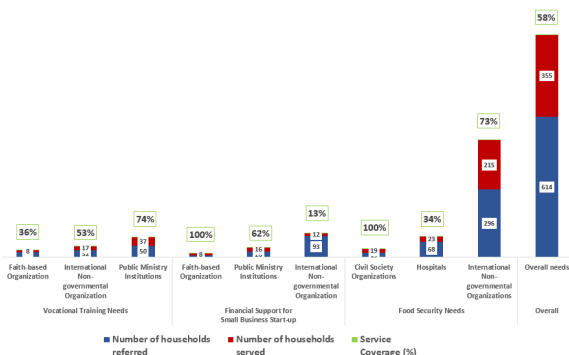


Figure 1. OVC Households supported with livelihood interventions through CoSMO partnership and referral system.

Through Feedback, Complaint, and Response Mechanism, CoSMO participants appreciate the impact of partnership efforts; "I thank the project for giving me hope to live again through advice concerning my health; the support from the Douala Council to boost my business which helped me to be financially stable". (female, 40-49 years).

Conclusions: Strong stakeholder collaboration fosters economic empowerment for OVC households, thereby, facilitating access to sustainable livelihood for improved wellbeing geared towards resilience while reducing OVC risk in acquiring or further transmitting HIV/AIDS.

EP158

Creating HIV prevention cohorts among vulnerable populations in varied geographies – a compelling model in the Indian context uniting diverse stakeholders

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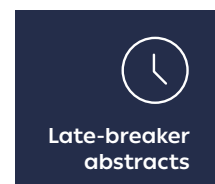
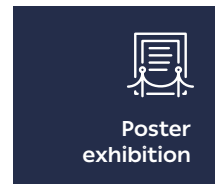
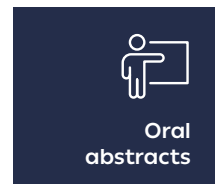
Background: India represents the second largest HIV-epidemic in the world with 2.4 million people living with HIV. While national incidence estimates continue to be low, evolving epidemiology, compounded with variability of circulating virus, host-genetics and population-behaviors, calls for concerted research and development (R&D) efforts towards locally-relevant prevention tools.

Methods: Cohorts for HIV Resistance and Progression in Indian Children and Adults (CoHRPICA), co-funded by Department of Biotechnology, Indian Council of Medical Research and IAVI, aimed to create a clinical research consortium in India to establish longitudinal HIV-cohorts across geographies and vulnerable populations, and enable resources for HIV R&D.

Regular stakeholder/expert consultations (n=13) were conducted to devise strategies for setting-up the model and ensure scientifically and ethically-sound clinical research.

Results: The key strategies are summarized below:

- **Collaborations** between various Departments/bodies/divisions under Government of India ministries of Science & Technology (MoS&T) and Health & Family Welfare (MoHFW) ensured research is as per public health needs. Partnership with National AIDS Control Organization, MoHFW was also critical to align participant procedures with the standard-of-care.
- A stringent **Governance and Management framework** was established with an independent *Program Oversight Committee* (POC) to provide strategic guidance for enhancing impact. POC was supported by a *central coordination unit*, comprising of funder representatives and lead Principal Investigator, to enable harmonization of systems/processes and capacity strengthening as per global best-practices/national guidelines, risk-management and quality-management. *Global/national advisors* were engaged to enable scientific rigor aligned with global advancements.
- A **network of 11 Clinical Research Centre (CRC) sites** was rationally selected to ensure geographical representation and access to population-of-interest, including 4 *satellite sites* for access to population from emerging pockets of incidence.
- **6 biorepositories** were established to ensure proximity to CRC sites for sample integrity and were linked to a **central biorepository** for long-term management and sample access.





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- An online **database**, managed by **central data management unit**, was developed to facilitate real-time data entry/monitoring.

Conclusions: The study enabled a strengthened network of 11 CRC sites to conduct HIV-trials and clinical research. It facilitated access to 1643 individuals impacted by HIV, 52,000 quality-controlled samples and systematical-ly-collected clinical-laboratory-socio-behavioral data to promote HIV-prevention research and characterize enriched population for HIV-prevention trials.

EP159

HIV stigma and treatment interruptions among people living with HIV in Zimbabwe: an age-stratified analysis

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Background: Continuation of antiretroviral therapy (ART) is crucial for the health of people living with HIV (PLHIV) and to achieve Undetectable=Untransmittable (U=U), but the relationship between stigma and ART use remains underexplored among young people in many high-HIV burden settings. In response, we examined stigma and their associations with HIV treatment interruptions among younger (18-24 years) and older (25+ years) PLHIV in Zimbabwe.

Methods: Data were collected as part of the PLHIV Stigma Index 2.0, implemented by PLHIV-led organizations in Zimbabwe in partnership with GNP+, ICW and UNAIDS. Treatment interruptions were based on reporting ever interrupting or stopping ART. Internalized and anticipated stigma scores were categorized into levels of "no", "low", "moderate" and "high" stigma. Modified Poisson regression models estimated associations between categorized stigma scores and treatment interruptions. Stratified analyses explored age-specific associations among younger and older adults.

Results: Among 1347 PLHIV who ever initiated ART, 20.9%(36/172) of younger adults and 10.3%(121/1175) of older adults reported treatment interruptions. Increasing levels of internalized stigma were associated with a higher prevalence of treatment interruptions (low:adjusted prevalence ratio (aPR) 1.7, 95% confidence interval(CI) 1.1-2.6, moderate:aPR 2.6, 95%CI 1.7-3.9, high:aPR 3.5, 95%CI 2.1-5.9) (Table 1).

Anticipated stigma showed similar associations (low:aPR 2.2, 95%CI 1.5-3.4, moderate:aPR 3.2, 95%CI 1.8-5.7, high:aPR 4.9, 95%CI 2.8-8.7). Both forms of stigma were associated with treatment interruptions among older adults, while only anticipated stigma was associated with ART interruptions among younger adults.

	Overall (n=1347)		Young adults (18-24 years) (n=172)		Older adults (>24 years) (n=1175)	
	aPR ¹	95% CI	aPR ¹	95% CI	aPR ¹	95% CI
Internalized stigma²						
No (ref)	-	-	-	-	-	-
Low	1.7	1.1-2.6	1.7	0.66-4.5	1.6	1.0-2.7
Moderate	2.6	1.7-3.9	1.6	0.64-3.8	2.9	1.9-4.6
High	3.5	2.1-5.9	2.7	0.98-7.2	3.7	2.0-6.8
Anticipated stigma²						
No (ref)	-	-	-	-	-	-
Low	2.2	1.5-3.4	3.1	0.90-10.5	2.1	1.4-3.3
Moderate	3.2	1.8-5.7	6.6	1.7-25.9	2.6	1.3-5.1
High	4.9	2.8-8.7	8.6	1.8-41.9	4.4	2.3-8.3

Abbreviations: aPR, adjusted prevalence ratios; CI, confidence interval
¹Adjusting for age, gender, education, employment, racial minority, and belonging to a social network/support group
²Internalized and anticipated stigmas were each modeled using disjoint indicator coding

Table 1. Adjusted prevalence ratios for the association of internalized and anticipated stigma with treatment interruption among PLHIV in Zimbabwe, stratified by young vs. older adults.

Conclusions: Treatment continuation is critical for maintaining viral suppression and achieving the promise of U=U. A strong association between anticipated stigma and treatment interruptions among young adults suggests the need to strengthen stigma-mitigation interventions, including fostering social support and safe spaces within youth networks and healthcare settings. Mitigating stigma appears to be critical in optimizing overall health and wellbeing and limiting HIV acquisition risks among young adult sexual networks in Zimbabwe.

EP160

Elevating community voices for accelerated access to long-acting PrEP: lessons from the Civil Society Caucus of the coalition to accelerate access to long-acting PrEP

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Background: The Coalition to Accelerate Access to Long-Acting PrEP, led by the Global Fund, PEPFAR, Unitaid, UNAIDS, and WHO, along with AVAC as the Secretariat, aims to ensure an accelerated, equitable, sustainable, and collaborative approach to optimizing access to new long-acting PrEP options. Established in 2022, the Civil Society (CS) Caucus of the Coalition, comprised of 21 organizations, advocates for community perspectives in decision-making processes to advance the rollout of long-acting HIV PrEP options.

Methods: From 2022-2023, the Caucus focused on collective literacy through bi-monthly calls, transitioning to engage key stakeholders like PEPFAR and the Medicines Patent Pool. Discussions over time covered country prioritization, generic manufacturing, implementation studies, pricing, and volumes for CAB for PrEP. In February 2024, the

Caucus hosted a virtual symposium with PEPFAR, ViiV, Population Council, and Gilead, to address R&D and access issues for long-acting PrEP products. Objectives included updating on PrEP development stages, setting 2024 R&D priorities, and enhancing stakeholder coordination and information sharing.

Results: These engagements boosted the CS Caucus members' knowledge on long-acting PrEP and enhanced their collaboration with stakeholders such as donors and developers, leading to commitments around consistent and meaningful engagement.

Furthermore, ongoing discussions culminating with the symposium have surfaced broad and specific advocacy actions such as: promoting fair pricing policies for wider access; increased understanding of generic production process and timelines, identification of priority gaps for DVR and CAB for PrEP; the need for proactive engagement with regulators; and need to determine precise demand to ensure production and access for products.

Conclusions: There is collective power in groups such as the CS Caucus, who bring together civil society organizations and networks to collaboratively call for action and drive the process of translating research to real-world implementation. The Caucus will continue to convene stakeholders in CS-led discussions that hold stakeholders accountable to commitments around price transparency, implementing the choice agenda, expeditious manufacturing of generics, and meaningful engagement in implementation studies and programmatic rollout.

EP161

Developing interventions with the voices of trans and gender expansive youth: transcend, triumph, thrive!

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Background: Trans and gender expansive youth face a multitude of barriers to accessing competent PrEP and other services. The CDC states that Transgender people, particularly transgender women, are heavily affected by HIV and transgender women are among the groups most disproportionately affected by HIV in the U.S. Interventions that address the diversity of barriers and social determinants of health identified by these youth are needed. Transcend, Triumph, Thrive or 3T is a PrEP (Pre-Exposure Prophylaxis) intervention specifically for trans and gender expansive youth incorporating their voices to address gaps that impact their PrEP uptake and adherence.

Methods: From 2019 to 2020 focus groups and in-depth interviews were conducted with thirty-eight gender diverse youth ages 16-24 in Philadelphia, Chicago, and Denver. Al-

most half of participants (17) identified as transfeminine. 21% (8) as transmasculine, 32% (12) and nonbinary, and 2% (1) male. The majority (27) of participants self-identified as African American, followed 7 White, 2 Hispanic/Latino, 1 Native American, and 1 Other. Transcripts were analyzed to codify the barriers to seeking PrEP and competent health care expressed by the participants.

Results: Results showed consensus on 6 major content areas to address: mental health, career/job skills, food and housing security, trauma, transitioning, and sexual and reproductive health. They also identified the need to hear from elders or mentors with experience navigating health care. The private website with buckets for each of these topics including video interviews with providers and mentors was created with youth input as a component of the intervention and real time resource.

Conclusions: In developing 3T, youth were clear that PrEP is important but should not be the sole focus of PrEP uptake and adherence interventions. In order to take PrEP they need other priorities addressed, especially nonmedical transitioning needs such as legal services and mental health. To ensure we address the needs of gender expansive youth it is imperative that we include their voices when developing new programming and services.

EP162

Harnessing the power of community involvement to promote access to combined HIV prevention services by rural population in Lufwanyama District of Zambia

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Background: Lufwanyama district is one of the rural districts of Copperbelt province. Copperbelt province is one of the provinces with HIV prevalence (11.9%) above the national average of 11%. The area is large and entirely rural. Due to the community members' low literacy rates and distance, accessing health services becomes challenging. Professional healthcare providers were the only ones providing HIV services, with little to no assistance from lay community counsellors. Only medical personnel such as nurses, midwives, and biomedical laboratory technologists provided and carried out HIV testing services (HTS).

Methods: In September 2023, the USAID DISCOVER-Health project, implemented by JSI, enlisted community lay counsellors to assist in mobilizing and providing HTS inside the communities. After receiving training, the lay counsellors began to mobilize throughout their communities, providing HTS, priority population HIV prevention messaging (PP_Prev), and referrals for voluntary medical male circumcision (VMMC) and pre-exposure prophylaxis (PrEP) commencement. At the baseline and endline, quantitative data was gathered and analyzed using Microsoft Excel.



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Results: As of September 2023, only four out of eleven health facilities have recorded HTS of 115 clients, zero PP_Prev, zero PrEP initiations, and zero VMMC accesses. Following lay counsellors involvement in demand creation and delivery of HIV services, all 11 facilities began reporting combined HIV prevention services. Between October 2023 and March 2024, 8,283 accessed HTS, 1,450 accessed VMMC, 4,563 PP_Prev, and 347 accessed PrEP. Facilities expanded from 4 to 11 (275%). HIV services access expansion as; HTS by 720%, PP_Prev by 4563%, PrEP by 347%, and VMMC by 1450%.

Conclusions: The rural people of Lufwanyama have greater access to combined HIV prevention programs because of community participation through the deployment of community lay counsellors. To lower the incidence rate of HIV in the community, this approach advocates providing comprehensive HIV prevention services to all underprivileged areas.

This approach is recommended to be utilization in various rural parts of the Zambia for the country to attain the UNAIDS goals by 2030.

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HIV self-testing intervention as a hope to reduce HIV among women vulnerable to HIV in Kazakhstan

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Background: Cis- and transgender women who exchange sex and use drugs (WESUD) represent a population that is highly vulnerable to HIV. High levels of stigma from community and healthcare providers are significant barriers to in-clinic HIV testing. A user-controlled HIV self-testing (HST) is a promising way to increase testing. The AEGIDA project in Kazakhstan was designed to support HST among this group.

Methods: The AEGIDA project adapted an evidence-based intervention (TRUST) to support consistent HIV testing among WESUD in Almaty, Kazakhstan. Between 2021-2024, we built partnerships with female advocacy non-profit organizations in Almaty, Kazakhstan. Organizations were actively involved in adaptation and participant recruitment. Over three hundred (N=305) WESUD completed screening interviews; 142 were eligible; 90 women enrolled in the study, completed baseline survey and received four session intervention. Sixty women were randomized to the intervention arm and received four structured sessions delivered by trained facilitators on self-care via HST; 30 women were randomized to the control arm and received health self-screening intervention.

Results: The Aegida project shows that HST as a prevention tool is feasible and acceptable for WESUD in Kazakhstan: 87.8% participants reported being able to do an HIV self-test at home, 88.9% would prefer to self-test and read the results themselves, 92.2% would seek help from the clinic if the test is positive. During intervention, participants expressed interest in learning how to conduct self-testing for HIV, making plans for taking tests in private spaces, and plans for dealing with positive tests. Over two-thirds (68%) of participants who practiced HST were willing to share information about it and educate their friends, or co-workers. This supports prior research that WESUD are interested in peer education and communication around HST and peer training is an important route of HST dissemination.

Conclusions: Aegida, which focused on HST training, may be an important way to engage WESUD in HIV testing and prevention/care and to improve their overall health. Our findings highlight the importance of dissemination of locally adapted and piloted HIV prevention/care interventions and partnerships with local experts.

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HIV incidence and transmitted drug resistance among YMSM in Rio de Janeiro, Brazil: findings from Conectad@s, a mixed-method study

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Background: Young sexual and gender minority populations bear a disproportionate burden of HIV. Monitoring HIV incidence and transmitted drug resistance (DR) in populations at highest risk helps optimize prevention and treatment strategies. We reported the HIV acute viral infections, estimated HIV incidence, and characterized transmitted DR among young cis/trans men and non-binary people assigned male sex at birth who have sex with men (YMSM) in Rio de Janeiro, Brazil.

Methods: The Conectad@s Study recruited YMSM aged 18-24 years through respondent-driven sampling between November/2021-October/2022. Fourth-generation HIV rapid testing was done at baseline and quarterly. Genotypic resistance testing was performed at baseline or at diagnosis occurring at a 48-week follow-up. The Stanford database characterized DR mutations.

Results: Of 409 participants (41.7% Black, 60.4% secondary education or lower, median age:21 years [IQR:20-23]), 0.8% were on PrEP at baseline. Among 371 with a negative HIV rapid test at baseline, 2 were identified as acute infections (positive HIV-RNA/negative 4th generation rapid test antibodies). Overall, 40 (9.8%) participants were living

with HIV at baseline, and 20 were newly diagnosed (including the 2 acute infections). Of the 20 participants with a previous HIV diagnosis, 17 (85%) were on antiretroviral therapy (ART).

During follow-up, 6 participants acquired HIV (1 acute infection): 2 reported irregular PrEP adherence and 4 had no PrEP prescription before diagnosis. HIV incidence was 1.96 per 100 person-years (95% confidence interval:0.88-4.36).

Genotyping was performed for 28 participants with HIV-RNA>1,000cps/mL (4 with previous ART prescription).

Most (n=26, 92.8%) had subtype B. One NRTI mutation (41L), 3 NNRTI mutations (103N/106I), and 2 INSTI accessory mutations (157Q/230R) were identified, including one dolutegravir-related mutation (participant with previous ART exposure). There was no major/accessory mutation for IP/r. No DR mutations were identified in participants with previous PrEP/PEP prescriptions.

Conclusions: Our results highlight high HIV incidence and low levels of PrEP use among YMSM in Rio de Janeiro. Findings underscore the need for prevention strategies tailored specifically for sexual and gender minority populations at an early age, including expanding sex education and access to PrEP. Continuous INSTI surveillance and improving adherence to HIV treatment are critical to strengthen HIV cascade of care especially among youth.

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HIV prevention strategies among MSM during chemsex: a Latin American approach

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Background: The practice of chemsex among Latin American gay, bisexual and MSM has the potential to increase new HIV cases given the dynamics of sex practices with stimulant drug use. Qualitative research was implemented to find out if there are HIV prevention strategies among chemsex users, particularly methamphetamine users.

Methods: From November 2023 to March 2024, we conducted 35 semi-structured interviews (COL 8, CR 7, BRA 10 and MEX 10) and three focus groups (BRA, MEX and COL) with MSM who practice chemsex, more than half living with HIV and one third were PrEP users. The analysis followed the steps of grounded theory.

Results: Most participants expressed having sexual health-related practices, including those living with HIV. Among those on PrEP and HIV-negative, good adherence to PrEP and serosorting were common.

Among the positive, having a good adherence to ARVs and harm reduction strategies were popular. Condom use was practically nonexistent in both groups, use of lub for anal intercourse was limited and considered almost useless. Most participants expressed having some information about HIV, including access and efficacy of PrEP, ARVs and harm reduction but more information was desired.

Conclusions: Chemsex users in Latin America have information about HIV prevention but there is a need to have access to the latest and complete information and strategies available in order to have more choices to protect themselves, including those already living with HIV. Access to PrEP and TASP is crucial for MSM using stimulant drugs for sex as the practice of chemsex becomes more popular in the region.

EP166

Evaluation of Pre-Exposure Prophylaxis (PrEP) provision and clinical attendance patterns in London Sexual Health Services

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Background: Pre-exposure prophylaxis (PrEP) for prevention of HIV acquisition became available on the National Health Service (NHS) in England in 2020. However, data are limited on how sexual health clinics perform PrEP provision alongside other prevention and sexually transmitted infection (STI) services. We present the STI treatments and vaccine outcomes of approximately 36,000 PrEP users from four community centres in London over a twelve-month period.

Methods: This is a retrospective analysis of clinic attendances from secondary clinic data from 10 October 2022 to 9 October 2023. PrEP provision, patient demographics, and STI diagnoses for chlamydia, gonorrhoea, and syphilis, and vaccinations were defined by clinical codes used for the Genitourinary Medicine Clinic Activity Dataset (GUMCAD). PrEP is coded at the point of dispensing PrEP, therefore a PrEP user may not have a PrEP code associated at every attendance. Analysis is descriptive and uses STATA v17.

Results: There were 194,117 attendances, of which 23.7% (n=45,979) had associated PrEP activity (either starting or continuing PrEP). Table 1 demonstrates patient demographics for those attendances with PrEP activity



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and non-PrEP activity. Of the attendances for PrEP; 12.7% (n=5846) received a vaccine, 7.2% (n=3,316) had a *Chlamydia trachomatis* diagnosis, 9.6% (n=4,392) had a *Neisseria gonorrhoea* diagnosis, and 1.7% (n=580) had a *Treponema pallidum* diagnosis.

		PrEP-related attendance (n=45,979)	Non PrEP-related attendance (n=148,518)
Median age in years (interquartile range)		35 (29-43)	32 (26-41)
Country of birth	UK born	21,050 45.8%	76,848 51.9%
	Non UK born	24,894 54.2%	71,325 48.1%
Ethnicity	White	31,818 69.3%	87,683 59.1%
	Mixed	1,405 3.1%	6,066 4.1%
	Asian	3,123 6.8%	11,515 7.8%
	Black	1,791 3.9%	13,196 8.9%
	Other	7,807 17.0%	30,026 20.2%
Gender and sexual orientation	Cis men-who-have-sex-with-men	40,358 87.8%	57,184 38.6%
	Cis heterosexual male	4,131 9.0%	30,498 20.6%
	Cis women	573 1.2%	53,544 36.1%
	Non binary	44 0.1%	192 0.1%
	Transgender male	281 0.6%	2,515 1.7%
	Transgender women	557 1.2%	4,240 2.9%

Table 1. Demographics of service users attending sexual health services in London for PrEP-related and non-PrEP-related attendances.

Conclusions: The proportion of PrEP attendances with other sexual health needs is high. These findings underscore the importance of tailoring PrEP consultations to meet service users' diverse needs and providing PrEP within a holistic package of HIV prevention and sexual health care. Our data are limited to STI needs at the point of PrEP dispensing and may underestimate need amongst all existing PrEP users. More detail on PrEP user needs would be helpful in the planning of future service provision.

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Perception and preferences for long-acting injectable or daily oral PrEP among young men who have sex with men (YMSM) in Nigeria

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Background: Men who have sex with men (MSM) have the highest HIV prevalence in Nigeria, reaching 25% in 2020. Despite this, uptake of daily oral PrEP has remained low among this population. Long-acting injectable PrEP

(LAI-PrEP) offers promise of HIV prevention without the challenge of daily drug adherence. However, its acceptability has not been widely studied in Nigeria. This study therefore aimed to assess the knowledge, perception, and preferences for LAI-PrEP among young MSM (YMSM) in selected states in Nigeria.

Methods: A cross-sectional study utilized an interviewer-administered LAI-PrEP questionnaire to collect data from participants in the ongoing NIH-funded Intensive Combination Approach to Roll back the Epidemic (iCARE) study in four states in Nigeria from June to December 2023. iCARE engages YMSM aged 15-24 years via social media (WhatsApp, Facebook, and Grindr) and peer navigation to increase HIV testing. Descriptive data analysis was completed in STATA.

Results: A total of 1,301 HIV seronegative YMSM completed the questionnaire. The mean age was 21.8 years (SD=3.6), 57% had tertiary education, only 3.9% were on oral PrEP, and none on LAI-PrEP. Most (60.9%) had adequate general knowledge of PrEP while 74.7% had not heard of LAI-PrEP before the survey. Most expressed interest in taking oral PrEP (71.4%) and LAI-PrEP (88.4%). Perceived benefits of oral PrEP or LAI-PrEP were similar, including protection against HIV (61.8% and 68.6%) and ease of use in comparison to other HIV prevention methods (40.8% and 59%). In addition, LAI-PrEP was viewed as providing longer-term protection than other methods (58.3%). The most common concerns about oral PrEP were taking a daily pill (70.1%), side effects (49.2%) and need for clinical contacts for refills (42.2%), while for LAI-PrEP were injection-site pain (72.7%), side effects (64.7%) and cost (48.8%). In a comparison of HIV prevention options alone and in combination, the most prevalent preference was use of condoms and LAI-PrEP together (42.1%); followed by LAI-PrEP alone (24.3%). Only 2.8% preferred to use oral PrEP alone.

Conclusions: Most respondents had a positive disposition towards PrEP with higher preference for LAI-PrEP than oral PrEP. Implementation of PrEP in Nigeria should factor-in preferences of high-risk groups such as YMSM.

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Strides made by ICAP Cameroon in HIV case finding in the Northern Regions of Cameroon from October 2019 to September 2023

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Background: ICAP Cameroon, a non-profit at Columbia University is in the fifth year of the implementation of the programmatic support award project in 85 Health facilities in the 3 Northern Regions of Cameroon, a project Funded by PEPFAR Via the U.S Centers for Disease Control and Prevention (CDC). ICAP supporting the Ministry of Health using community and facility based interventions as contributed significantly in increasing the number of active users of ART (TX_CURR).

Methods: We did analysis of data reported by health facilities in DATIM using a graph to describe the trend of the TX_CURR over time and a multiple linear regression model to analyze the relationship between the TX_CURR and the variables that capture new initiations (TX_NEW), returns on treatment (TX_RTT) and drop out of treatment for various reasons (TX_ML).

Results: The number of PLHIV on ART increased from 44,971 in the period September to December 2019 to 71,966 in the period July to September 2023, a 60% increase. During the same period a loss of 17,885 PLHIV on ART was recorded. The results of the linear regression indicates a statistically significant increase of approximately 1,939 PLHIV in the TX_CURR in each quarter ($p < 0.001$), which is significantly associated with the enrollment of new PLHIV each quarter ($p = 0.009$). Loss of PLHIV on ART due to various reasons also contributed to a statistically significant reduction in the TX_CURR ($p < 0.001$). Returns to treatment after stopping didn't have a statistically significant influence on the TX_CURR ($p = 0.643$).

Conclusions: Huge strides have been made in case finding through innovative strategies and enrolment on ART has increased by 60% from 2019 to 2023 as against 99 per cent theoretical increase had losses of PLHIV of at least 17,885 not occurred during this period. While aggressively testing and identifying new PLHIV, attention must be paid to strategies that retain PLHIV in care.

EP169

Barriers and facilitators to pre-exposure prophylaxis uptake among Black/African American men who have sex with other men in rural Iowa, United States: a COM-B model analysis

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Background: In 2022, men who have sex with other men (MSM) accounted for 73% ($n=120$) of new HIV diagnoses in Iowa. Non-Hispanic Black/African Americans were over eight times more likely to be diagnosed with HIV than non-Hispanic white Iowans. To address this disparity in HIV incidence, one of the four strategic goals of the US government's 'Ending the HIV Epidemic' (EHE) initiative is to expand coverage of pre-exposure prophylaxis (PrEP). Recent data showed that 8,260 Iowans would benefit from PrEP, but only about 23.3% had active prescriptions in 2021, and Black Iowans were less likely to engage with PrEP services.

Against this backdrop, this study sought to identify the barriers and facilitators to effective uptake of PrEP among Black/African American MSM in rural Iowa.

Methods: Following informed consent, in-depth semi-structured interviews were conducted with 12 Black MSM aged 20-42 years in two rural counties between March and September 2023 to understand barriers and facilitators to PrEP use in the Black MSM community. Broad themes were identified from the interview transcripts and analyzed inductively following the Capability, Opportunity, Motivation, and Behavior (COM-B) model for behavior change.

Results: Drawing on the COM-B model, lack of medical insurance associated with socioeconomic status and limited PrEP awareness affected Black MSM's capability, while PrEP-related stigma (e.g., sexual promiscuity) and fear of distrust among partners limited their opportunity to access and use PrEP.

Also, doubt about PrEP effectiveness and anticipated side effects demotivated some Black MSM from accessing PrEP. Government investment in PrEP to cover all modalities for low-income earners, targeted PrEP education (including flyers placed in strategic spots like barber's shops), healthcare providers' buy-in, and recommendations were some strategies suggested to increase PrEP uptake in the Black MSM community.

Conclusions: To reduce the current disparity in HIV incidence and prevalence and to achieve the EHE goals of expanding PrEP coverage in Iowa, efforts should be directed towards the provision of PrEP education, low-cost or free PrEP services, healthcare providers' training on cultural competence, and the development of culturally affirming strategies to deliver PrEP to the Black MSM community.



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Successful integration of recent HIV infection in routine HIV testing service to identify risk factors among newly diagnosed HIV individuals aged 15 years and above in North-Eastern Uganda, 2020-2023

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Background: Despite Uganda making significant progress in reducing HIV incidence per 1000 population from 3.25% in 2010 to 1.38% in 2019, still more than 53,000 new HIV infections occurred in 2019.

In this study, we integrated HIV recency testing in routine HIV testing services (HTS) to identify risk factors for recent infection among newly diagnosed HIV individuals aged 15 years and above in Northeastern Uganda.

Methods: From May 2020 to July 2023, HIV recency testing among newly diagnosed HIV-positive individuals aged 15 years and above was integrated into routine HIV HTS at 23 Health facilities in 14 districts of North-eastern Uganda. Newly diagnosed HIV-positive individuals were counseled on HIV recent testing and those that consented had a sample drawn and tested for HIV recent infection using Asante Rapid Tests for Recent Infection (RTRI). The clients who consented to recency provided an extra blood sample that was analyzed centrally. Clients with recent RTRI results and unsuppressed viral load results (>1000 copies/ml) were classified as recent infections as per the RTRI testing algorithm. Data was collected from electronic medical records and cross-checked with the HTS registers for completion and accuracy. logistic regression was used to identify the association between recent infection and sociodemographic variables.

Results: A total of 1,098 persons were offered recency testing. Of these, 12.84%(n=141) had a recent infection, of which 66.7% (n=94) were female and 61.7%(n=87) were identified individuals tested by Health workers from low-level facilities. The Odds of having an HIV recent infection were higher among those aged 20-29 [Odds ratio (OR); 1.46, 95% confidence interval (CI):1.00-2.14, P=0.047], Never married/being single [OR: 1.42, 95% CI:0.89-2.26, P=0.137], conducting the recency test within the community rather than at the facility [OR 1.43, 95%CI:1.00-2.04, P=0.04], using health worker-initiated testing and counseling [OR; 1.07, 95% CI: 0.65-1.76, P=0.78].

Conclusions: Conducting recency testing within the community, being young aged 20-29, and never married/single was associated with a higher risk of having a recent HIV infection. Therefore, using patient-centered approaches such as community testing approaches while scaling up HIV prevention interventions among these high-risk populations can prevent new infections to achieve epidemic control.

EP172

Factors associated with willingness to participate in future clinical trials of long-acting PrEP implants for HIV prevention among adolescent girls and young women in Kampala, Uganda

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Background: Adolescent girls and young women (AGYW) remain at a substantial risk of HIV infection globally. There are many experimental prevention products at different stages of development making AGYW potential volunteers for future efficacy trials. We evaluated willingness to participate (WTP) in future clinical trials of long-acting PrEP (LAP) implants among AGYW at a high risk of HIV infection in Kampala, Uganda.

Methods: From January to October 2019, we conducted a cross sectional survey nested within an AGYW cohort at risk of HIV acquisition. Inclusion was having HIV negative test results, age of 14-24 years old, willing to use contraception, negative for Hepatitis B, not being pregnant and at least 9 months stay in the study area. Participants completed a willingness to participated (WTP) questionnaire for hypothetical future trials of LAP at 9 months. Multivariate logistic regression models were fitted to estimate odds ratios and the 95% confidence intervals of independent predictors associated with WTP in future clinical trials of LAP.

Results: We screened 523 participants of which 285 (62%) were eligible and enrolled. The median age of our study was 20 years, interquartile range 19-20 years, 144 (52%) reported at least a secondary level education, 163 (57%) were single or never married and 114(40%) had one child. Most participants had one or more male partners 124 (44%), 39 (24%) reported no condom use with new male partners, 124 (93) reported having received payment for sex from a male partner and 95 (33%) reported drinking alcohol before sex in the past three months prior to enrollment.

WTP was associated with having three or more partners (OR2.54,95% CI 1.2-4.98) after adjusting for education level, marital status, number of children and alcohol use before sex in the past three months. In our survey, 131 (46%) reported being willing to participate in an HIV prevention study of LAP and 154 were not willing.

Conclusions: Despite some hesitation, nearly half of the AGYW enrolled in this study expressed WTP in future clinical trials of LAP implant. Experience with contraceptive method with similar mode of delivery may encourage WTP in future clinical trials.

EP173

Key population sensitivity training package: a crucial DSD model in optimizing HIV services for key populations in public health facilities

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Background: In Zambia, key populations face perpetual stigma and discrimination, factors which exacerbate the high risk of HIV infection among the populations. In this paper, key populations include men who have sex with men (MSM), female sex workers (FSWs), and transgender persons (TGs). These factors limit the populations' access to much-needed healthcare services and equal access to legal and social services.

Failure to respect human rights and a lack of legal understanding expose key populations to abuse and violation of their rights.

Methods: The USAID Controlling HIV Epidemic for Key and Underserved Populations (CHEKUP II) Activity works to provide comprehensive health services to key and underserved populations in Zambia. As part of service delivery, we trained 213 in key population sensitivity. The training comprised 140 client advisors and 75 health service providers. The training package includes stigma and discrimination, sexual and reproductive health, rights of all clients clinical and interpersonal skills on providing services to respond to the needs of KPs. The Activity further employed service data analysis and qualitative approaches to evaluate the impact of care, attitude, and support provided to KP clients by Wellness Center staff and client advisors.

Results: The number of KP individuals who tested for HIV increased by 292%, while the number of KP individuals who tested positive for HIV increased by 137%. The linkage rate to ART services increased by 98%, while 539% of people were newly enrolled on pre-exposure prophylaxis. As more key populations continue to access services at wellness centers, more inclusive, person-centered care and support towards the KPs are evident. Healthcare providers and client advisors have developed a fuller understanding of the need for inclusivity in the delivery of health services.

Conclusions: The review asserts that building diversity among providers and Key populations through key sensitivity training enables self-reflection about stigma and discrimination in community and clinical settings, increasing access to prevention and treatment services. This intervention significantly reduced microaggression against key populations in targeted districts.

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Barriers and facilitators to antiretroviral therapy (ART) access among adolescents and young adults (AYA) with HIV/AIDS in Africa: systematic review

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Background: Antiretroviral therapy (ART) coverage is disproportionately lower among adolescents and young adults (AYA) compared to other age groups. Besides, a growing share of new HIV transmissions in Africa are among AYA. Many African countries experience access related challenges to ART. Hence, this research aims to systematically examine the barriers and facilitators of Antiretroviral Therapy (ART) Access among AYA living with HIV/AIDS in Africa.

Methods: We conducted a systematic search on PubMed, Cochrane, EMBASE, CINAHL and conference databases (International AIDS society, IAPAC, CROI, ICASA). Studies published in English between January 2004 and July 2022 reporting barriers and facilitators to ART access, initiation, and linkage to care among AYA (10-24years) in Africa were included. Two authors independently screened studies for eligibility and quality assessment using The Mixed Methods Appraisal Tool (MMAT).

Results: A total of 120 studies were initially identified. Only 13 studies from 5 countries were eligible for review majority from Uganda (6). None was from a West African country. Barriers cited were grouped into organisational/system, personal, and financial (Table).

Barrier	Reported Examples	Number of studies
Personal	Self stigma/discrimination/blame (e.g feeling ashamed or guilt of having HIV)	3
	Fear of Disclosure, and Side Effects	3
	Knowledge of HIV and treatment	2
	Caregiver decision and health seeking behaviour	2
	Societal Stigma and discrimination (community and clinic)	5
Organisational	Poor linkage or connection of HIV care services	1
	Negative attitude of healthcare workers and adult clients	5
	Long waiting time	1
Financial	Cost of transportation & Cost of time	3

Table.

Stigma and discrimination were most reported barriers to accessing ART services. The creation of AYA community and peer group, community health education on the effectiveness of ART reduces personal and social



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barriers to ART access among AYA. The establishment of youth-friendly clinics, early preparedness of the AYA for adult transitioning, and training of health workers reduced healthcare system/ organizational barriers to access. Besides, family/household-centered and community-led HIV self-testing and linkage, decentralization of HIV will reduce cost of transportation, increase social supports and ART access among AYA.

Conclusions: This review identified major barriers preventing AYA from accessing ART and highlighted interventions that have facilitated initiation, uptake and usage of ART among AYA in Africa. Programs need to consider these accelerating and mitigating factors in improving access to care and treatment for AYA.

EP175

Enhancing HIV exposure awareness: lessons from ISPD/BRIDGE's community-based HIV self-testing (CB-HIVST) initiative and its implications for the Haitian Ministry of Health

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Background: In Haiti, HIV blood test was for decades the only way to objectively determine someone's exposure to HIV. Given the testing requirements, the burden of stigma and fear of needles, many individuals were left out. However, through the lens of health equity, HIV self-testing (HIVST), which is an oral test was introduced in community settings (CB-HIVST) to help fill the gaps in HIV testing services (HTS).

Methods: Description: In January 2019 we collaborated with the National AIDS Control Program of the Ministry of Health to develop HIVST guidelines, data reporting tools and training package. We designed an HIVST assessment tool to better capture eligible individuals. We conducted training sessions for community health workers in collaboration with the National Public Health Laboratory to ensure accurate interpretation of HIVST results. Anyone with reactive HIVST received assistance to freely access HIV blood test to confirm HIV status at a facility of their choice. We conducted community-based sensitization sessions targeting priority populations: male/sex workers/public transportation drivers/communities at the borders/homeless/pregnant women without prenatal care. To strengthen the outreach, we partnered with faith-based leaders and offered HIVST at Voodoo temples/Churches. We participated in interviews to disseminate knowledge about the value/limitations of HIVST.

Results: Lessons learned: The integration of CB-HIVST into the prevention package has helped individuals become aware of potential HIV-exposure in stigma-free

and confidential environment. In FY22_Q1(October-December2021), 598 HIVST were performed including 51% (N=303/598) females and 49% (N=295/598) males; HIVST reactivity was higher among females 9.2% (N=28/303) than males 7.5% (N=22/295).

During the following three quarters (FY22_Q2-Q4), CBHIVST increased steadily to reach a total of 6236 clients with an average of 2079 per quarter; of whom 45% (N=2784/6236) were females and 55% (N=3452/6236) males. HIVST reactivity is higher among females than male 15% (N=408/2784) and 9% (N=311/3452) respectively.

Despite being a nondefinitive result on HIV status, targeted HIVST outreach approach increased individuals access to services by addressing major barriers: transportation fees, waiting time, stigma, blood test.

Conclusions: CB-HIVST has helped bring services to individuals unaware of HIV-exposure. That strategy is relevant to reaching the first 95-UNAIDS goal and needs to be readily available at all borders and in more rural areas nationwide through the lens of health equity.

EP176

Using Good Participatory Practices (GPP) in engaging mobile people for clinical trials participation during the COVID pandemic. A case of the IAVI C100 trial conducted at UVRI-IAVI HIV Vaccine Program

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Background: Good Participatory Practice (GPP) guidelines provide a framework for the effective engagement of communities and stakeholders at different levels including; policy makers, local leaders, health workers in the development and conduct of clinical trials. UVRI-IAVI embraced these guidelines for the success of C100 study. A Phase 1 Safety [MP1] [GN2] and Pharmacokinetics of the Combination Broadly Neutralizing Antibodies, in Healthy American and African adults to evaluate the safety and tolerability of two broadly neutralizing monoclonal human antibodies, when given alone and in combination, intravenously (IV) or subcutaneously (SC) to healthy adults. We share our experience with GPP in this trial, conducted in Uganda during the COVID-19 pandemic.

Methods: Community stakeholder engagement was done following GPP through; consultative dialogue meetings with District Health Teams and community gate-

keepers, to seek for their support, guidance during trial implementation, provide feedback and manage issues that could arise the fact that the study was conducted during COVID-19 restricted environment. A Community Advisory Board (CAB) comprised of 14 members representing health workers, media, policy makers, local and religious leaders, was also engaged in the development of community engagement plan, translation of the study documents into the local language and provided feedback on the myths and misconceptions. Willing participants were invited to the UVRI-IAVI clinic hubs for pre-screening and later screening and enrolment.

Results: Following the GPP framework for meaningful community engagement, the study recruited 21 participants with 99.5% retention.

Lessons learned:

- Under GPP, we aligned trial research priorities with community needs, and observed good community engagement and strong trial retention.
- Individual community leaders supported community mobilization, volunteer tracking, identified issues, and provided comprehensive feedback to the researchers.
- When community leaders are engaged before start of the trial, recruitment for participation in the trial is made easy CAB members provided feedback on issues arising from communities in a timely manner.
- Myths and misconceptions about the study were reported and addressed through meetings.

Conclusions: Stakeholder engagement across the trial lifespan in research may lead to improved community ownership and acceptance of the trial and participation. Effective feedback loops through dialogues and communication strategies can lead to a successful implementation of trials.

EP177

Task shifting strategy for enhancing timely PCR testing in early infant diagnosis at Aduku Health Centre IV, Kwania District, Northern Uganda

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Background: Timely PCR testing is crucial for early infant diagnosis (EID) of HIV and timely initiation of antiretroviral therapy (ART) among HIV-exposed infants. Polymerase chain reaction (PCR) testing is the gold standard for diagnosing HIV infection in infants under 18 months of age. However, delays in PCR testing due to limited laboratory staff at Aduku H/C IV impedes the process leading to missed opportunities for early treatment initiation and increased morbidity and mortality among HIV-infected infants. The continuous quality improvement (CQI) objective was to increase the percentage of exposed infants done timely PCR from 30% in May 2023 to 100% by March 2024 at Aduku Health Centre IV.

Methods: The CQI project was implemented at Aduku H/C IV in Kwania District, Northern Uganda. Starting in June 2023, non-laboratory personnel, including Community Health Workers, Young adolescents Peer Support (YAPS), nurses and midwives, were trained to collect specimens from exposed infants due for PCR at the facility and within the community and dispatch samples to the National Public Health Laboratory for PCR testing Via the Hub system.

Results: Implementation of the task shifting strategy resulted in notable improvements in timely PCR testing from 30% (3/19) in May 2023, to 43% (3/7) in June 2023, to 55% (5/9) in July 2023, to 60% (6/10) in August 2023, to 57% (4/7) in September 2023, to 67% (8/12) in October 2023, to 87% (7/8) in November 2023, to 90% (10/11) in December 2023, to 100% (3/13) in January 2024, to 100% (7/7) in February, 2024 and to 100% (8/8) in March 2024.

Conclusions: Task shifting, by training non-laboratory personnel to collect samples for PCR testing, proved to be an effective strategy for enhancing timely PCR testing in EID at Aduku Health Centre IV. This approach addresses the challenges of limited laboratory capacity and staff, ensuring prompt sample collection and transportation, and ultimately contributing to improved early diagnosis and management of HIV in infants.

EP178

Pre-exposure prophylaxis (PrEP) indicators by race/ethnicity among young men who have sex with men (YMSM) receiving CDC-funded HIV testing in the United States

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Background: Pre-exposure prophylaxis (PrEP) is effective at reducing risk of HIV acquisition, but utilization is low among young men who have sex with men (YMSM). We examined indicators for PrEP use and PrEP-related services by race/ethnicity among YMSM with negative CDC-funded HIV test results in non-healthcare settings.

Methods: We used 2019-2022 HIV testing data submitted by CDC-funded health departments (n=60) and community-based organizations (n=150) to the National HIV Prevention Program Monitoring & Evaluation system. We analyzed the following for YMSM (aged 13-34 years): current PrEP use, eligibility for PrEP referral, referral to PrEP provider among those eligible, and linkage assistance to PrEP provider among those referred.

To compare each indicator by racial/ethnic group, we calculated adjusted prevalence ratios (aPRs) with 95% confidence intervals (CIs) and p-values (adjusted for age, U.S. Census region, and year).

Results: The prevalence of current PrEP use among YMSM overall was 16.6%; in adjusted models, current use was lower for Native Hawaiian/Pacific Islander (12.0%; aPR:



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0.65), American Indian/Alaska Native (13.7%; aPR: 0.77), Black/African American (14.1%; aPR: 0.71), Multiracial (14.6%; aPR: 0.86), and Hispanic/Latino (17.4%; aPR: 0.93) YMSM versus White YMSM (18.0%; all $p < 0.001$).

Eligibility was lower for Hispanic/Latino (70.9%; aPR: 0.99) YMSM, but higher for Black/African American (78.5%; aPR: 1.05), Multiracial (73.8%; aPR: 1.03), and American Indian/Alaska Native (73.4%; aPR: 1.07) YMSM, versus White YMSM (74.6%; all $p < 0.05$). Referral was lower for Asian (47.5%; aPR: 0.93) YMSM, but higher for American Indian/Alaska Native (64.2%; aPR: 1.24), Native Hawaiian/Pacific Islander (58.5%; aPR: 1.14), and Black/African American (58.2%; aPR: 1.03) YMSM, versus White YMSM (53.5%; all $p < 0.0001$).

Linkage assistance was lower among Asian (76.7%; aPR: 0.97), Hispanic/Latino (78.5%; aPR: 0.96), and Black/African American (78.6%; aPR: 0.96) YMSM, but higher among Native Hawaiian/Pacific Islander (84.1%; aPR: 1.07) and American Indian/Alaska Native (80.8%; aPR: 1.06) YMSM, versus White YMSM (78.6%; all $p < 0.01$) in adjusted models.

Conclusions: PrEP use was suboptimal among YMSM with negative CDC-funded HIV test results. The prevalence of PrEP-related services varied by racial/ethnic group and indicator, suggesting that PrEP-related services could be expanded broadly to reach all YMSM to increase PrEP use and thereby reduce HIV acquisition.

EP179

Thetha Nami Ngithethe Nawe (let's talk): iterative co-development of a community-based peer-led intervention to deliver biosocial HIV prevention in rural KwaZulu-Natal, South Africa

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Background: Peer support is a scalable model to strengthen adolescents and young adults (AYA) resilience to HIV. Between March 2018 and September 2019, we co-developed an innovative biosocial intervention called Thetha Nami (talk to me) to foster youth-led transformative action for HIV prevention with young people aged 15-30. We describe how we iteratively co-developed this intervention to Thetha Nami ngithethe nawe (Let's Talk) in 2022.

Methods: Between 2019-2021 Thetha Nami was evaluated through a randomised controlled trial (RCT), which showed that peer support did not improve uptake of HIV prevention services but supported retention. Between 2021-2022 we used a participatory approach to engage 54 peer navigators (who were delivering the intervention) with trial findings and process evaluation to improve the

peer-led biosocial intervention. We conducted 93 weekly team debriefings and four participatory workshops to iteratively evolve Let's Talk which is being tested in a cluster RCT.

Results: The following areas have been strengthened in Let's Talk:

1. Adding a social and youth development module led by a linking social worker to support peers responds to young people's social needs,
2. Bridging connections with local stakeholders through engagement by peers as local youth champions mobilises local resources,
3. Incorporating virtual and physical support broadens the reach of young people,
4. Increasing youth solidarity through providing safe spaces where young people discuss issues of safety, efficacy, and debunking myths of using PrEP and PEP,
5. Improving real-time integration of peer support with service delivery through an electronic management tool used by peer navigators to conduct assessments and generate person-centred action plans that are reviewed by supervisors, a nurse, and a social worker.

Lack of family support to tackle sociocultural barriers related to young people's sexuality was identified as a limitation. Furthermore, while partner notification exists in the programme, it needs strengthening to support linkage and retention in care.

Conclusions: Co-developing the intervention with peer navigators supports the building of AYA resilience to HIV strengthening social development, providing solidarity, and nurturing person-centred care through case-based management and real-time supervision support. Further development will require engaging sexual partners and families.

EP180

The role of drug transporter mRNA expression and genital inflammation in South African women taking oral pre-exposure prophylaxis (PrEP)

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Background: South Africa is severely affected by HIV, with most new HIV acquisitions occurring in young African women. Previously tested antiretrovirals as different pre-exposure prophylaxis (PrEP) formulations in African women have shown inconsistent levels of protection against HIV. Leading to the investigation of host biological factors that can affect PrEP efficacy besides adherence. Drug transporter proteins have been increasingly recognized as key modulators of PrEP levels. Their mRNA expression has been significantly correlated to varying PrEP levels in different tissues. Inflammation has also been identified as a further modifier of drug transporter mRNA expression in turn affecting PrEP levels.

Methods: We, therefore, aimed to determine possible concordance between drug transporter mRNA expression in the female genital tract (FGT) and blood of N=45 South African women taking oral PrEP-Truvada® [a combination of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC)] over 6 months for HIV prevention.

Additionally, we determined associations between drug transporter mRNA expression, genital inflammation (GI), and plasma tenofovir. mRNA-expression of four efflux P-gp; MATE-1; MRP-2; MRP-4 and two influx OAT-1 and OAT-3 drug transporters were determined by qualitative real-time PCR. Multiplexed technology was used to measure 27 cytokines/chemokines to define GI.

Results: Spearman's rank correlation analyses showed significant positive correlations of mRNA expression for P-gp, MATE-1, MRP-2, and MRP-4 between the FGT and blood at 3- and 6-months post-PrEP initiation ($p < 0.05$). For OAT-1 however, significant correlations (positive) were observed pre-and-post-PrEP ($p < 0.05$).

Linear-mixed models showed moderate associations between FGT cytokines/chemokines and drug transporter mRNA expression, with a positive relationship observed between MIP-1 β concentration and MATE-1 mRNA expression. Partial least squares discriminant analyses likewise showed that in women with GI, consistently higher mRNA expression of MATE-1 was observed compared to wom-

en without GI. No significant associations were observed between drug transporter mRNA expression and plasma tenofovir.

Conclusions: Our results suggest that drug transporters may be similarly expressed in the FGT and blood after PrEP exposure. Furthermore, GI may alter efflux or influx drug transporter expression, thereby modifying PrEP disposition. Collectively, our data may be used to better understand biological factors that may affect PrEP efficacy, particularly in African women who remain vulnerable to HIV.

EP181

Advancing young adolescents' sexual health development support: perspectives and recommendations of caregivers in ending HIV pandemic in Western New York, USA

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Background: Addressing sexual and reproductive health needs of young adolescents (ages 10-14) is urgently needed in the fight against HIV and other Sexually Transmitted Infections (STIs) which disproportionately burdens adolescents. Caregivers of young adolescents must be confident and competent in providing support for healthy sexual development and preventing early sexual debut and its related diseases. However, the support that primary caregivers give to young adolescents to empower them to prevent early adverse sexual activities, HIV and STIs is under investigated.

We conducted a community-engaged qualitative descriptive study to ascertain caregivers' perspectives and experiences with supporting healthy sexual development of young adolescents in Rochester, NY, USA.

Methods: We purposively sampled 20 primary caregivers of 10-14 years old for individual semi-structured in-depth interviews from February 2023-June 2023. Data analysis followed the conventional content analysis approach using MAXQDA. We employed triangulation, team analysis, and respondent validation to enhance rigor. The study was approved by the University of Rochester Institutional Review Board.

Results: Participants were predominantly female (80%), ranging from 23-68 year of age, and identifying as Black/African American (65%), Caucasian (30%), and Mexican American (5%). Five major themes emerged: meaning of young adolescents' sexual health support; parental strategies for supporting healthy sexual development, perspectives on school-based sexual health education, uncertainty over sexual health conversations, and perceived need for research with young adolescents. Care-



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givers conceptualized sexual health support for young adolescents as providing access to sexual health information and care and providing anticipatory guidance for disease prevention.

Collectively, caregivers described multilevel challenges attributing to the inadequacy of sexual health support and the need to introduce sexual health conversations early. Moreover, participants reported the need for mandatory sexual health education in schools, along with research to understand the best approaches for supporting young adolescents' developing sexuality.

Conclusions: Early sexual health support is critical to address HIV and STI disparities among young adolescents. More research is needed to identify strategies for increasing caregivers' comfort and skillset for supporting young adolescents' sexual development. Programming is needed to adopt a multilevel approach that addresses barriers to young adolescents' access to sexual health development support.

EP182

Strategies development and validation for same-day ART initiation, tracing HIV/AIDS patients lost to follow-up and viral load monitoring mechanisms in Ethiopia

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Background: To meet the ambitious goal of eradicating the HIV epidemic by 2030, the Joint United Nations Programme on HIV/AIDS has set 95-95-95 targets. These targets aim for 95% of HIV-infected individuals to know their status, 95% to initiate antiretroviral therapy (ART), and 95% to achieve virologic suppression by 2030. In Ethiopia, progress towards these targets has been made, but challenges persist. Strengthening health systems is crucial to achieving these global targets.

Methods: A three-phased exploratory sequential mixed methods design was employed in two healthcare facilities in Ethiopia. Strategies were developed based on qualitative findings from in-depth cell phone interviews with 30 healthcare providers, quantitative results from document analysis of 332 clinical records, integration of Phases 1 and 2, application of a theoretical framework, logical reasoning, and review of relevant literature.

Results: The study findings indicate varying retention rates over different time intervals: 35% at 6 months (n=49), 81% at 12 months (n=50), 89% from 13 to 18 months (n=63), and 94% at 24 months (n=34), with an overall retention in HIV/Care at 59%.

Additionally, viral suppression rates were observed to be 93% at 6 months, 95% at 12 months, and 86% at 24 months. Based on guiding principles such as the integration of Phases 1 and 2, utilization of theoretical frameworks, logical reasoning, and literature review, the researcher developed 16 comprehensive strategies aimed at enhancing

the effectiveness and efficiency of HIV/AIDS service provision. Fifteen out of these 16 strategies were approved by the supervisor and validated using the Modified Delphi technique by health experts from HIV programs at the Federal Ministry of Health and regional health bureaus.

Conclusions: Fifteen final strategies were validated to enhance same-day ART initiation, tracing of patients lost to follow-up, and viral load monitoring mechanisms through system strengthening and capacity building. These strategies encompass three thematic areas and 16 strategic key areas. After validation, the strategies were modified and presented with a description of each, expected outcomes, and key activities for implementation.

EP183

From intention to actual use: systematic review and meta-analysis of studies on PrEP intention and uptake across populations in sub-Saharan Africa

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Background: Bimonthly injections of long-acting injectable pre-exposure prophylaxis (LA-PrEP) may be more appealing than daily pill taking of PrEP (oral PrEP). Real world data on uptake of oral/LA-PrEP are scarce.

Often, results from intention studies are used to inform decisions and/or to estimate the impact of scaling PrEP. We assessed the extent to which intention predicts uptake.

Methods: We conducted a systematic review and meta-analysis quantifying the proportion intending to use and/or uptake of any PrEP, and the difference between these within the same sample, across population subgroups in sub-Saharan Africa.

We searched databases (Medline, Embase, Global Health, Web of Science) between 01/01/2012-11/10/2022. For each outcome, we report pooled estimates (95% confidence intervals) and conducted univariate subgroup analysis by participant and study characteristics.

Results: We identified 38 and 45 records (out of 11,785) providing $N_i=42$ and $N_u=47$ independent estimates on intention and uptake, respectively. The pooled overall proportion who intended to start PrEP was 78.0% (69.5-84.7, $N_i=42, I^2=99\%$). Intention varied by study population but not by region, study design, or PrEP type. Intention was higher for female sex workers (FSW) (85.7% (73.0-

93.0), $N_u=10$) than adolescent girls and young women (71.9%(56.6-83.4), $N_u=7$), men who have sex with men (57.9% (34.9-77.9), $N_u=8$), and adult women (54.2%(29.4-77.1), $N_u=3$). Pooled uptake was 54.7% (41.4-67.4, $N_u=47$, $I^2=100\%$).

Uptake was higher for western Africa (84.7% (81.1-87.7), $N_u=2$) and lowest for southern Africa (46.0% (26.1-67.3), $N_u=11$).

Uptake was higher for serodiscordant couples (97.4% (96.3-98.2), $N_u=2$) and people at elevated HIV risk (74.6%(25.8-96.1), $N_u=4$), than for FSW (42.8%(20.2-68.7), $N_u=8$), adult men and women (34.5(30.9-38.4), $N_u=6$) and adult women (27.2%,(15.7-42.9), $N_u=7$).

Uptake was higher in clinical trials (78.6% (33.4-96.4), $N_u=3$) than other study designs (range:~25.6-38.9%) and in studies including participants interested in PrEP (94.5%,(91.5-96.5), $N_u=4$) than in studies including PrEP eligible (~72%), participants at increased HIV risk (~33%), or sexually active(19%).

In six studies reporting both, the pooled paired difference between intention and uptake was 40.7% (10.5-70.9), meaning that overall, almost half the sample had not initiated PrEP despite reporting intending to.

Conclusions: In between- and within-study comparisons, intention overestimated uptake by 20-40%. Intention is a weak predictor of PrEP uptake and should be interpreted with caution. More real-world data are needed.

EP184

Low pre-existing endemic human coronavirus (HCoV- NL63)-specific T cell frequencies are associated with impaired SARS-CoV-2-specific T cell responses in people living with HIV

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Background: Understanding how HIV affects SARS-CoV-2 immunity is crucial for managing COVID-19 in sub-Saharan populations due to frequent coinfections. Our previous research showed that unsuppressed HIV is associated with weaker immune responses to SARS-CoV-2, but

the underlying mechanisms are unclear. We investigated how pre-existing T cell immunity against an endemic human coronavirus HCoV-NL63 impacts SARS-CoV-2 T cell responses in people living with HIV (PLWH) compared to people without HIV, and how HIV-related T cell dysfunction influences responses to SARS-CoV-2 variants.

Methods: We used flow cytometry to measure T cell responses following PBMC stimulation with peptide pools representing beta, delta, wild-type, and HCoV- NL63 spike proteins. Luminex bead assay was used to measure circulating plasma chemokine and cytokine levels. ELISA and MSD V-PLEX COVID-19 Serology and ACE2 Neutralization assays were used to measure humoral responses.

Results: Regardless of HIV status, we found a strong positive correlation between responses to HCoV-NL63 and SARS-CoV-2. However, PLWH exhibited weaker CD4+ T cell responses to both HCoV-NL63 and SARS-CoV-2 than HIV-uninfected individuals. PLWH also had higher proportions of functionally exhausted (PD-1high) CD4+ T cells producing fewer pro-inflammatory cytokines (IFN γ and TNF α) and had elevated plasma IL-2 and IL-12(p70) levels compared to HIV-uninfected individuals. HIV status didn't significantly affect IgG antibody levels against SARS-CoV-2 antigens or ACE2 binding inhibition activity.

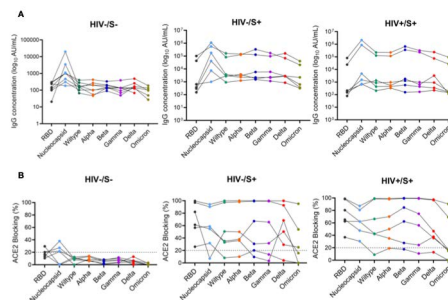


FIGURE 5 Comparison of anti-SARS-CoV-2 IgG antibodies and ACE2 blocking potential in healthy controls and COVID-19 convalescent HIV-infected and HIV-uninfected individuals. Serum samples collected between 1- and 22-days post infection were used to measure anti-SARS-CoV-2 IgG antibodies and ACE2 blocking in HIV-infected (HIV+, n = 6), HIV-uninfected (HIV-, n = 6) and healthy controls (n = 6) by the MSD V-Plex assays. (A) Summary plots of SARS-CoV-2-specific IgG antibody concentrations in the three groups. (B) Summary plots showing ACE2 blocking of SARS-CoV-2-specific antigens in the three groups.

Conclusions: Our results indicate that the decrease in SARS-CoV-2 specific T cell responses in PLWH may be attributable to reduced frequencies of pre-existing cross-reactive responses. However, HIV infection minimally affected the quality and magnitude of humoral responses, and this could explain why the risk of severe COVID-19 in PLWH is highly heterogeneous.



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EP185

HIV testing uptake: when testers are not tested – implication for reaching the first 90

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Background: About 3.5million Nigerians are living with HIV with just 23% of males and 29% of females aware of their HIV status. The UNAIDS 90-90-90 vision looks towards ensuring access to HTS services for all by reaching at least 90% of the population. Studies have examined factors affecting HIV-testing uptake, none focused attention on how uptake among counselors/testers impact overall uptake within the general population.

This study measures the level of uptake of HIV-test among HIV-testers/counselors and highlights implication on reaching the first 90.

Methods: 200 HTS Centres were randomly selected within Ekiti and Ondo State, South-West Nigeria. Counselors and testers were interviewed using a structured pre-coded questionnaire. Participants were limited to those who have been consistent counselors/testers over the last 12 months.

Analysis was done using a combination of SPSS version 26 and MS-Excel 2013. Results were compared with existing HTS reports and presented in tables and charts.

Results: 786 individuals participated in the study. 23% were counsellors, 17% testers while 60% functions as both counsellor and testers. Only 23% of all respondent had HIV-test within the last six months while 11% had never had a test. Testers were more likely to uptake a test than counsellors as analysis shows 53% of testers had a test within the last six months compared with 8% of counsellors.

Counsellors report an average of five clients per week. The rate of actual HIV test uptake among counselled clients is significantly higher ($P \leq 0.0005$ CI: 95%) at 87% among counsellors who had a test within the last six months compared with 42% for those who did not. The figure for client's uptake of HIV-test drops to 12% for counselors and testers who had never had a test themselves.

Conclusions: There is a strong evidence to conclude that HIV-test uptake among counselors and testers have a significant impact on client's successful uptake of HIV-testing.

Results also shows that despite encouraging others to know their status, up to 11% of counsellors/testers don't actually know their HIV status. Efforts at reaching the first 90 should take into account strategies for reaching the service providers.

EP186

Performance of community centers led by non-governmental organizations to offer HIV prevention combination services in Western Mexico: an analysis of the first 2 years of the Mexican PrEP Program

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Background: PrEP has been included as a universal HIV preventive tool in Mexico since 2021 but is not known what is the real life performance of community centers (CC) led by non-governmental organizations in the outreach of key populations (KP) including Men who have sex with Men (MSM), Female Sex Workers (FSW), Serodiscordant Couples (SDC), Transgender Women (TGW), People who Inject Drugs (PWID), Adolescents/Young Adults (AYA), migrants, indigenous and homeless people in Mexico.

Methods: In 2021, four CC with a broad experience in the approach of key populations began to offer PEP/PrEP free of charge as a public policy at their facilities in western Mexico (Guadalajara and Puerto Vallarta). All data and the outcomes of the users were prospectively recorded in a database previously designed by the National Institute of Public Health.

Results: From June 2021 to October 2023, a total of 2,178 services were given in 4 CC; main KP included MSM (1,306/73.5%), FSW (219/12.3%) and SDC (92/5.2%). Another priority populations included migrants (68/3.8%), TGW (48/2.7%), PWID (10/0.6%) and AYA (1/0.1%). No indigenous nor homeless people were evaluated. A total of 1392/63.9% evaluations resulted in same day PrEP (Daily PrEP 1,320/94.8%; ED-PrEP 72/5.2%), PEP (242/11.1%), deferred PrEP initiation (196/8.9%); finally, 116 PrEP candidates (5.3%) were sent to other centers. A sub analysis about the medic consults made in the first 12 months at one center (n=364) revealed that 1 per every 3.5 persons was in need of a medic evaluation, mainly by a STD (178/45%), PrEP/PEP evaluation (103/26%), a reactive HIV test (73/19%), suspicion of AHI (24/6%) and other causes (15/4%). Main STD by specific etiology (n=158) were syphilis (138/88%), M-pox (7/4%), HBV (6/4%), HCV (6/4%) and Chlamydia (1/0.6%); main STD by the syndromic approach (n=30) included urethral/vaginal/rectal discharge syndrome (9/30%), GUD (9/30%), genital warts (7/23.3%), inguinal adenopathy (2/6%); orchitis, pharyngitis and PID were counted by 1 (3.3%) each.

Conclusions: CC led by NGOs work as excellent tools to offer HIV prevention combination services for MSM, FSW and SDC in western Mexico. However, seems necessary to design better approaches for the less outreached key populations including TGW, AYA, PWID, indigenous and homeless people.

EP187

Differentiated care model, low level viremia and viral load suppression among people living with HIV in Rwanda

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Background: Low level viremia (LLV) (HIV-RNA 50-999 copies/mL) has been widely associated with decreased likelihood of subsequent viral load suppression (VLS) (HIV-RNA <1000 copies/mL). In 2015, the World Health Organization recommended a differentiated care model (DSD) involving immediate antiretroviral therapy (ART) initiation after the HIV diagnosis. VLS is critical in HIV prevention. We assessed the impact of immediate ART initiation on LLV.

Methods: We conducted a retrospective cohort analysis study using routinely collected data of adults living with HIV from 28-healthcare facilities in Rwanda before and after the introduction of DSD. Viral load results of people enrolled in care between January 2014 and May 2022 were analyzed. Proportions of VLS, LLV at 6-,12-, and 18-months were quantified. Multivariable logistic regression models were used to assess the effect of immediate ART initiation on LLV and effect of LLV on VLS. For the association between immediate ART initiation and LLV, those with HIV-RNA ≥ 1000 were excluded. Those with HIV-RNA ≥ 1000 at 6-months were excluded for the association of LLV on VLS.

Results: Of 982 people living with HIV, 649(66.1%) were female and 463(47.1%) initiated ART immediately. The median age was 37 [interquartile range:32-43] years. A total of 721(73.4%), 669(68.1%) and 416(42.4%) participants had viral load results at 6-,12- and 18-months respectively. LLV was 7.5%, 6.7% and 5.3% and VLS was 92.0%, 92.7% and 95.0% at 6-,12- and 18-months respectively. Compared to those who initiated ART after several counselling sessions, those who initiated ART immediately had increased odds of having LLV at 6-months [adjusted odds ratio (aOR)=2.20;95%CI (1.12-4.35)], but not at 12-[aOR=1.76;95%CI (0.84-3.68)] and 18-months [aOR=0.33;95%CI (0.10-1.10)]. Although 6-month LLV decreased odds of VLS at 12-months, the association was not statistically significant, [aOR=0.74; 95%CI (0.17-3.32)].

Conclusions: Although VLS was high in this cohort, immediate ART initiation was associated with increased odds of LLV at initial viral load test, possibly due to the minimal amount of counselling sessions and time people living with HIV had in pondering and accepting the HIV diagnosis. Continued support is needed among people receiving immediate ART initiation to prevent development of LLV which may have impact on non VLS.

EP188

Clinician perspectives on HIV molecular surveillance

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Background: Molecular HIV surveillance (MHS) and cluster detection and response (CDR) are used by public health departments to identify and respond to emerging HIV clusters. In the United States (US), MHS relies on partial HIV gene sequences obtained from antiretroviral resistance testing (ARVRT) performed during routine clinical care of people living with HIV (PLWH). In 2018, the US Centers for Disease Control and Prevention required health departments to include MHS with CDR.

However, critics have argued that this practice raises significant social and ethical concerns, including the lack of consent for public health uses of these clinical data. Several advisory panels and advocacy groups have called for increased transparency around this practice, including having clinicians disclose the public health use of ARVRT data to PLWH at the time of testing.

Methods: A 10-item survey was administered to attendees of the, "Molecular Cluster Surveillance for HIV: Is It Needed? Is It Worth It?" session at the 2023 IDWeek Conference (Boston, MA). Attendees followed a QR code provided during the session to access an anonymous Qualtrics survey. Data analysis was limited to clinician respondents who reported treating PLWH, and involved calculating percentages to depict the distribution of responses.

Results: Thirty-six of the 43 survey respondents were clinicians who treated PLWH, with the majority (72%) having ordered ARVRT in the context of clinical care. Sixty-seven percent were aware that ARVRT test results were reported to public health agencies without explicit consent of those tested, and 60% were comfortable or very comfortable with this practice.

A substantial majority (92%) agreed with the recommendation that clinicians ordering ARVRT testing should inform PLWH about the public health use of their ARVRT data, though only 20% reported currently doing so. The majority (69%) believed it is feasible for clinicians to disclose this information, and 74% indicated they would be comfortable doing so.

Conclusions: Our results suggest that clinicians are supportive of and comfortable with disclosing public health use of ARVRT data to PLWH at the time of testing. If implemented, this may help resolve one of the ethical concerns regarding public health uses of ARVRT data.



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Social capital and sustained viral suppression among people living with HIV/AIDS initiated on anti-retroviral therapy in South-Eastern Nigeria

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Background: The global health challenge posed by the human immunodeficiency (HIV) virus persists. Although significant strides have been made in enhancing the quality of life for individuals with HIV through expanded access to anti-retroviral therapy, the attainment of continuous viral suppression remains a multifaceted challenge.

Consequently, this research explored the relationship between social capital and viral suppression in individuals undergoing anti-retroviral therapy (ART) for HIV.

Methods: We conducted an hospital-based unmatched Case-control study among 1,202 PLHIV, aged ≥ 10 yrs on ART. Cases were people living with HIV (PLHIV) on ART who had achieved viral suppression, while controls were those with viral non-suppression. Multi-stage random sampling techniques was utilised in selecting cases and controls. The Word Banks social capital integrated questionnaire – SC – IQ) was adapted and used to measure social capital among study participants, their viral-load records were extracted from hospital-based electronic medical records.

Data were entered into SPSS Version 26 software and analyzed using descriptive statistics; (frequency, percentages, mean, standard deviation), and inferential statistics using logistic regression at <0.05 statistical significance.

Results: Majority were females 748 (62.2%), 365 (30.4%) were aged 25–34 years, the smallest age group was ≥ 55 years 131 (10.9%) and mean age was 17.7 years (St. dev =12.2 years). A 35.8%, 21.3% and 42.9% level of low, moderate and high social capital respectively was discovered among participants. High social capital was chiefly recorded among PLHIV that were virally suppressed (cases) – 81.8%, while low social capital was majorly seen among virally non-suppressed (controls) – 80.9%.

Low and high social capital were shown to be significantly associated with viral suppression among PLHIV on ART at ($P < 0.0001$). Revealing that clients with high social capital were 2.88 times more likely to achieve sustained viral suppression as compared to those with low social capital (AOR= 2.88, 95% CI = 1.68 - 4.93).

Conclusions: Social capital was discovered to be positively associated with viral suppression, therefore, promoting strong social capital can enhance sustained viral suppression among PLHIV on ART, which is the ultimate goal of HIV care and treatment interventions, as well as pivotal achieving in HIV epidemic control efforts.

EP190

Comparing approaches for estimating HIV incidence among high-risk populations in Lima, Peru

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Background: Traditional gold-standard clinical trial designs for evaluation of new HIV prevention methods are exceedingly difficult to implement due to ethical (i.e. inactive/placebo-controlled trials) and/or feasibility (i.e. non-inferiority trials) concerns.

We examined a number of potential alternative strategies for estimating a counterfactual HIV incidence (e.g. in the absence of an intervention) for use in future prevention trials.

Methods: We used data from 3 studies conducted in the past 10 years in our population of interest, men who have sex with men (MSM) and transgender women (TW) in Lima, Peru. We included data from study sites in Lima from the HVTN 704/HPTN 085 clinical trial, the Sabes longitudinal observational study and the ImPrEP cross-sectional sero-incidence study. Methods tested include

1. Gold-standard method of follow-up to directly measure HIV incidence;
2. Estimating HIV incidence from cross-sectional studies based on recency testing algorithm; and
3. Predicting HIV incidence using incidence of rectal gonorrhoea (RG).

We compared different approaches directly based on estimated HIV incidences from data collected from the same study; and further evaluated population adjustment approaches through comparing HIV incidence estimates using data collected from different studies.

Results: Within study estimates: Using HVTN 704/HPTN 085 data, the estimated incidences from the follow-up and RG approaches are 5.6 (95% confidence interval [CI] 4.5-7.0) and 5.9 (5.4-6.5) cases/100 PY, respectively. The estimated incidences from the follow-up and recency testing of baseline samples in *Sabes* are 10.9 (9.6-12.4) and 12.0 (8.7-16.5) cases/100PY, respectively.

Between study estimates: Using recency testing of specimens from ImPrEP and baseline specimens from *Sabes* we obtained adjusted incidence estimates for a clinical trial population similar to HVTN 704/HPTN 085 ranging from 10.6 (7.4-13.2) to 12.4 (9.6-16.0) cases/100PY. Using follow-up and RG data from HVTN 704/HPTN 085 and recency testing data of ImPrEP, we obtained adjusted incidence estimates for a longitudinal study similar to *Sabes* ranging from 6.1 (4.3-8.3) to 8.6 (4.7-14.0) cases/100PY.

Conclusions: The recency testing and RG approaches are consistent with the gold-standard follow-up approach when they utilize data collected from the same study. However, understanding and fully accounting for heterogeneity of study populations is critical when combining different studies to generate counterfactual estimates.

EP191

CD4 testing optimization through equipment mapping for diagnosis of clients with Advanced HIV Disease

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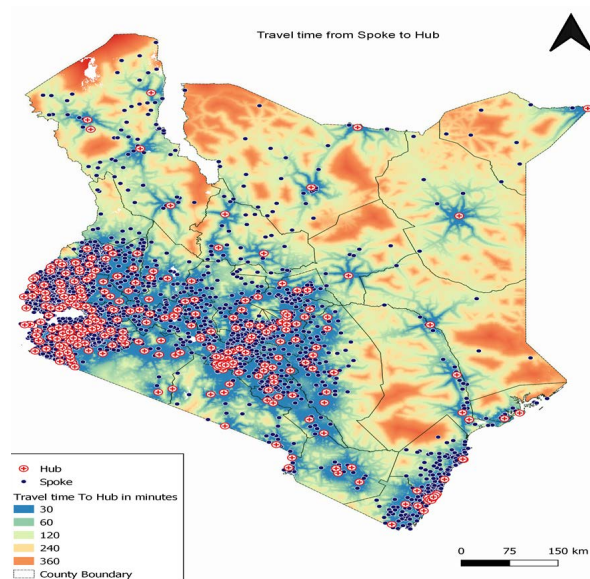
Background: CD4 testing is the gateway to the package of care for Advanced HIV Disease (AHD). Timely CD4 testing is key in identifying severely immunocompromised clients, i.e., those presenting with CD4 below 200 cells/mm³. Currently, Kenya uses equipment based conventional and point-of-care CD4 testing platforms distributed in all 47 counties in high volume facilities. Out of 3,878 facilities offering ART, only 9.7% (376) had a CD4 platform (hub).

Mapping of the CD4 equipment was done with an aim of drawing a clear spoke and hub model for CD4 equipment-based testing that will enable optimal access to testing and maximize the overall efficiency of the system.

Methods: County Medical Laboratory Coordinators (CMLT) from the 47 counties in Kenya shared data on facilities with the CD4 equipment, functionality, and their respective spokes in the period of July to sept 2023. An ODK tool was used in data collection. GIS Mapping was done using QGIS to determine the travel time between the hub and the spokes. A report was done and disseminated to the technical working group as well as the counties to enhance CD4 testing.

Results: There was a great disparity in travel time from the spokes to the hub by county and sub-counties indicating variations in CD4 testing accessibility and efficiency across different Counties and sub-counties(map).

Further, there were facilities without access to CD4 even after the optimization. The data showed that even with an optimal mapping, the utilization was below 10%. Further, 31 of 376(8.2%) equipment were not functional while 25% required maintenance and repair.



Conclusions: Use of lateral flow assay for CD4 testing in facilities with no access to CD4 equipment or those far from the hub has the potential to decentralize access to CD4 testing at a lower cost since there is no equipment and no sample networking cost for such facilities.

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Associations between mental health indicators and mucosal immune biomarkers among recent survivors of forced sex: a case-control analysis

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Background: Over 25% of cisgender women in the U.S. experience attempted/completed rape, which increases risk for HIV through physiological trauma, adverse mental health and subsequent high-transmission sexual behaviors. Biologically, sexual violence may increase HIV risk via immune dysregulation from stress-mediated psychological distress and female genital tract (FGT) mucosal trauma/injury. Few studies have assessed mental health and FGT immune dysregulation among survivors of violence. We sought to explore this relationship among recent survivors of rape compared to consensually sexually active counterparts.





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Methods: We recruited HIV-negative cisgender women in San Diego, California, U.S.A. aged 14-45, who experienced past-month male-perpetrated nonconsensual vaginal penetration (cases, n=23) or past 15-day consensual vaginal sex with a man (controls, n=41).

Participants completed validated measures for perceived stress, depression, post-traumatic stress disorder (PTSD) and resilience, blood draw, and collection of cervical vaginal lavage (CVL; testing for inflammatory biomarkers (IL-1 α , IL-1 β , IL-6, IL-8, TNF- α , MIP3 α), mucosal antimicrobials (SLPI, Elafin, HBD2), and in-vitro %HIV inhibition). We employed descriptive statistics and fit unadjusted and adjusted linear regression models to examine associations.

Results: Participants (n=64) identified as Hispanic (42.1%), White (34.4%), Black (25.0%), and Asian or Pacific Islander (18.8%), and had a median age of 22 (IQR:18-26). Case participants had higher perceived stress, depression, PTSD, FGT TNF- α , and SLPI. In adjusted regression analyses among Cases, perceived stress was negatively associated with IL-1 α , depression was negatively associated with TNF- α . In contrast, strong positive associations were noted between PTSD and IL-1 α .

Among Controls, perceived stress was negatively associated with IL-8 and IL-1 α , depression was negatively associated with IL-1TSD showed strong positive associations with HBD2 and % HIV inhibition.

Conclusions: We found that IL-1 α was associated with numerous mental health indicators, including a strong positive association with PTSD in Cases. PTSD symptoms were associated with a compensatory protective immune response among controls, but not cases, and immune biomarkers associated with depression were distinct from those associated with PTSD. Clinical and behavioral treatment for PTSD are essential to mitigate HIV risk among survivors of sexual violence. Longitudinal research is needed to explore the pathways between mental health and HIV immunity.

EP193

Mobilising young people for HIV prevention awareness through social media in Uganda: outcomes of a targeted digital campaign

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Background: In Uganda, 1.4 million people are living with HIV, with 54,000 new infections annually. Young people account for a large proportion (37%) of all new HIV cases. Innovative strategies are required to effectively communicate prevention and testing information and with over 78% of the population below the age of 30 who strongly use the Internet for social media networking.

This study presents an analysis of a Social Media Campaign aimed at tackling the challenges surrounding HIV prevention awareness among younger demographic in

Uganda. It focused on leveraging the power of social media influencers and platforms and the campaign sought to educate, destigmatize, and encourage positive behavioural changes within the youth community.

Methods: We conducted a digital campaign from 14th November to 10th December 2023 using social media platforms. The campaign targeted all adolescents and young adults (13-39) as they are at a higher risk for HIV, students, sexually active youth, and minority groups using "social media influencers."

The platforms included Twitter (X), Facebook, Instagram, YouTube, WhatsApp, and SnapChat. The Hashtags used were in local language #BeeraMuClass, #TosuulaStep, #KnowYourStatus, #KnowTheVibe, #StopTheSpread, and #LivePositive. The collected data included mentions, unique user engagement, content analysis, and sentiment trends across multiple platforms.

Results: The campaign successfully generated over 247 million impressions, with a significant increase in mentions (3,942; +186.7%) and unique users (1,388; +9.15%) and reached 247.22 million. Engagement primarily (80%) involved the 18-35 age demographic, predominantly males (66.58%), with the majority of activities centered around entertainment.

Analysis revealed a considerable peak in discussions during mid-week, with heightened engagement in the afternoon and evening hours. Positive sentiments were noted in content that highlighted personal stories and endorsements by influencers, while negative reactions were largely tied to misconceptions about HIV. The top-trending hashtags, such as #testedapprovedtrustedug and #obulamuug, facilitated the widespread dissemination of the campaign's key messages.

Conclusions: The campaign demonstrated that social media is an effective tool for engaging youth in HIV prevention awareness, especially males. The continuation of such digital initiatives coupled with educational programs is crucial for sustaining momentum and fostering an environment conducive to long-term public health improvement.

EP194

Effectiveness of HIV prevention programs for women in Nigeria: an analysis of the integration of gender mainstreaming strategies in global fund grant cycle 7 projects in Nigeria

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Background: The HIV/AIDS epidemic continues to disproportionately affect women in Nigeria, emphasizing the need for effective prevention strategies tailored to their specific needs. However, there is a gap in understanding the extent to which gender mainstreaming strategies are integrated into HIV prevention programs targeting women in Nigeria.

This study sought to analyze the integration of gender mainstreaming strategies in Global Fund Grant Cycle 7 projects in Nigeria and assess their effectiveness in preventing HIV among women.

Methods: The principles outlined in the Global Fund Gender Equality Strategy [2023-2028] and the UNAIDS Guidance Note: Integrating Gender into National HIV & AIDS Policies [2021] guided a systematic document selection process. Selected documents included Global Fund Grant Proposals (Cycle 7), Global Fund Monitoring, Evaluation, and Reporting (MER) Guidelines, Nigeria's National HIV/AIDS Strategic Plan [2023-2027] and final reports of Global Fund Grant Cycle 7 Projects in Nigeria. Thematic analysis was used to identify recurring themes and patterns, focusing on gender mainstreaming strategies like targeted interventions, capacity-building initiatives, and community engagement efforts, in order to evaluate their inclusion and how they address factors influencing women's vulnerability to HIV.

Results: The analysis revealed an absence of gender-specific interventions such as targeted initiatives, capacity-building programs, and community engagement efforts. The coverage of HIV testing services for pregnant women was found to be inadequate, with only 30% receiving testing compared to the recommended 95%. Similarly, prevention of mother-to-child transmission (PMTCT) coverage remained stagnant at approximately 45% since 2018. Factors contributing to women's vulnerability to HIV, including limited access to education and healthcare services, were not addressed.

Conclusions: The lack of gender-specific interventions and inadequate essential services emphasizes the urgency to prioritize gender mainstreaming in HIV prevention for Nigerian women. Neglecting to integrate gender-responsive strategies risks deepening gender disparities and elevating the rates of HIV cases among women, reinforcing cycles of inequality and health inequity. Therefore, it is imperative to adopt gender-responsive approaches and tailored interventions, as outlined in global frameworks, to significantly mitigate the impact of HIV/AIDS on women in Nigeria.

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Tracking priority evidence gaps to facilitate effective rollout of Cabotegravir for PrEP

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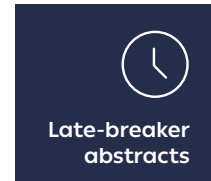
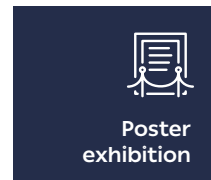
Background: As of April 2024, injectable cabotegravir (CAB) for PrEP had been approved by 16 countries and the European Medicines Agency, with programmatic rollout ongoing in the USA, and beginning in Malawi, Zambia, and Zimbabwe, and 41 additional implementation science studies taking place across 22 countries.

Methods: The Biomedical Prevention Implementation Collaborative (BioPIC) consists of more than 100 HIV prevention experts from 80 organisations and 20 countries and supports successful introduction of biomedical HIV prevention options, including CAB. BioPIC coordinates bi-monthly Think Tanks to identify priority CAB evidence gaps and review evidence from implementation and modelling studies to track progress against addressing them.

Results: Results from the priority evidence gap tracker are summarised in Table 1.

Category	Research Question	Evidence from Clinical, Implementation, and Modelling Studies	Remaining Gaps to Be Addressed
HIV Testing and Drug Resistance	What potential is there for increased resistance to integrase strand transfer inhibitors (INSTIs) due to the introduction of CAB for PrEP?	Though modelling has shown that the rollout of CAB for PrEP could lead to an overall increase in INSTI resistance, it is also likely to lead to an overall decrease in HIV incidence and deaths	How to detect INSTI resistance, use of dolutegravir as a first line treatment; optimal strategies to manage and treat current and former CAB users who have seroconverted
	What is the appropriate HIV Rapid testing should be testing approach for people on CAB for PrEP?	sufficient for initiation and continuation	The number of positive cases rapid testing misses, how to manage false negatives
Patterns of Use	Which users prefer CAB vs oral PrEP and why?	CAB users have cited convenient method and dislike of pills; ability to choose from multiple options can lead to higher coverage	User preference in real-world contexts and how to offer choice at scale
	What are the most meaningful indicators for patterns of use?	None to date- a subset of the PrEP Choice Investigators group is looking into harmonising indicators around patterns of use	Meaningful indicators for patterns of use
Safety, acceptability, and efficacy for diverse populations	Is CAB safe, acceptable, and efficacious in diverse populations?	Initial data shows CAB well tolerated in pregnant populations with no adverse events; found to be safe and effective in people >35 kg regardless of age, and safe and effective in trans women and sex workers	Additional data on use during pregnancy and by trans men and people who inject drugs; data on interactions between CAB and gender-affirming hormone therapy
Service delivery models	Where and how can providers deliver choice and acceptable services?	Choice of CAB for PrEP, oral PrEP, and PEP has been effective delivered across outpatient facilities, antenatal clinics, and community health workers going door-to-door	Best practices for CAB delivery via a variety of service delivery models at scale
Costing	How much does CAB for PrEP cost to deliver?	This evidence is being collected across multiple implementation science studies but is not yet available	Data on cost of CAB delivery via a variety of service delivery models
	At what price is CAB for PrEP cost effective?	Cost-effectiveness studies suggest that CAB for PrEP can be cost-effective at up to two times the cost of oral PrEP, though this is dependent on the degree to which PrEP use corresponds with seasons of risk	Data on cost effectiveness of CAB delivery via a variety of service delivery models and optimal strategies to collect information on PrEP usage and seasons of risk

Table 1- Summarised CAB for PrEP Priority Evidence Tracker.





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While rapid testing may be sufficient for initiation and continuation on CAB, gaps remain around detection and management of users who seroconvert, which is especially important given the heightened risk of drug resistance.

Offering choice increases PrEP coverage, though indicators to effectively monitor usage patterns are still lacking. CAB is safe and effective for adolescents, trans women, and sex workers, but questions remain around use in pregnancy, by trans men, and by people who inject drugs.

Many evidence gaps persist around optimal service delivery strategies, though CAB has been effectively delivered in clinical settings. While it has been estimated that CAB is likely to be cost effective up to twice the cost of oral PrEP, actual costs of delivering CAB are still unknown.

Conclusions: Identifying priority evidence gaps is essential to direct research questions for maximum impact, especially in a resource-limited environment. Tracking and communicating progress helps ensure lessons learnt guide introduction and scale-up.

As more studies and national PrEP programmes generate evidence through CAB delivery, BioPIC will continue to track and disseminate insights and experiences from these early rollout activities to support PrEP programming with greatest impact.

EP196

HIV risk perception trajectories and multi-level determinants among high school learners in rural South Africa: implications for enhancing HIV prevention efforts

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Background: Understanding the temporality and composition of HIV risk perception (HIV RP) is crucial to contextualizing how, when, why, and for whom HIV RP manifests and affects uptake, persistence, and effective use of prevention interventions. We examined HIV RP trajectories and determinants among adolescent girls and young women (AGYW) and adolescent boys and young men (ABYM) in KwaZulu-Natal.

Methods: Students in the control arm of a trial completed questionnaires and provided specimens for HIV and HSV-2 serologic testing at three annual timepoints (T1-T3). HIV RP was dichotomized (High vs. Low). Trajectories were generated using cumulative high HIV RP across three timepoints, and inter- and intra-trajectory characteristic differences were analyzed. We estimated determinants of high HIV RP in the overall sample by fitting cross-lagged models, producing adjusted risk ratios (aRR).

Results: High HIV RP fluctuated in AGYW (N=423, T1: 47.0%, T2: 12.8%, T3: 26.0%) and ABYM (N=435, T1: 47.8%, T2: 17.7%, T3: 29.9%), yielding four (Never, Infrequent, Frequent, Persistent) trajectories (Figure 1).

Compared with their other trajectories, Frequent and Persistent trajectories in AGYW had more partnerships and less knowledge of partners' HIV status; ABYM's had higher sexual violence survivorship, drug use, and age-disparate sex. HSV-2 significantly increased in all trajectories except Persistent (Figure 1). HIV RP determinants of ever-sex participants primarily included sociodemographic, attitudinal, and behavioral factors (Figure 2).

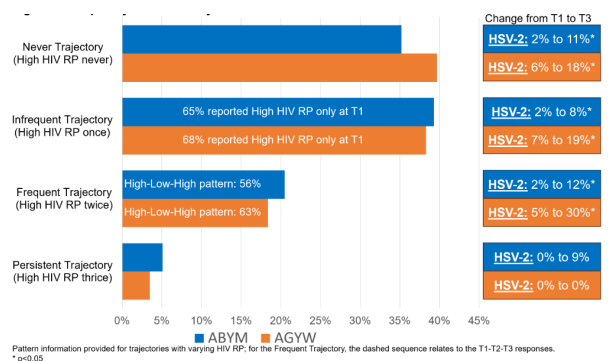


Figure 1. Frequency of HIV RP trajectories.

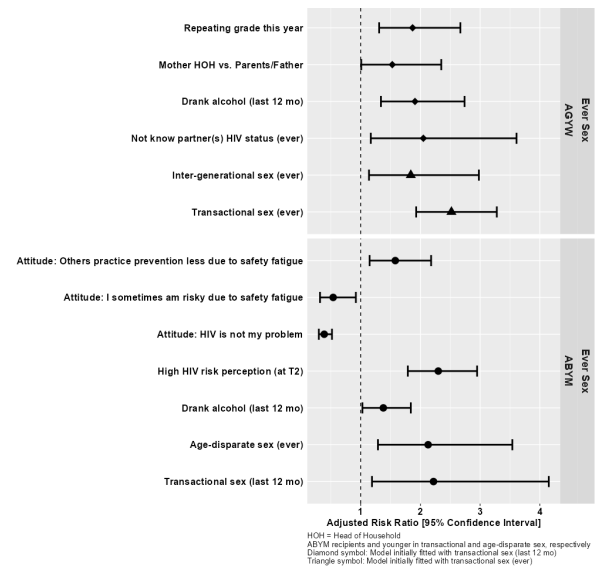


Figure 2. Factors at T2 that significantly predicted high HIV RP at T3.

Conclusions: AGYW's and ABYM's HIV RP was dynamic and underpinned by sociodemographic, attitudinal, biological, experiential, and behavioral factors. Future investigations of HIV RP's temporality and mechanisms are warranted to enhance HIV prevention efforts in these settings.

EP197

Interest in long-acting PrEP modalities among women in the United States with a history of injectable medication use: findings from the MACS/WIHS combined cohort study

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Background: PrEP uptake among U.S. women remains low: in 2022 only 15% of women who could benefit from PrEP received a prescription—versus 41% of men. Given the novel long-acting injectable (LAI) PrEP option that could potentially increase uptake, and to explore uptake-related drivers and inform interventions, we examined associations between previous injectable medication use and PrEP modality preferences among U.S. women.

Methods: This cross-sectional study (October 2020–November 2021) occurred across nine cities in the MACS/WIHS Combined Cohort Study: Atlanta, GA; Birmingham AL; Jackson MI; Bronx NY; Brooklyn NY; Chapel Hill NC; Chicago, IL; Miami, FL; San Francisco, CA; and Washington DC. We assessed self-reported prior injectable med-

ication use and categorized use as antibiotic (e.g., STI treatment) or chronic disease-related (e.g., for diabetes or pain management). Two separate multinomial logistic regression models assessed the association between prior injectable medication use (i.e., antibiotic or chronic disease-related) and preferred PrEP modality (LAI; daily oral; unsure; no PrEP regardless of modality) and adjusted for socio-behavioral characteristics, insurance status, and depressive symptoms.

Results: Participants (N=475; median age 52) primarily identified as Black (73%) and heterosexual (83%); many had used antibiotic (41.5%) or chronic disease-related (55.6%) injections. When choosing a PrEP modality: 30% preferred LAI PrEP, 10% oral PrEP, 21% were undecided, and 37% unwilling to use PrEP. Women who had used antibiotic injections (aOR: 2.49; CI: 1.47–4.23) were more likely to prefer LAI PrEP versus no PrEP, as were those who perceived themselves to be at some/high perceived HIV risk (aOR: 5.56; CI: 1.89–16.35). In a separate model, women who had used chronic disease-related injections also preferred LAI PrEP versus no PrEP (aOR: 1.81; CI: 1.08–3.04).

Conclusions: In a geographically diverse cohort, women preferred LAI over oral PrEP, but one-third were unwilling to use any form of PrEP. Women with a history of injectable medication use—as an antibiotic or for chronic disease management—preferred LAI versus no PrEP. Increasing education and outreach efforts for women about the importance of PrEP are needed; tailoring such initiatives for women with no history of injectable medication use, lower perceived HIV risk and uncertainty around PrEP use, could maximize uptake.

EP198

A retrospective examination of the role of community and facility-based partnerships in sustaining the gains of HIV service delivery among key populations in Delta State, Nigeria

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Background: The HIV epidemic continues to disproportionately affect key populations (men who have sex with men (MSM), female sex workers (FSWs), Transgender(TG) and people who inject drugs PWID) in Delta State, Nigeria. Despite significant progress in HIV service delivery, sustaining these gains remains a challenge. There is a need to bolster partnership between communities and health facilities.

Methods: A quantitative data analysis approach was utilized in this study. The research team developed a protocol to identify effective practices for enhancing and lever-



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aging the role of community and facility-based partnerships. A trend analysis was conducted from five distinct health facilities and community-based organizations offering HIV services to key populations in Delta state from 2019 to 2023. Key performance indicators such as HIV testing rates, linkage to care, treatment initiation, and viral suppression were examined to evaluate the durability of the progress made.

Results: In 2019, a total of 2,659 KPs underwent HIV testing, resulting in a positivity yield of 4.8%. 100% of those who tested positive were successfully linked to Antiretroviral Therapy, and the viral load suppression rate was 61.1%. In 2021, the number of KPs tested increased significantly to 157,777, with a positivity yield of 11.6%. Again, 100% of positive cases were linked to ART, and the viral load suppression rate improved to 92.3%.

Moving to 2023, 23,929 KPs were tested for HIV, with a positivity yield of 5.0%. All individuals diagnosed with HIV were connected to ART, and the viral load suppression rate rose to 98.5%. The Key Population members expressed trust in the healthcare system and noted improved access to comprehensive HIV care as a direct result of these collaborative partnerships.

Conclusions: Results underscore the significance of community and facility-based partnerships in the advancements in HIV service provision for KPs. These collaborations have demonstrated effectiveness in widening the reach of HIV testing, seamless linkage to care, and bolstering treatment adherence. It is now imperative to reinforce and allocate resources to partnerships, harnessing the capabilities and assets of both CBOs and health facilities. The cultivation of collaboration, trust, shared responsibility and sustainable progress in HIV care for key populations can be ensured.

EP199

Validation of analytical quality parameters for a novel HIV viral load test

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Background: The accessibility and accuracy of viral load testing are crucial for preventing new infections in the age of U=U (undetectable=untransmittable). The new cobas 5800 system platform enables the quantification of HIV through real-time PCR to diagnostic and management. This study aims to validate the performance of the cobas 5800 platform by confirming its analytical quality for use in a biochemical analysis laboratory.

Methods: Plasma HIV positive samples previously quantified using the standard methodology stored in our laboratory were used. Normal human plasma was utilized for dilution purposes. Performance evaluation included tests for linearity, precision, and accuracy at two different viral

load levels (2.4 and 3.4 logs copies/mL) and the quantification limit was verified through the study of a viral load concentration level of limit of quantification +/- total allowable error TEa).

An Alternate Method Comparison assay utilizing EP Evaluator was also conducted, with the cobas 4800 system serving as the reference. Acceptance criteria were based on manufacturer specifications and TEa=20%.

Results: The cobas 5800 system demonstrated linearity within the tested range (1.69-6.38 logs copies/mL), with a slope of 1.008 (ranging from 0.951 to 1.065) and an intercept of -0.220 (ranging from -0.448 to 0.007). Precision was satisfactory, with SDr=0.061, SDi=0.060, and SDR=0.088, SDi=0.085 for the two viral load levels examined. Accuracy was within acceptable limits, showing a Bias of 6.1% and 4.9% at the specified levels. The quantification limit met requirements, achieving a CV of 12.2% with an average of 1.54 log copies/mL.

The cobas 5800 system method proved to be comparable to the cobas 4800 reference method, with a slope of 1.031 (ranging from 0.966 to 1.096) and an intercept of -0.044 (ranging from -0.320 to 0.232).

Conclusions: Manufacturer parameters were successfully validated. The cobas 5800 system exhibited acceptable and comparable performance to the cobas 4800 reference method, making it a valuable tool for determining HIV viral load in clinical practice.

EP200

Strategies for successful recruitment of pregnant women into HIV prevention research: challenges and lessons learned from MTN 042/DELIVER study at MU-JHU site Kampala, Uganda

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Background: Pregnant women are considered high risk for HIV acquisition. Their inclusion in clinical research to advance prevention and treatment options is important. We describe our experience, lessons and strategies used to facilitate their enrollment.

Methods: MTN-042/DELIVER was a Phase 3, open-label, multi-site and randomized trial to assess the safety, adherence and acceptability of the dapivirine vaginal ring (DVR) and oral tablet (FTC/TDF) used for HIV prevention during pregnancy. Enrollment was in three successive cohorts beginning with late gestation. The site target enrollments per cohort were 40, 40 and 75 respectively. Key stakeholder meetings were held to engage community and maternal health personnel. Recruitment was mainly at the health facility and communities where women

attended antenatal clinic (ANC) services. Strategies included: intensive engagement of community and health-based contact persons, engagement of community ultrasound scan providers to refer pregnant people, referral of mothers by enrolled participants, DELIVER / B-PROTECTED HIV prevention study educational video and male partners involvement which took precedence over others.

Results: Of 476 prescreened for cohort 1, 68 were screened at the site and 44 enrolled. 357 were prescreened in Cohort 2; 51 screened and 41 enrolled. In cohort 3, 350 were prescreened, 88 screened and 68 enrolled. See Table 1.

Challenges included: Male partner refusal, mothers who delayed ANC care, limited familiarity with the DVR and oral PrEP. Recruitment was completed in 2 years from 2020 to 2022 for all 3 cohorts. It was extremely difficult to get the desired number for Cohort 1, but with time, lessons learned enabled the study team to identify anticipated challenges in subsequent cohorts by using creative and extensive prescreening that enabled faster recruitment in the last cohort.

	Cohort 1 8-9 months	Cohort 2 7-8 months	Cohort 3 3-7 months	Total
Mothers prescreened for the study	476	357	350	1183
Mothers screened for the study*	68 (14.3%)	51 (14.3%)	88 (25.1%)	207 (17.5%)
Mothers enrolled for the study**	44 (64.7%)	41 (80.4%)	68 (77.3%)	153 (73.9%)

*Percentages reflect the proportions screened and enrolled by Cohort

Table 1.

Conclusions: Despite the potential challenges of recruiting pregnant mothers into prevention trials; engagement between the research team, health center staff and local communities to facilitate referral helps to meet the pressing need to expand the biomedical HIV prevention evidence needed for this population.

EP201

PrEP choice implementation in Africa: early experiences of health facilities delivering informed choice of daily oral PrEP and the PrEP ring through the CATALYST study

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Background: PrEP options are expanding, but there is limited information around PrEP choice implementation. CATALYST is a PEPFAR/USAID-supported study providing an enhanced service delivery package of PrEP choice for women across public health facilities in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe. We describe chal-

lenges to effective implementation of PrEP service delivery when facilities offered oral PrEP and the PrEP ring during the CATALYST study.

Methods: Between October 2023 and January 2024, structured site assessments were conducted at CATALYST facilities to evaluate staff capacity, infrastructure, and commodity availability. Authors from the five countries considered assessment findings and implementation experiences to identify shared barriers at client, provider, and facility levels.

Results: Client level: PrEP initiation visits are prolonged by counseling, laboratory, and pharmacy wait times, and poor service integration, contributing to client dissatisfaction. Study staff noted low community awareness and negative misconceptions around the PrEP ring, and persistent PrEP stigma. While check-in phone calls are the primary PrEP use support offered (63% of facilities), clients without private phones or reliable service are unreachable.

Provider level: Over half (52%) of facilities had experienced PrEP provider turnover since study initiation, 43% of whom reported turnover-related interruptions in PrEP service provision. Provider retention challenges included salary dissatisfaction, better opportunities elsewhere, and high workload. Study staff observed that PrEP ring insertion (upon client request) was initially difficult for providers due to inexperience, and delivering quality PrEP choice counseling remains challenging given staffing constraints.

Facility level: Overall, 44% of facilities experienced electricity interruptions, and 40% reported inadequate space for storage of client records. Three facilities experienced stock-outs of oral PrEP and one of HIV tests in the month preceding the site assessment. Authors also observed insufficient space to accommodate additional PrEP clients, water shortages, and poor state of facilities.

Conclusions: CATALYST is illuminating operational challenges that could impede PrEP choice implementation. Although these limitations alone do not disrupt PrEP delivery, successful introduction and scale-up of new PrEP methods hinges on reducing these barriers.

The study team is collaborating with Ministries of Health to implement sustainable solutions through quality improvement and health service reinforcements.



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EP202

Effectiveness and acceptability of counselling based on point-of-care urine tenofovir test on HIV pre-exposure prophylaxis adherence in young South African women

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Background: Despite high oral PrEP uptake, adherence remains low in adolescents, undermining PrEP's potential public health impact. Real-time adherence support based on objective monitoring using a point-of-care (POC) urine tenofovir test may improve PrEP adherence. We conducted a pilot randomised trial to evaluate whether real-time adherence counselling based on results of a POC-tenofovir test detecting recent use (past 4-7 days) improved PrEP adherence in young South African women.

Methods: INSIGHT was a prospective, observational, open-label study of PrEP among cisgender women aged 16-30 years conducted across 20 African sites from August 2022-July 2023. Participants were included if they were sexually active, HIV negative and interested in PrEP. At the Johannesburg site, at month 1, participants on PrEP were randomized 1:1 to receive adherence counselling based on POC-tenofovir test result or standard of care (SOC). The primary outcome was high long-term adherence, defined as tenofovir diphosphate (TFV-DP) ≥ 700 fmol/punch in dried blood spots at month 3, compared across arms using chi-squared tests.

Acceptability was assessed at month 3 using a 9-item self-administered questionnaire with 4-point Likert scale responses dichotomised to agree or disagree.

Results: Of 230 screened, 200 were enrolled and 103 randomised at month 1 based on available kit supplies. Median age 24 (interquartile range 21-27) years, 15% (15/103) had previous PrEP experience and 28% (29/103) had a curable STI at enrolment. Of those randomized, 96% were retained at month 3. At month 1, 84% in the POC arm had detectable tenofovir. At month 3, 19% (10/53) in the POC arm compared to 14% (7/50) in the SOC arm had high adherence (relative risk 1.35; 95% confidence interval [CI] 0.56-3.27). Participants generally understood results (97%), liked real-time feedback (97%), said POC-based counselling helped improve communication with PrEP providers (95%), and would motivate more frequent PrEP use (100%).

Conclusions: In this pilot trial, real-time counselling based on POC test results showed a positive trend towards adherence improvement when compared to SOC, although

not statistically significant, and was acceptable to young women. These findings should be confirmed in larger randomised studies with robust estimates of effectiveness and cost to inform program implementation.

EP203

Impact of remote versus in-person navigators on linkage to HIV care of people newly diagnosed with HIV in a large emergency department in a safety-net healthcare system

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Background: Rapid linkage to HIV is critical to reducing morbidity and mortality among people newly diagnosed with HIV, particularly in the first year after diagnosis. Linkage to HIV care after diagnosis occurring in the emergency department (ED) is challenging, driven by uninsuredness, limited telephone access, housing instability, low health literacy, language barriers, and medical mistrust. In our large safety net health system in Atlanta, GA, we placed an in-person patient navigator in the ED to provide rapid HIV disclosure and support rapid linkage to care. In 2022, this position transitioned from in-person to remote patient navigation. After this change, the navigator provided HIV disclosure and linkage support exclusively by phone and electronic health record messages. We sought to evaluate the impact of this change on the rates of linkage to HIV care.

Methods: We abstracted monthly reports that included the number of people newly diagnosed with HIV in our system and how many were linked to care, defined as attending their first HIV outpatient appointment within the month after diagnosis. We compared HIV linkage rates over one year of in-person navigation (September 2021 to August 2022) to the first year of remote navigation (September 2022 to August 2023). We compared differences in linkage rates utilizing a z-test of proportions.

Results: During the in-person navigation period, out of 30,315 people who received HIV tests, 333 received a new HIV diagnosis, of which 67 (20%) linked to care. During the remote navigation period, 31,746 people received HIV tests, with 235 receiving a new diagnosis of HIV, of which 45 (19%) linked to care. Linkage rates were low in both periods, with no significant difference ($p = 0.29$).

Conclusions: HIV linkage rates throughout the study period were low, but switching from in-person navigation to remote did not negatively impact linkage rates. This suggests that remote patient navigation may be a viable option for healthcare systems to link people newly diagnosed with HIV-related care, but further study is needed to evaluate methods to increase HIV linkage after diagnosis in the ED.

EP204

A multi-level assessment to inform implementation strategies of a machine learning model to identify PrEP candidates in Southeastern Louisiana

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Background: Machine-learning models to identify people who may benefit from PrEP are a promising approach to enhance PrEP engagement. Yet, it is critical to develop implementation strategies for model delivery that are acceptable to communities.

Methods: We are conducting a multi-level assessment, guided by PRECEDE-PROCEED (Figure), to gather implementer and community member perspectives prior to model implementation in New Orleans and Baton Rouge, Louisiana.

Here, we focus on the pre-assessment consultation (two focus group discussions [FGDs] with community advocates and healthcare personnel) and the ecological assessment (eight in-depth interviews [IDIs] with demographically diverse PrEP-eligible individuals) in which we inquired about the acceptability of two proposed implementation strategies:

1. Periodic, centralized reporting in partnership with community-based organizations (CBOs), and;
2. Real-time alerts in partnership with acute healthcare centers (AHCs).

We analyzed the FGDs and IDIs separately using applied thematic analysis and combined similar topics to describe the findings.

Results: Participants said the model would be beneficial in enhancing equity by identifying PrEP candidates who might otherwise be overlooked and in increasing PrEP linkage by extending the reach of providers and CBOs. Participants expressed that the periodic strategy would help in educating patients, yet emphasized that patients may have privacy concerns about how their medical information was accessed.

Participants stressed the importance of safeguarding patient data when used by CBOs. They said the real-time strategy could build trust between patients and providers, although explained that patients may be offended by a PrEP offer or unreceptive to discussing their sexual health when visiting an AHC for unrelated reasons. Participants suggested ways to sensitively initiate PrEP conversations.

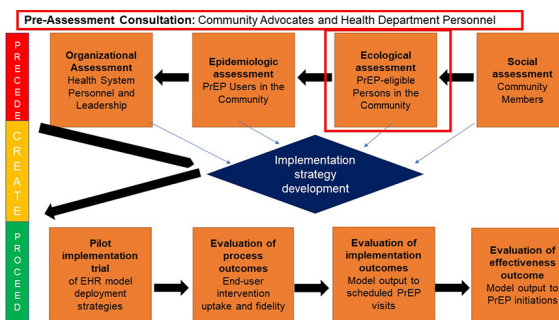


Figure. Multi-Level Assessment Guided by the PRECEDE-PROCEED Conceptual Model

Figure. Multi-level assessment guided by the PRECEDE-PROCEED conceptual model.

Conclusions: Concerns about model implementation mostly revolved around privacy and approach to discussing PrEP with patients. Careful attention to these concerns, and collaboration with community partners, will be necessary to ensure that model implementation is conducted with acceptance from impacted communities.

EP205

“We are transferred not transitioned” young peoples experiences of moving from paediatric to adult HIV clinic in Kampala. A qualitative exploratory study

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Background: Adolescents and young people represent a significant number of people living with HIV/AIDS in Sub Saharan Africa. The introduction of ART has significantly reduced mortality rates for people living with HIV however; HIV related mortality is increasing among adolescents as they have poorer rates of viral suppression when compared to the adults living with HIV. This is due in part to the multiple co-occurring transitions (developmental and clinical setting) in this period of the lifespan.

The aim of this study was to explore the barriers to successful transitioning to adult HIV services among adolescents in Uganda.

Methods: This formative exploratory qualitative study (May 2023 - October 2023) involved the conduct of in-depth interviews among two categories of people i.) 40 young people between the ages of 13-23 years; ii.) 10-15 young peer supporters/ expert clients at an HIV clinic in Kampala. Data was Interviews were conducted between May and October 2023. Data were analyzed thematically and managed using Nvivo 14.

Results: Our findings revealed that:

1. The adult clinic environment composed of:

- a. Scary adult conversations such as marital problems, challenging co-morbidities,



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- b. Poor attitude of the healthcare workers and adult clients,
- c. Large clients volumes, inflexible service hours and long waiting times, and;
- d. Change of health workers who have cared for them over the years.

2. Unpreparedness of adolescents for the transition composed of:

- a. Abrupt change of services,
- b. Fear and loss of privileges provided by the youth friendly services,
- c. Reduced opportunities for leadership, active engagement with healthcare workers, and;
- d. Lack of autonomy, responsibility, shyness, intimidation and stigma affected the successful transition to the adult HIV clinic.

Conclusions: Co-development of transition models with youth living with HIV to address these barriers can help enhance participants' transition experiences and preparation for healthcare services in the adult HIV clinics.

EP206

Innovative strategies for HIV research engagement in marginalized communities

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Background: The purpose of our research was to explore the barriers hindering marginalized communities' engagement in HIV prevention research and to propose innovative strategies to address these challenges. We sought to understand the impact of legal restrictions, fear of surveillance, and stigma on participation in research activities.

Additionally, we examined gender and age dynamics within these communities to identify specific vulnerabilities and needs. Through our investigation, we aimed to contribute to the development of more inclusive and effective approaches to HIV prevention research among marginalized populations.

Methods: Our study, utilizing qualitative methods, examined barriers to HIV prevention research engagement among marginalized groups. Legal restrictions, surveillance fears, and stigma hindered participation, particularly among youth and women. Innovative strategies, such as virtual and underground networks, and community-led initiatives, were identified to overcome these challenges. Specific findings stressed the need for age-specific interventions and gender-sensitive approaches.

Overall, our study emphasizes the importance of addressing systemic barriers and implementing tailored strategies to foster meaningful engagement in HIV prevention.

Results: In our study, we delved into the obstacles inhibiting marginalized communities' involvement in HIV prevention research. Legal constraints, surveillance apprehensions, and pervasive stigma posed significant hurdles, disproportionately affecting youth and women. However,

we identified innovative approaches like virtual networks, underground connections, and community-led initiatives as effective means to surmount these barriers.

Notably, our findings underscore the necessity of tailored interventions targeting specific age groups and adopting gender-sensitive strategies. In essence, our research highlights the imperative of addressing systemic challenges and implementing customized solutions to foster genuine engagement in HIV prevention research within marginalized populations.

Conclusions: Our study's findings illuminate key barriers to HIV prevention research engagement among marginalized communities. By addressing legal restrictions, surveillance fears, and stigma, we pave the way for tailored interventions and strategies. Innovative approaches like virtual networks empower marginalized individuals to actively participate. Tailoring interventions to age and gender dynamics ensures inclusivity and equity.

Looking forward, our research informs broader discourse and action in the global HIV/AIDS response, advocating for rights-based approaches that prioritize dignity and justice. Embracing these insights is crucial for advancing inclusive and effective HIV prevention.

EP207

Breaking barriers: improving HIV testing access for key populations in Nigeria

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Background: In Nigeria, 80% of new acquires HIV are caused by unprotected heterosexual intercourse, with most people living with HIV happening in key populations. In Nigeria, the HIV epidemic is focused on Key Populations (KP) such as person who inject drugs (PWID), men who have sex with men (MSM), female sex workers (FSW), and partners of person living with HIV. These people face limited access to HIV testing services (HTS) and encounter challenges in accessing treatment due to stigma and discrimination.

In response to this challenge, index partner testing was introduced in 2017, aiming to reach sexual and injecting partners of KP index clients to improve testing and linkage to care within these vulnerable population

Methods: This study retrospectively analyzed community-driven HIV index partner testing by examining secondary data from partner notification service records. HIV testing within this program was conducted at nightclubs, hotels, and community ART clinics in Akwa Ibom, Cross River, and Lagos states. Peer navigators supported index testing, utilizing provider and passive Partner Notification (PN) methods, along with in-person and social network approaches to engage partners of Key Populations (KP).

Results: Provider referral accounted for 68.3% and passive/client referral for 30.1% of Partner Notification (PN). 3,119 index partners identified 8,989 sexual and injecting

partners, with a ratio of 1:2.9. Among these, 84.1% were first-time testers, and 79.4% of male partners were tested. Of the partners who tested positive (49.7%), 93.0% were linked to HIV care. HIV seropositivity rates were 65.5% among females and 45.5% among males.

Notably, PWID injecting partners (99.1%), PWID sexual partners (98.9%), and MSM sexual partners (95.6%) in Cross River had higher seropositivity rates compared to FSW sexual partners (71.4%).

Conclusions: Index partner testing has demonstrated potential in enhancing HIV testing access for Key Populations (KP) in Nigeria. However, significant challenges persist, including addressing stigma and discrimination, increasing access to HIV testing services (HTS), and improving linkage to treatment.

Further studies are required to determine the most effective strategies for reaching KP and ensuring they receive the necessary care and support.

EP208

CD40-VS4, a *Chlamydia trachomatis* antigen-presenting cell targeting vaccine induces systemic and mucosal immunity in mice with TLR4 or TLR3 agonists as adjuvants

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Background: *Chlamydia trachomatis* (Ct) is a common STI with serious health consequences, underscoring the need for an effective vaccine. The platform targeting CD40 antigen-presenting cells is been used in vaccine development in HIV-1 and HPV-16 infections (NCT04842682, NCT06007092).

We developed and assessed the immunogenicity of a CD40-based vaccine targeting the VS4 sequence from the Major Outer Membrane Protein from Ct.

Methods: VS4 was selected based on the presence of neutralizing B-cell epitopes by an *in silico* analysis. A fusion protein of the CD40-specific 12E12 humanized mAb and the VS4 sequence at the C-terminus regions of Heavy chains was produced in CHO cells.

Recall memory T-cell responses from PBMCs from Ct-convalescent (CtC) individuals was analyzed in *in vitro* restimulation assays. Systemic and mucosal immunogenicity of the CD40.VS4 vaccine (10mcg/injection, co-administered intramuscularly and subcutaneously at days (D) 0, D21, and D49) combined with SLA-SE (10mcg, Gr1) or Poly-ICLC (60mcg, Gr2) was tested in hCD40 transgenic mice (n=12-14/group).

Controls received adjuvants alone (n=18, Gr3). B- and T-cell responses were evaluated in lymphoid organs and vaginal mucosa at D56.

Results: Immunogenicity of VS4 regions was confirmed by detecting high levels of VS4-specific IgG in the sera from CtC and recalling memory T cells in *in vitro* assays. CD40.VS4 vaccine also recalled higher and polyfunctional CD4⁺ T cell memory responses (TNF+/-IFN-γ+/-IL-22+/-) from CtC's PBMC (n=6) as compared to HD (n=7).

Mice studies showed that CD40.VS4:

- Induced higher levels of systemic VS4-IgG and IgA responses than Gr3, regardless of the adjuvant;
- All CD40.VS4 vaccinees exhibited mucosal VS4-IgG, with 40% displaying mucosal VS4-IgA in Gr2 and 25% in Gr1;
- CD40.VS4 induced in Gr1/Gr2 expansion of GC B cells and Tfh cells, which were positively correlated (R=0.87, p<0.001);
- All vaccinees (Gr1/Gr2) developed potent VS4-specific IFN-γ T-cell responses including VS4-specific CD4⁺ T-cell responses while CD8⁺ T-cell responses were induced mainly in the SLA-SE group.

Conclusions: CD40.VS4 vaccine induced systemic and mucosal humoral and cellular immune responses. Further protection studies in challenge models will complete the go/no go decisions to move CD40.VS4 into clinical development. These findings emphasize the vaccine's potential significance in chlamydia prevention.



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EP209

Building better HIV models: a framework for incorporating evidence on structural determinants and interventions to estimate their impacts on HIV epidemics

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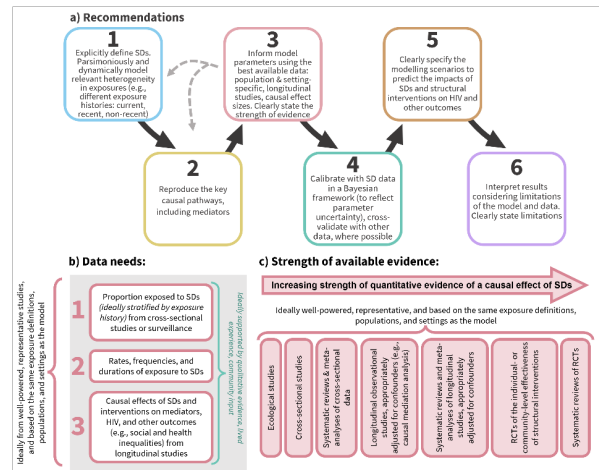
Background: Structural determinants (SDs) are social, economic, political, cultural, organizational, and environmental factors that shape HIV inequalities across individuals and populations. UNAIDS' 10-10-10 targets aim to reduce exposure to SDs including punitive regulations, violence, stigma, and discrimination. Evidence-based dynamic HIV transmission models can help quantify the population-level impacts of SDs and structural interventions to inform decision-making.

We appraised previous representations of SDs in HIV models to develop a new framework that supports the modelling and analysis of SDs.

Methods: We performed a scoping review of HIV transmission dynamic modelling studies that modelled SDs, published until August 28, 2023, using Ovid Embase and Medline databases. To develop our framework, we considered how models represented exposures to SDs (statically vs dynamically) and reproduced causal pathways to estimate impacts on HIV, and the data they used.

Results: We found 17 HIV modelling studies of SDs and/or structural interventions including incarceration of people who inject drugs (n=5) or Black men (n=2), violence against women (n=3), HIV-stigma (n=1), and homelessness (n=1), among other less well-defined exposures (e.g., "positive and negative attitudes"). Eight studies modelled SDs dynamically using granular exposure histories (e.g.,

current, recent, non-recent) that captured variation in duration and intensity of exposure. SDs mostly influenced HIV indirectly through simple causal pathways with single intermediate variables (mediators) – largely sexual/injecting partner numbers (n=9), mixing patterns (n=8), or condom use (n=6). Effects of SDs were mostly informed by cross-sectional data. Only seven studies fitted to observed trends in SDs or their effects on mediators/HIV. Using this, we developed our framework (Figure).



Conclusions: The representation of SDs in models could be refined to improve projections of their impacts and interventions using our framework. Fundamentally, this requires better inputs: more longitudinal studies investigating heterogeneity in SDs and their causal effects. Methods, findings, and limitations should be transparently communicated.

EP210

Profiles of potential PrEP users: a segmentation analysis to inform long-acting and oral PrEP communication in Malawi

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Background: Long-acting injectable (LAI) PrEP has the potential to reduce HIV incidence by offering an alternative to oral PrEP, however, there is a need to consider drivers and barriers to use when integrating LAI-PrEP into national programmes. This study aimed to identify groups of PrEP users in Malawi defined by their attitudes and perceptions of PrEP.



Methods: In September 2023, cross-sectional surveys were conducted using interception recruitment at clinics and drop-in centres. Eligibility criteria included being HIV-negative, and inclusion in one of the following non-exclusive groups: adolescent girls and young women (AGYW), female sex workers (FSW), men who have sex with men (MSM), heterosexual men at high risk (HRM), transgender women (TGW) and pregnant and breastfeeding women (PBFW). A multi-step segmentation analysis was conducted using dimension reduction based on hierarchical cluster and k-means analysis, grouping respondents based on commonalities across the canonical variables. We tested differences between groups using one-way ANOVA; Bonferroni correction was applied given different segment sizes.

Results: A total of 550 interviews were conducted and our statistically unique segments were identified (Table 1). Segment 1 (20%) was predominately PrEP-naive AGYW or PBFW. Segment 2 (32%) were experienced PrEP users, predominantly AGYW and HRM who were likely to have discontinued PrEP due to negative clinic experiences or side effects. Segment 3 (31%) were confident PrEP users, predominantly FSW and MSM. Segment 4 (18%) demonstrated moderate PrEP usage and were most likely to experience barriers related to stigma, predominantly MSM or TGW. Openness to LAI was high across segments, but highest in Segments 3 and 4. Drivers and barriers to using PrEP differed by segment, but all segments cited feeling in control of their health as a driver.

Conclusions: There is high demonstrated interest in oral and LAI PrEP in Malawi across a broad range of users. Attitudinal segmentation reveals distinct drivers and barriers which could lead to tailored interventions per group.

EP211

Preferences for starting daily, on-demand, and long-acting injectable HIV pre-exposure prophylaxis among transfeminine persons in the United States: results from the Transgender Women's Internet Survey and Testing (TWIST) study

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Background: HIV pre-exposure prophylaxis (PrEP) utilization is reported to be low among transfeminine persons (TFP) assigned male at birth. Long-acting (LA) injectable PrEP may improve PrEP utilization among TFP. However, little information is available on the preferences of TFP for initiating PrEP across different PrEP options.

We examined PrEP option preferences and factors associated with willingness to use LA PrEP among a US nationwide sample of TFP.

Methods: Sexually active TFP age 15+ were recruited online between June 2022 and October 2023 through social media advertisements.

TFP not living with HIV who had not used PrEP in the past year were given brief descriptions of three PrEP options (daily oral, on-demand, LA PrEP) and were asked "If [PrEP option] were available from your local doctor and you could access it for free, would you go to your doctor in the next month to start [PrEP option]?"

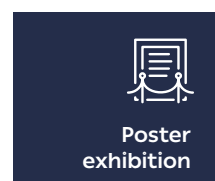
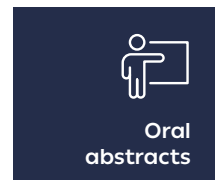
Those who said yes to multiple options were asked to rank them in order of preference. Log-binomial models were used to examine willingness to start LA PrEP by sociodemographic and behavioral characteristics.

Results: Among 2657 TFP, 51% reported willingness to start at least one PrEP option. The highest willingness was reported for on-demand PrEP (42.6%), followed by daily oral (38.1%) and LA PrEP (27.1%). LA PrEP was ranked the most preferred PrEP option among TFP who reported willingness to start multiple options (43%, 277/651).

Willingness to start LA PrEP was significantly higher among participants who had both public and private insurance, had condomless anal sex, had multiple sex partners, used recreational drugs in past 12 months, and who were previously aware of LA PrEP (Table).

	Segment 1: PrEP-naive (AGYW, PBFW)	Segment 2: Discontinued users (AGYW, HRM)	Segment 3: Confident users (FSW, MSM)	Segment 4: Sensitive to stigma (MSM, TGW)
% heard of PrEP	59%	95%	100%	96%
% using oral PrEP	28%	48%	78%	46%
Drivers for using PrEP	Feeling in control of my health (95%) Reducing risk during breastfeeding (91%) Reducing risk during pregnancy (86%)	Feeling in control of my health (88%) Makes me worry less about HIV (72%)	Feeling in control of my health (99%) Worry less about risk (92%) Freedom in my sex life (88%)	Feeling in control of my health (95%) Freedom in my sex life (91%) Worry less about risk (90%)
Barriers to using PrEP	Triggers problems with partner(s) (56%) Need partner approval to use PrEP (52%) Side effects (35%)	Want to avoid the clinic (40%) Side effects (33%)	Triggers problems with partner(s) (72%) People may think I have HIV (57%) Taking medicine makes me feel like I'm sick (33%)	Triggers problems with partner(s) (87%) Don't want to see anyone at the clinic (75%) People may think I have HIV (73%)
Openness to injection	91%	91%	98%	98%
Drivers to using LAI PrEP	Easier to hide than pills (99%) Two-month break between doses (95%) Injection feels safer than pills (81%)	Two-month break between doses (93%) Gives more flexibility in my day (83%) Don't like taking pills (45%)	Two-month break between doses (99%) Easier to hide than pills (98%) Gives me flexibility in my day (98%)	Easier to hide than pills (100%) Would suit my schedule (99%) Protects me for longer (86%)
Barriers to using LAI PrEP	Would need more information (71%) Injection will last longer in my body (42%) Likely to forget every two months (24%)	Would need more information (52%) Harder to stop when I want (37%) Side effects could be worse (21%)	Would need more information (62%) Harder to stop when I want (40%)	Likely to forget every two months (29%) Clinic visits would be too long (28%) Someone may see swelling at injection site (20%)

Table 1.





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	Willing to use long-acting injectable PrEP n (%)	Not willing to use long-acting injectable PrEP or not sure n (%)	Unadjusted prevalence ratio and 95% confidence interval	Adjusted prevalence ratio and 95% confidence interval
Total	720 (28.3)	1825 (71.7)		
Age (years)				
15-24	291 (28.8)	720 (71.2)	1.05 (0.86, 1.29)	0.95 (0.78, 1.17)
25-29	146 (26.7)	400 (73.3)	0.98 (0.78, 1.23)	0.83 (0.66, 1.04)
30-39	194 (29.3)	468 (70.7)	1.07 (0.87, 1.33)	0.92 (0.75, 1.14)
40+	89 (27.3)	237 (72.7)	ref	ref
Health insurance				
None	66 (31.4)	144 (68.6)	1.20 (0.97, 1.49)	1.15 (0.93, 1.43)
Private only	421 (26.2)	1188 (73.8)	ref	ref
Public only	154 (30.5)	351 (69.5)	1.17 (1.00, 1.36)	1.10 (0.94, 1.28)
Both private and public	59 (45.7)	70 (54.3)	1.75 (1.42, 2.15)	1.56 (1.28, 1.91)
Other	15 (23.8)	48 (76.2)	0.91 (0.58, 1.43)	0.96 (0.62, 1.48)
Condomless anal sex in past 12 months				
No	387 (25.5)	1130 (74.5)	ref	ref
Yes	333 (32.4)	695 (67.6)	1.27 (1.12, 1.44)	1.16 (1.03, 1.32)
Number of partners				
One	281 (20.1)	1120 (79.9)	ref	ref
More than one	430 (38.9)	676 (61.1)	1.94 (1.71, 2.20)	1.79 (1.57, 2.04)
Recreational drug use in past 12 months				
No	494 (26.0)	1404 (74.0)	ref	ref
Yes	226 (34.9)	421 (65.1)	1.34 (1.18, 1.53)	1.22 (1.06, 1.41)
Heard of LA PrEP				
No	521 (26.1)	1479 (74.0)	ref	ref
Yes	197 (36.5)	343 (63.5)	1.40 (1.23, 1.60)	1.28 (1.12, 1.47)

Abbreviations: NCHS: National Center for Health Statistics, PrEP: pre-exposure prophylaxis
 *Age, race/ethnicity, health insurance, NCHS rural-urban category, census region, STI diagnosis in past 12 months, condomless anal sex in past 12 months, condomless vaginal sex in past 12 months, number sex partners, marijuana use in past 12 months, illicit drug use past 12 months, taking daily prescription pills, prior awareness of LA PrEP were included in the models to estimate adjusted prevalence ratios
 **Bold text indicates statistical significance.
 *** Data does not add up to the total number of participants due to missing information resulting from non-response from some of the participants

Table 1. Willingness to use long-lasting injectable PrEP among transfeminine persons who have a high likelihood of HIV and who did not use PrEP in the past 12 months, The Transgender Women's Internet Survey and Testing (TWIST) project, United States, 2022-23.

Conclusions: There is substantial interest among TFP towards multiple PrEP options. LA PrEP may help close the PrEP coverage gap as an additional PrEP option among TFP who can benefit from PrEP.

EP212

Facilitators, barriers and robust informed consent for HVTN805/HPTN093/A5393 analytical treatment interruption (ATI) participation: insights from ATI participants and decliners screened from the antibody mediated prevention (AMP) study in Southern Africa

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Background: Antiretroviral therapy (ART) prevents and treats but doesn't eradicate HIV. Potential ART alternatives can be safely, effectively evaluated through carefully monitored, temporary ATIs. ATI conduct can be improved by better understanding facilitators, barriers, and optimal informed consent for individuals considering ATI participation. We assessed these in an ATI conducted among women who received placebo or anti-HIV bnAb VRC01, acquired HIV, and initiated early, virologically-suppressive ART in the AMP Africa HIV prevention study.

Methods: Fifty-three AMP Africa participants met ATI prescreening criteria and consented to be contacted; 33 were excluded after prescreening. Twenty completed

screening, including a robust informed consent process with decision aid questionnaires exploring personal motivators and barriers to ATI participation. Seven declined enrollment; thirteen women from South Africa, Malawi, Botswana, and Zimbabwe enrolled (Figure 1). They completed periodic questionnaires regarding their experience, including at key transitions throughout the study (e.g., starting ATI, restarting ART).

EP213

Examining the impact of COVID-19 on sexual behavior and HIV treatment and prevention access among gay, bisexual, and other men who have sex with men in Latin America

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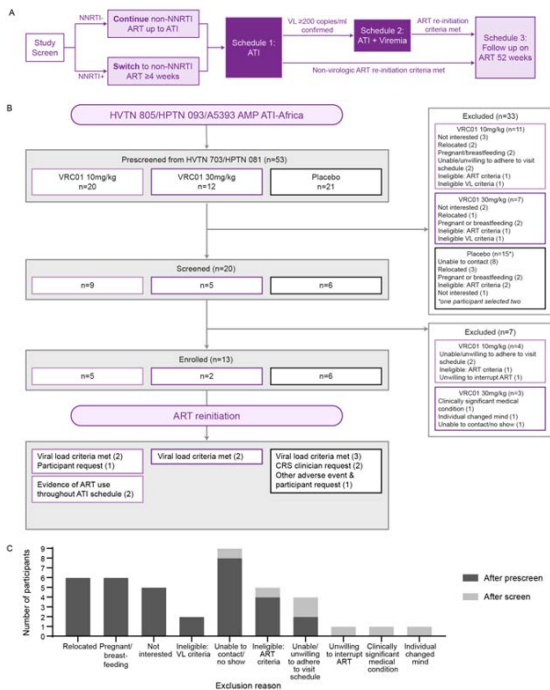


Figure 1. ATI Design, Screening & Enrollment. (A) AMP ATI-Africa design schematic. (B) CONSORT and ART re-initiation criteria. (C) Graph of exclusion reasons after prescreening (dark grey) and screening (light grey). NNRTI: non-nucleoside reverse transcriptase inhibitor. ART: antiretroviral therapy; ATI: analytical treatment interruption; VL: viral load.

Results: All enrolled participants reported that primary facilitators of their participation included careful study monitoring of their health and HIV, with free STI testing and physical exams, and being able to restart ART at any time. Most (n=11, 84.6%) identified altruism as a motivator, but only two (18%) ranked this of comparable or greater importance than personal health- and HIV-related motivators. Enrolled participants and decliners reported comparable concerns/barriers, including the risk of transmitting HIV to sexual partners and the possibility of having HIV symptoms, detectable viral load, and CD4 count decline upon rebound. All enrolled participants reported receiving enough support and information to decide upon enrollment; throughout the study they reaffirmed their certainty about, and their largely consistent motivators and barriers for, their choice to enroll. Retention was 95%. **Conclusions:** Robust informed consent supports successful enrollment and retention in novel, complex study designs like ATIs. Identified facilitators and barriers can inform future ATI design and implementation.

Background: Little global research exists exploring the impact of COVID-19 on the sexual health behaviors of gay, bisexual, and other men who have sex with men (GBMSM) in Latin America. This study used a subset of a large global dataset with representation of GBMSM from 132 countries to assess the impact of the pandemic on sexual behaviors, HIV-related service disruptions, and comfort attending social and sexual venues among GBMSM in Latin America.

Methods: Data for this study come from a cross-sectional survey implemented by *Hornet*, a popular gay social-networking app among GBMSM. *Hornet* users were invited to participate in an online survey related to the impact of COVID-19 on diverse health-related outcomes from October to November 2020. Multivariable regression analyses were used to describe correlates of sexual contact during the pandemic.

Results: A total of 3,216 participants from 21 Latin American countries were included in these analyses. At the time of being surveyed, over half (64.7%) of participants had physical sexual contact with a partner they met on a gay social networking app since the COVID-19 crisis began. Some participants (12.9%) reported having no or less access to condoms and/or lubricants during the COVID-19 crisis and 13.1% of those who had ever taken HIV pre-exposure prophylaxis (PrEP) stopped due to COVID-19. Nearly three quarters (70.1%) of GBMSM living with HIV did not have the option to refill their HIV medications remotely and over a quarter (26.8%) were not able to see their HIV service provider since the start of the pandemic.

Relative to those who felt comfortable going now, GBMSM waiting to attend social and sexual venues until public health officials indicated it was safe, there was a vaccine, or their friends started going were less likely to have an app-based sex partner.

Conclusions: Sexual partnerships forged online continued among GBMSM during the COVID-19 pandemic despite limitations to accessing sexual health resources, including condoms, PrEP, and HIV treatment.

Reasons for waiting to attend social and sexual venues provide insights for improving public health messaging and resources for GBMSM during times of public health crisis.



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HIV-1 entry inhibition capabilities of isoflavones

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Background: Over the years, HIV has persisted as a global health challenge. Although there is availability of anti-retroviral therapy, a cure remains elusive and the development of drug resistance to current drugs necessitates the development of novel therapies. This study investigated novel isoflavones which could be classified as flavanoids. These are a bioactive group of molecules that have been extensively researched for their ability to inhibit HIV in many areas of the HIV life cycle, such as reverse transcription, integration and protease activity inhibition. The novel conversion of benzoylbenzofurans into isoflavones by tandem demethylation and ring-opening/cyclization of methoxybenzoylbenzofurans produced five novel isoflavones with a distinct 2',5'-oxygenation pattern.

Methods: Post synthesis and characterisation, five isoflavones were investigated for their effects on the infectivity of CAP 210, an HIV subtype C pseudovirus using the luciferase reporter gene assay. The cytotoxicity of these compounds was evaluated in TZMbl cells, a modified HeLa cell line that allows for infection with HIV. To determine the possible target of the compounds in the HIV life cycle, time of addition studies were performed and the compounds were introduced at two different time points. In silico docking was performed to determine the possible mechanism of viral inhibition exhibited by the compounds.

Results: The five isoflavones inhibited the infectivity of CAP 210 with IC₅₀ values ranging between 6.2 and 10.6 μ M. These were non-toxic to TZMbl cells, making the compounds highly selective to the virus (SI values range from 4.4 to 32.3). Two of the five compounds showed significant differences in their percentage inhibition when added at different times to the reaction, with higher inhibition at time 0. This suggested that these compounds could be entry inhibitors. In silico docking studies showed that the possible entry inhibition mechanism of the compounds was through interactions with Trp427 and Glu370 of gp120 via hydrogen binding. Binding to Trp427 is hypothesised to function antagonistically by displacing the gp120 β 20-21 strands into regions the CD4 receptor would normally occupy, thus preventing CD4 binding.

Conclusions: The further development of these compounds could ultimately contribute to the collection of available entry inhibitors in clinical use.

EP215

Awareness, perception and willingness to use Doxy-PEP by young people in government-mandated service corps in Abuja, Nigeria: a cross-sectional study

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Background: Doxycycline-based post-exposure prophylaxis (Doxy-PEP) is a novel, cost-effective strategy for the prevention of STIs after a possible exposure through sexual activity. Young people are a key population at risk of acquiring STIs, and there is a need for multiple strategies to reduce the incidence rate.

This study evaluated the knowledge, attitudes, and willingness to use Doxy-PEP among young individuals in Abuja, Nigeria's government-mandated service corps.

Methods: A cross-sectional study was conducted in January 2024 among 600 randomly sampled young people (aged <30 years) in the government-mandate service corps in Nigeria. Using a 19-item validated questionnaire, their awareness, perception, and willingness to use Doxy-PEP were assessed. Appropriate descriptive and inferential analyses were conducted, with $p < 0.05$ considered statistically significant. Ethical approval was obtained from the service corps.

Results: Out of the 432 responses (72% response rate), 306 (70.8%) were female, and 243 (56.3%) were aged between 20 and 24 years old. Only 93 (21.5%) have heard of Doxy-PEP. Only a few, 93 (21.6%), believe that Doxy-PEP is effective in preventing STIs. As regards the potential side effects and safety issues of Doxy-PEP, only 174 (40.3%) are concerned. On willingness to use, only 144 (33.3%) are willing to use Doxy-PEP, with 105 (24.3%) being female. Only 163 (37.7%) stated factors that would influence their willingness to use or not to use Doxy-PEP, with side effects and safety issues being the most stated factors, as expressed by 57 (35% of those that stated factors that would influence their willingness to use).

Conclusions: There is poor awareness, inadequate perception, and a lack of willingness to use Doxy-PEP as a prophylaxis strategy. The majority of factors being stated as side effects and safety issues show that inadequate information and awareness on Doxy-PEP are available to young people as a key population.

It is recommended that public health campaigns and educational interventions be focused on young people as a key population to increase awareness and create a more positive perception and willingness to use Doxy-PEP as a post-exposure prophylaxis.

EP216

Lowering age of consent to 15: impact on HIV testing for adolescents in Tanzania

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Background: Tanzania is home to approximately 20 million adolescents in the age group of 10-19 years, accounting for 23% of the country's population. Further breaking this down, very young adolescents (VYAs) between ages 10-14 make up 13% of the total population. Thus, VYAs represent a huge opportunity to transform the social and economic fortunes of the country if they are healthy, educated, and empowered. (Tanzania Adolescent Health and Development Strategy (AHDS) 2018 – 2022). Adolescents and young people, particularly adolescent girls and young women (AGYW) aged 10-24 years, are an important population group for the Government of Tanzania. AGYW have for a while and continue to be disproportionately affected by HIV and various other sexual and reproductive issues compared to their male counterparts of the same age band. COMPASS Tanzania coalition conducted a survey in 2017 to collect evidence towards advocating for lowering age of consent for HIV testing to 15 from 18 years old. The study based on the analysis of the existing HIV PEPFAR programmatic report.

Methods: A total of 420 adolescents and young people living in Dodoma and Dsm aged 15-24 years were interviewed from January to December 2017. Information was collected on socio-demographic characteristics, substance use, and sexual behaviors, information on livelihood and survival means, survival sex, encounter with community and other forms of violence and access to services. Health service providers shared experiences of their work with street children and youth. Descriptive multivariate statistical were used in the analysis.

Multi-sectoral approach were used as the approach of reaching the government officials presenting the findings at the Ministry of Health, TACAIDS, NCP and the Mistry of community development, gender, children and elders by then.

Results: lowered age of consent to 15 years old and increased the uptake of HIV testing services to Adolescents 15 years and above.

Conclusions: Lowered age of consent from 15 to 18 years old has increased the uptake of the HIV testing to adolescents, considering PEPFAR programatic reports of 2020 - 2023 there is increase to 30% of the uptake of the testing services and reduced to 5% HIV acquisition according to THIS 2022-2023.

EP217

Pre-Exposure Prophylaxis protective against intimate partner violence: results from the first PrEP demonstration project among Men having Sex with Men and Transgender Women in India

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Background: Men having Sex with Men (MSM) and Transgender Women (TGW) are known to experience more Intimate Partner Violence (IPV) than heterosexuals. We estimated the prevalence and present correlates of IPV among MSM and TGW enrolled under a demonstration project of pre-exposure prophylaxis (PrEP).

Methods: Between December 2019 and July 2023, a demonstration project to study the feasibility of the provision of oral TDF containing PrEP was conducted at Pune, Maharashtra and Jalandhar, Punjab in India. Self-identified MSM or TGW, aged 18 years and above, at substantial risk of HIV within last 6 months, who were willing and able to provide written informed consent and willing for PrEP were enrolled. The prevalence of IPV at baseline and recurrent physical or emotional IPV during the study follow-up were estimated in percentages along with 95% confidence intervals. The bivariable and multivariable model was executed using Stata 16.1. The factors with P value <0.05 were considered as statistically significant.

Results: Out of the 650 enrolled MSM and TGW initiated on oral PrEP, 95 (15%) reported ever facing either physical or emotional abuse from intimate partners; 10.9% (36/331) and 18.5% (59/319) at Jalandhar and Pune respectively. Of the total 95, 56 (58.9%) were MSM. Being transgender ($p=0.014$), having first experience of sex at an age below 18 years ($p=0.007$), and having ever experienced forced sex ($p < 0.001$) were found to be independently associated with any one type of IPV. Of the 54 MSM/TGW who reported IPV at baseline, 29.6% (16/54) and 16.6% (9/54) continued to experience IPV at 6 and 12 months respectively.

Conclusions: TGW; young MSM/ TGW and survivors of forced/ minor sex episodes render them vulnerable to IPV. PrEP appears to be protective against IPV in this population. The IPV experience among MSM and TGW enrolled in PrEP study reduced. IPV is known to be peripheral determinant of HIV, HIV prevention program needs to focus on TGW and MSM seeking PrEP for IPV prevention.

Further studies are needed to explore if PrEP could provide MSM/ TGW experiencing IPV an option of HIV prevention without condom negotiation or without compromising safety.



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Characterization of chemsex in PrEP users in a reference Sexual Health Clinic of Buenos Aires

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Background: The practice of chemsex consists of the intentional use of substances, including methamphetamine, γ -hydroxybutyrate (GHB), γ -butyrolactone (GBL), mephedrone, cocaine, MDMA (ecstasy) and ketamine, to increase activity or sexual pleasure. This practice could be associated with high-risk sexual behaviors that can increase the transmission of STIs as well as expose users to substance overdoses. A history of having practiced chemsex was associated with a greater probability of having a diagnosis of syphilis, gonorrhoea, or chlamydia in PrEP users. In Argentina there is a lack of information regarding this problem.

This research aims to measure the prevalence and characterize the practice of chemsex and STIs in PrEP users in a Sexual Health Clinic in the City of Buenos Aires, where more than 600 people receive clinical care.

Methods: This is a descriptive, cross-sectional study. The medical records and a self-administer questionnaire were used to obtain the information.

Results: From Feb, 2024 to March, 2024 all the PrEP users attending the Sexual health Clinic of the Hospital Ramos Mejia were invited to participate. The study is still enrolling and we report here preliminary results. 55 participants contribute with data for this report. The median age was 34 years (range 20-57). 52 (94,5%) identified as men, and 3 (5,5%) as women. Regarding condom utilization, 41 (74,5%) reported an irregular use, while 10 (18,2%) reported that they never used condom. Related to the medical history of STIs in the last 12 months, 23 (57,5%) had had at least one. In relation to Chemsex 27 (49,1%) reported to have used it in the last 12 months.

Within the drugs, MDMA as the most common (9, 33,3%), followed by cocaine (8, 29,6%), GHB (7, 25,9%), Ketamine (6, 22,2%), Methamphetamine (4, 14,8%), GBL (2, 7,4%), mephedrone (2, 7,4%). 15 (44,1%) reported use of two or more drugs at the same time.

Conclusions: In this preliminary analysis we have found a significant prevalence of chemsex use in PrEP users in ClinSex Buenos Aires. This highlights the need to deepen our understanding of chemsex practice, including risks and adverse events, in order to develop new strategies according to the needs in our community.

EP219

The value of measuring outcomes of HIV advocacy: utilising a novel and participatory approach for advocacy evaluation

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Background: Informed civil society activism and advocacy have driven change throughout the HIV epidemic, and remains essential now for a sustainable, comprehensive epidemic response. The Coalition to build Momentum, Power, Activism, Strategy & Solidarity in Africa (COMPASS), is an innovative, data-informed and audacious North-South collaboration of civil society organizations working in the global North and in East and Southern Africa; to advocate for truly comprehensive, effective programs that lead to epidemic control. It can however, be difficult for advocates as well as funders and partners, to demonstrate how their efforts contribute to real, but incremental impact on the HIV response; largely due to a lack of tools to assess the impact of HIV advocacy.

Methods: Within the MERL hub under COMPASS, Pangaea Zimbabwe (PZ) and AVAC developed the COMPASS Campaign Outcomes Assessment Tool (C-CAAT) which recognizes the unique and collaborative characteristics of advocacy; and enables civil society advocates to track processes, outcomes, and improve impact.

Since 2017, COMPASS partners have utilised the tool on a bi-annual basis to identify the key outcomes and setbacks of their HIV advocacy through consultation and group discussion amongst individuals working on the same campaign. Using guiding questions in the C-CAAT, group members conduct self-assessments toward set advocacy goals. This is followed by rating the significance, influence, and durability of the outcomes; and to substantiate each rating with an explanation. The information generated from using the C-CAAT on COMPASS has fed into semi-annual reporting; and promoted learning, and refinement of advocacy strategies; leading to improved health outcomes, programs and funding for HIV.

Results: The use of standardised tools like the C-CAAT enables simplified evaluation of advocacy efforts, and data use to improve impact and demonstrate value to stakeholders and funders. Describing advocacy, activism, impact, and wins requires a common language for evaluating accomplishments.

Conclusions: It is important to monitor HIV advocacy using simple tools. The C-CAAT enabled advocates to substantiate the impact of advocacy in the field of HIV. The sustainability of the advocacy network in sub-Saharan Africa depends on civil society capacity to achieve, measure and effectively showcase their results.

EP220

Enacted HIV prevention strategies and interest in PrEP among Venezuelan migrant men sex workers in Peru

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Background: Complex and intersectional socio-economic, legal, and health-related factors increase Venezuelan migrant men sex workers' vulnerability to HIV when they relocate to Lima, Peru. More than 1 million Venezuelans now live in Lima, yet scant research has examined HIV prevention needs and enacted strategies among Venezuelan migrant men who engage in worker.

Methods: From June to December 2023, twenty-one Venezuelan migrant men sex workers living in Lima, Peru, participated in semi-structured interviews that asked about sexual health, sex work dynamics, and migration trajectories. Thematic analysis was used to explore enacted HIV prevention strategies at the intersection of sex work, including interest in PrEP.

Results: Participants (mean 32 years old) mostly identified as gay (n = 18; 86%). All participants initiated sex work after migrating from Venezuela. While all described interest in HIV prevention and care and described enacted self-protection strategies, economic hardships were described as the common barrier to HIV prevention. Ongoing financial strains were described as limiting condom use with clients as more money was often offered to forego condom use; lack of insurance and costs also limited access to purchasing condoms and lubricants and seeking routine HIV testing. Most participants did not know about PrEP and, once described, voiced disinterest in PrEP unless it was offered free of cost. Enacted HIV prevention strategies reported included: avoidance of street-based sex work due to increased exposure to violence and other HIV vulnerabilities, including drugs, and limited ability to negotiate with clients due to space restrictions; charging high rates for unprotected sex to encourage condom use; preference to procure their own condoms to ensure quality and usage rather than relying on clients to provide them; and maintaining condom use even when clients claimed they were recently tested or using PrEP.

Conclusions: Our findings highlight a need for targeted educational interventions to raise awareness of PrEP among migrants who engage in sex work, especially given its recent availability since August 2023.

Yet, improving HIV prevention also required increased knowledge about and free access to condoms, and low-cost HIV and STI testing for Venezuelan migrant men sex workers in Peru.

EP221

Strategy for the re-engagement of people with HIV (PLwHIV) being treated in public institutions in Buenos Aires City (CABA), Argentina

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Background: Access to antiretroviral treatment (ART) is essential to achieve undetectable viral load, and reduce HIV transmission with its consequent impact on individual and collective health.

In 2020, starting with the COVID-19 pandemic, we have worked on the active search for PwHIV treated in public institutions who abandon their TAR in order to relink them to care and TAR access.

In CABA, 16018 PwHIV are being treated in the public sector (end of 2023). 59% reside in CABA, the rest in the outskirts. 95% are treated in hospitals and 5% in peripheral care centers.

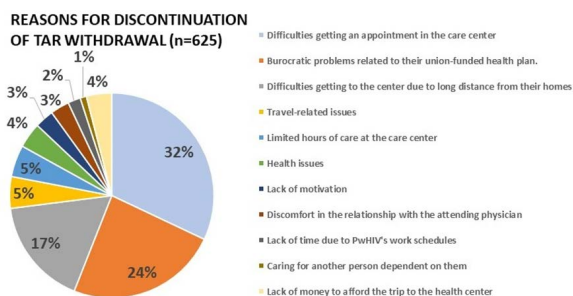
Methods: PwHIV who didn't withdraw TAR for more than 1 month were identified in the national epidemiological information systems (SIGEHOS/SVIH) and contacted by WhatsApp messages, emails or telephone calls. They were asked about the reasons why ART was not being withdrawn and reconnected by granting appointments with their treating doctor. A subsequent follow-up was carried out to ensure reintegration into the care system.

Results: During 2022, 4,058 PLwHIV living in CABA stopped withdrawing TAR for more than a month. (338/month): 65.6% men, average age 40.9 years.

5.1% had died. Of the living, we obtained contact data for 77.5%: Effective contact was achieved with 26,2%.

48% were in TAR through a union-funded health plan or it was an error in the reporting system.

51% of contacted people were active again the following month.



Conclusions: The strategy was partially successful. Improvement in obtaining data on PLwHIV is necessary. Lack of response to the demand for care and long distance to care centers are important obstacles to treatment adherence. Strengthening efforts, such as increasing hours of care and decentralizing care in primary care centers is mandatory. It's essential to reinforce public policies to ensure access for the most vulnerable socio-economic sectors.



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HIV Pre-Exposure Prophylaxis (PrEP) knowledge, attitude, and intentions among African American men: a mediation analysis

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Background: African American men are disproportionately affected by HIV epidemic in the United States (US). Pre-exposure prophylaxis (PrEP) is a biomedical prevention for reducing HIV transmission. Although 42% of the new HIV occur among African American people, they comprise only 14% of total PrEP users in the US, which is the lowest among all races.

This study aims to determine the potential mediational role of PrEP attitudes between PrEP knowledge and PrEP intentions among African American men in the US.

Methods: The study used data collected from adult (≥18 years) HIV-negative African American men from all over the US using a cross-sectional online survey (N=568).

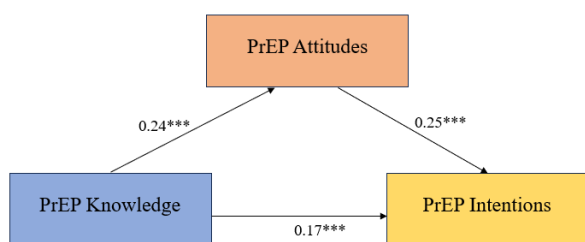
The study used the PrEP knowledge scale, which includes 8 items (Cronbach's alpha=0.63); the PrEP attitudes scale, which includes 5 items (Cronbach's alpha=0.80); and the PrEP intentions scale, which includes 3 items (Cronbach's alpha=0.88).

Results: The majority of the participants were non-Hispanic (92.9%), heterosexual (95.9%), full-time employed (49.9%), single (64.9%), and housed (89.8%).

Average scores for PrEP knowledge, PrEP attitudes, and PrEP intentions were 2.42 (range:0-8), 6.44 (range:0-10), and 2.80 (range:0-6), respectively (Table 1).

Scale	Number of Items	Mean [SD]	Range	Eigenvalue	Cronbach's alpha
PrEP Knowledge	8	2.42 [1.90]	0-8	1.40	0.63
PrEP Attitudes	5	6.44 [2.53]	0-10	2.17	0.80
PrEP Intentions	3	2.80 [2.17]	0-6	2.00	0.88

Table 1. Exploratory Factor Analysis for PrEP Knowledge, PrEP Attitudes, and PrEP Intentions scales.



Note: ***p<0.001
 Solid arrows (→) indicate statistical significance at p<0.05.
 *Adjusted for age, ethnicity, sexual orientation, education, employment status, marital status, homelessness, rural/urban location, history of incarceration, HIV risk self-perception.

Figure 1. Mediating pathway between PrEP knowledge, PrEP attitudes and PrEP intentions.

After adjusting for sociodemographic characteristics, PrEP knowledge was positively associated with PrEP intentions (B=0.17; p<0.001). PrEP knowledge was positively associated with PrEP attitudes (B=0.24, p<0.001). PrEP attitudes were positively associated with PrEP intentions (B=0.25; p<0.001). The indirect effect of PrEP attitudes on the relationship between PrEP knowledge and PrEP intentions was also statistically significant (B=0.06, p<0.001) (Figure 1).

Conclusions: PrEP knowledge contributed to positive attitudes toward PrEP and in turn increased PrEP intentions among African American men. Increasing PrEP knowledge and awareness among African American men may improve their PrEP attitudes and intentions.

EP223

Implementing long-acting cabotegravir for HIV Pre-Exposure Prophylaxis in a large academic hospital-based urban HIV clinic

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Background: Long-acting cabotegravir (CAB-LA) offers a novel HIV PrEP option for individuals unable to effectively take or tolerate oral PrEP and may expand access to PrEP to populations that have been difficult to reach. We describe the development of a CAB-LA program in a large urban HIV clinic and characterize the program's first patient cohort.

Methods: The UCSD Owen Clinic is an HIV primary care clinic that also provides PrEP to over 450 patients. Starting in January 2021, individuals interested in initiating CAB-LA were referred to a PrEP pharmacist and navigator for an insurance check and as-soon-as same-day initiation with on-site injection delivery. Patients were included who initiated CAB-LA and had at least one follow-up injection. Demographic data were collected through EMR review, and reasons for discontinuation and missed doses were documented and continually reviewed. Logistic regression was performed to evaluate predictors of discontinuing CAB-LA.

Results: Between 1/2021 and 12/2023, providers referred 254 patients to the CAB-LA program, and 187 patients (74%) received at least one injection. Median age was 33 (IQR 27, 40) among 47% White, 3% Black and 32% other race individuals with 40% (n=75) reporting Hispanic ethnicity.

Ninety-one percent (n=171) identified as cisgender male, and 77% (n=144) reported previous oral PrEP use. Thirty-nine (21%) discontinued therapy, with n=15 citing injection site reactions or pain caused by injection.

Other discontinuation reasons included lost-to-follow-up (n=7), moving/transferring care (n=6), change in HIV risk (n=4), insurance change (n=3), scheduling issues (n=2) and other side effects (n=2). One-hundred and seven patients were covered through pharmacy benefits (47 with

Medicaid, 60 with private insurance), 52 through medical benefits, and 28 by a patient assistance program (PAP). Younger age (OR 1.05, 95% CI 1.00-1.10, $p=0.037$) and having non-PAP coverage (OR 4.88, 95% CI 1.26-18.9, $p=0.022$) were associated with discontinuation of CAB-LA.

Conclusions: We observed robust uptake of CAB-LA as PrEP among individuals with a clinical need or preference for non-oral PrEP. Most previously used oral PrEP, highlighting the desire for choice among people using HIV PrEP. Younger individuals and those without PAP support may need additional support to stay engaged with CAB-LA for HIV prevention.

EP224

Unveiling gender disparities and state dynamics in Viral Load outcomes among people living with HIV (PLHIV): insights from Southern Nigeria

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Background: This study aimed to elucidate gender disparities and states dynamics in Viral Load (VL) outcome among PLHIV in Southern Nigeria. It focused on understanding the factors that contributed to varying VL outcomes among PLHIV, particularly in relation to marital status, health facility location, and the duration of Multi-Month Dispensing (MMD) of antiretroviral therapy (ART) on the USAID funded Accelerating Epidemic Control of HIV/AIDS in Nigeria - Cluster 6 (ACE 6).

Methods: The study employed an *ex post facto* research design while using multiple logistic regression to analyse data collected from PLHIV in three Southern States in Nigeria - Bayelsa, Edo and Lagos. Demographic factors, including gender and marital status, were examined alongside geographical variables such as health facility location and the MMD duration. The routine data management of PLHIV computed on Lafiya Management Information System (LAMIS) for the period of January 2022 to September 2023 encompassed a diverse variable, offering a comprehensive understanding of the complex interplay of factors influencing VL outcomes.

Results: The results indicated a notable gender-based discrepancy, wherein females demonstrated a higher probability of having unsuppressed VL outcome compared to males (OAR: 1.638; CI: 1.382-1.942). Marital status played a significant role, particularly for separated individuals, who exhibited an elevated likelihood of unsuppressed VL outcome (AOR: 1.383; CI: 1.000-1.913). Geographical variations were evident, with residents in Edo (AOR: 0.358; CI: 0.254-0.504) and Lagos (AOR: 0.733; CI: 0.545-0.987) States having a reduced likelihood of achieving suppressed VL outcome compared to Bayelsa. The temporal dimension introduced by the duration of Multi-Month Dispensing revealed 60 days (AOR: 1.144; CI: 1.008-1.299) being associated with an increased likelihood of unsuppressed VL outcome, while 180 days (0.797; CI: 0.729-0.871) was linked to a decreased likelihood of unsuppressed VL outcome.

Conclusions: Tailored interventions, especially for separated individuals and specific states, are crucial for enhancing overall VL suppression outcomes in the studied population. The findings provide valuable insights for building biomedical models of understanding and intervention in the context of HIV care in Southern Nigeria.

EP225

Leveraging social media for engaging young adults (ages 15-30) in sustainable HIV prevention and services: insights from the "REAL KOOL is knowing your status" campaign in Uganda.

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Background: The "REAL KOOL is Knowing Your Status" HIV campaign targeted young individuals in Uganda, where the Uganda Demographic Health Survey (UDHS) 2022 revealed that 51% of individuals aged 10-30 lacked comprehensive knowledge of HIV, even though they accounted for two-thirds of new infections in the country. The campaign's overarching objective was to increase the uptake of HIV/AIDS services by improving knowledge, self-efficacy, and risk perception. Leveraging young people's interest in new technology, the campaign employed innovative strategies such as HIV self-testing to facilitate engagement with HIV/AIDS services. Commencing in December 2023 as part of the World AIDS Campaign, the initiative ran until March 2024.

Methods: The campaign primarily leveraged social media channels due to their popularity among young demographics, interactive capabilities, and influence on mainstream media. Social media influencers, including individuals living with HIV, played a pivotal role in engaging audiences through interactive campaign activities such as X Spaces, TikTok Live events, and radio talk shows. Additionally, the campaign utilized traditional media platforms. Notably, the campaign involved the introduction of "Dr. Ezzy," a virtual real-time fictional doctor accessible through WhatsApp chatbot, a toll-free hotline, and SMS.



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Furthermore, the campaign piloted a collaboration with the private sector to distribute free HIV testing kits, condoms, and informational flyers on HIV and modern contraceptives.

Results: The campaign yielded significant engagement, with over one million interactions recorded on social media and influencer platforms. Mass media outreach efforts resulted in exposure to HIV/AIDS messaging for over four million individuals. The Dr. Ezzy platforms received 4,087 inquiries, with notable interest from males and individuals aged 10-29. Distribution efforts facilitated the dispersal of 7,000 testing kits and 5,000 condoms.

Conclusions: The campaign underscores the effectiveness of utilizing social media as a platform to engage young people in discussions surrounding HIV/AIDS. Targeted outreach and education, particularly for under-represented demographics like the 10-14 age group, are imperative. Moreover, there is a pressing need to develop inclusive strategies to bridge the digital divide. The partnership with the private sector to deliver HIV self-testing kits and condoms to young people emerges as a promising avenue for future endeavors in HIV prevention and care.

EP226

Enhancing SRHR-HIV integration for adolescents living with HIV in Tshwane, South Africa: a comprehensive situational analysis and participatory model development

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Background: South Africa faces a critical imperative for integrating sexual and reproductive health and HIV services, particularly concerning adolescents and young people living with HIV (ALHIV). Despite rising proportions of ALHIV and their engagement in high-risk sexual activities, access to sexual and reproductive health (SRH) services remains inadequate, compounded by limited knowledge and support for advocacy.

This study undertakes a situational analysis in Tshwane district, South Africa, to evaluate SRHR-HIV integration policies' implementation and understand ALHIV and health providers' perceptions and experiences regarding integrated services. Subsequently, it aims to refine a model for SRHR-HIV integration to better serve ALHIV need.

Methods: Aligned with the World Health Organization's Framework on Integrated, People-Centered Health Services, the study emphasizes equitable access to quality, comprehensive, and coordinated services. Conducted between August 2022 and October 2023 in Tshwane District, Gauteng Province, South Africa, the research focused on four health facilities implementing the Youth Care Club program. Targeting ALHIV aged 15 to 19 accessing both Anti-Retroviral Services and SRHR services, the study adopted a phased approach.

Phase 1 entailed a situational analysis via document reviews, policy maker interviews, adolescent surveys, and health provider interviews. Phase 2 involved participatory workshops using Participatory Action Research methodology to refine the integrated model. Data analysis encompassed SPSS quantitative analysis and thematic content analysis for qualitative data, integrating findings across phases.

Results: The study illuminates adolescents' experiences, preferences, and challenges with SRHR-HIV services, emphasizing the imperative of integration to meet community needs effectively. Despite existing barriers such as transportation costs and stigma, satisfaction levels, especially among adolescents, remain high. Key themes and recommendations identified underscore the necessity for continuous collaboration, training, and stakeholder involvement for successful integration.

Conclusions: The proposed integrated SRHR-HIV model for ALHIV in Tshwane District outlines core components and service delivery approaches, informed by study engagements and findings. A collaborative, iterative process grounded in Participatory Action Research principles drives model development, ensuring responsiveness to ALHIV's evolving needs.

Sustained commitment to collaboration and adaptability is vital for successful implementation, ultimately enhancing well-being for ALHIV in Tshwane district, South Africa.

EP227

Combination collaboration: expanding HIV testing services through engaging private sector in India's EMTCT programme - experience from Global Fund supported Ahana project in India

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Background: Govt. of India has set a goal to achieve EMTCT and thus saturation of pregnant women with HIV testing is the first step towards achieving EMTCT of HIV. While the country has an extensive public health system, there is an estimated 20-25 percent out of 29 million annual pregnancies catered by the private sector. Project Ahana funded by The Global Fund engages private hospitals to ensure HIV screening of PW and reporting back to national data systems.

Methods: Complementing the effort in the public sector towards expansion of HIV testing, a fourfold approach was introduced to engage and integrate private sector effort to country's overall EMTCT programme.

- Mapping of all private entities,
- Carrying out service assessment of the facilities,
- Establish programme engagement with the hospital towards HIV testing and reactive linkages, and;
- Report HIV testing information to national database.

Results: Ahana adopted a cascaded approach, with A) 21,486 private hospital mapped for potential engagement, B) assessment carried out in 21, 462 hospitals with C) 8,083 hospitals assessed as ANC service providers, and D) 5,380 hospitals engaged in the project during the period of Jan, 18 to Dec, 23. These engaged hospitals then starts reporting back with the HIV testing information as well as aligning for any HIV reactive cases needs confirmatory testing at Govt. ICTC centre and followed up with ART linkages. 14% (n=11 million) HIV screening has been carried out in private sector during April- Dec, 23.

Contribution from private sector has increased to 14% during the period April- Dec, 23 from 10% achieved during Jan, 18- March, 21 period. This has ensured identification of additional HIV positive pregnant women.

Conclusions: There is a strong coordination established with the private health facilities contributing towards attaining EMTCT. Over the years Plan India evolved private sector strategy to map, assess and engage more and more private health facilities. While there is a long way to go and a complete saturation of all cases in the private facilities, the intervention suggests, that EMTCT can be possible only through an integrated public and private sector response.

EP228

Transgender women in the Midwest region of Brazil exhibit an unacceptably high prevalence of HIV, a large proportion of recent HIV acquisition, and high viral genetic diversity

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Background: In Brazil, the HIV epidemic disproportionately affects key populations, such as transgender women (TGW). Data about the dynamics of the HIV epidemic among TGW are still scarce in regions far from the HIV epicenter. This study aimed to evaluate the HIV prevalence, proportion of recent acquisition, genetic diversity, transmission clusters, and drug resistance mutations (DRM) among TGW from Goiás, Midwest region of Brazil.

Methods: We included TGW aged 16-59 years from three cities in Goiás, Brazil: Goiânia, Itumbiara, and Jataí. Participants were recruited between April 2018- November 2019 using respondent-driven sampling (RDS). HIV testing was conducted according to the Brazilian algorithm and the Maxim HIV-1 Limiting Antigen Avidity EIA (LAG) was used to identify recent HIV acquisition in plasma samples. A region of the *pol* HIV-1 gene (PR/RT) was PCR amplified and sequenced. We performed phylogenetic analysis to determine HIV-1 subtypes and possible transmission clusters and identified DRM through the Stanford HIV drug resistance database.

Results: We enrolled 440 TGW: 285 in Goiânia, 74 in Itumbiara, and 81 in Jataí; the median age was 25 years (IQR: 28-30), 312 (71.2%) self-identified as Black, 269 (61.1%) completed secondary school, 372 (84.5%) were single, and 262 (59.5%) had the sexual debut before 15 years of age. A total of 143 participants tested positive for HIV (HIV prevalence: 32.5%), 135 (94.4%) had available plasma samples for LAG testing, of which 54 (40.0%) had recently acquired HIV. Phylogenetic analyses from 86 participants revealed that the HIV-1 subtype B was the most prevalent clade (55.8%) in our sampling, followed by F (17.4%), C (15.1%), and recombinants (11.6%), 9.3% BF and 2.3% BC. We detected an alarming high prevalence of DRM (33.7%): NNRTI (22.6%), NRTI (16.9%), and PI (8.1%). Small possible transmission clusters (2-3 participants) were observed.

Conclusions: Our findings emphasize the considerable impact of the HIV epidemic on TGW in the Midwest region of Brazil despite the implementation of public health prevention strategies that are primarily aimed at key populations. It is crucial to develop more effective policies and interventions that address the needs of vulnerable populations to curb the spread of HIV in our region.

EP229

Plural bodies and desires: challenges for promoting sexual and reproductive health among young people

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Background: As part of the thematic research (action research), we held a workshop with high school students from 3 public schools in the peripheral areas of São Paulo. The "combined prevention", traditional for STIs/AIDS and made available by AIDS programs in Brazil, was reorganized as "integral prevention" in direct collaboration with young people.

Methods: From a psychosocial perspective based on Human Rights, during seven meetings, we expanded the comprehension that situations of exposure to infection – here elaborated as "scenes" – change according to the "scenario" and "characters" in each experience. Based on the conversation about the daily experiences of adolescents and young people (A&J), we integrated practical knowledge with technical-scientific knowledge, co-producing a map of access to inputs and prevention information. We integrate discussions about plural bodies and desires (genders, sexual orientation, ethnic-racial diversity), in specific contexts, in the development of strategies to promote sexual and reproductive health among young people.

Results: We discovered that places for affective-sexual encounters include the school itself, classmates' homes when parents are not there and spaces around the school. Throughout the workshops, the intersectionality between race-ethnicity, gender and sexual orientation



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was highlighted: how the transfeminine body modeled in the session related to the sexual body and the characteristics of race and sexuality highlighted in the mapping session, in addition to discussions focused on practices and/or inputs for prevention.

Conclusions: It was possible to visualize different bodies, desires and sexual practices, articulating forms of protection (inputs) and sexual practices aimed at pleasure and with less risk – the idea of harm reduction.

Is important the active participation of A&J and critical reflections on meeting places, the plurality of bodies, desires and ways of reducing individual exposure and understanding aspects of social (stigma and discrimination) and programmatic vulnerability (lack of services and health supplies) in the places where they live with a view to mobilizing political activism.

EP230

Expanding access to PrEP services for young people through a person-centered digital health service, in Central and Copperbelt Provinces of Zambia

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Background: For priority populations in Zambia, like young people (15-24) stigma and confidentiality issues continue to limit their uptake of HIV testing, prevention, and treatment services. Also, adolescents and young people (AYP) are often unwilling to access health services, for fear of their information reaching their parents.

The USAID DISCOVER-Health project, implemented by JSI, in collaboration with AYP and other stakeholders have developed a person-centered digital health service to address these barriers to help them access services.

Methods: In January 2023, the project launched a virtual health hub to help priority population access HIV services online, in their safe spaces, using the unstructured supplementary service data (USSD) information management system. Following an easy registration process, clients access information and services, ranging from routine screening for health conditions to HIV pre-exposure prophylaxis (PrEP) at their convenience.

Additionally, the project partnered with local organizations who possess specific mandates and skill-sets for working with young people to gain their buy-in and widely share information about it through their channels/outlets. This proved vital in increasing awareness and encouraging utilization of the Health Hub, harnessing these trusted networks and working closely with the people within them.

Results: For HIV prevention, in the 6 months prior to the launch of the Health Hub, 8,013 young people (15 to 35 years old) started PrEP. In the 6 months following the launch, this increased by 214% to 25,153 young people. For adolescent girls and young women (15 to 24 years old), in

the 6 months prior to the launch, 5,136 were initiated on PrEP. In the 6 months following the launch, there was an increase of 101% to 10,324.

Conclusions: Use of the digital health system improved access to PrEP access by AYP. Building partnerships with local community stakeholders and generating support for a digital health service, proved invaluable in creating a support system for young people to access health services in a convenient and private manner.

This approach may increase the numbers of young people accessing HIV prevention services, aiding the move towards epidemic control.

EP231

Evaluating HIV prevention information on twitter: a content analysis

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Background: In recent years, Twitter has emerged as a source of health information, with key organizations and professionals using the platform to share health information, including HIV prevention strategies. And, like any other social media channel, it is prone to misinformation spread by non-health professionals. And these tweets may either enforce or correct current HIV prevention norms, so there is a need to effectively analyze and address any gaps or misinformation.

Methods: We conducted an advanced search on Twitter using the keywords "HIV Prevention", "Safe sex", "Unsafe sex", and "Condom" between March 30, 2024 and January 1, 2019. Using a qualitative content analysis method, we identified content themes for each tweet (preventive methods, testing information, stigma reduction, and treatment information), focused on the target population, and measured credibility against HIV preventive strategies on CDC and WHO websites, while analyzing the number of retweets, likes, and replies to determine tweet reach. The user type was also investigated.

Results: Our search results yielded approximately 500 tweets, only 70 of which met the inclusion criteria. The majority of them were published in 2023 (n=24). Most of them receive 0-4 likes (n=18), 5-10 retweets (n=25), and 5-10 replies (n=30). The tweets covered preventive measures (n=65), testing methods (n=21), stigma reduction (n=12), and treatment information (n=4).

Most of the articles (n=50) appear to be accurate and evidence-based, with some (n=23) citing credible sources such as the CDC and the World Health Organization. Twelve of the tweets contain misconceptions. Non-health-care professionals (n=27) published the majority of the tweets, followed by healthcare organizations (n=23).

Conclusions: There are significant gaps in the dissemination of HIV prevention information on Twitter, with the majority of misinformation being spread as jokes, by influencers, and with greater engagement. As a result,

more health educators are needed to develop new strategies to better disseminate accurate information rather than allowing false information to thrive, while health policy analysts create policies governing the dissemination of health information on Twitter, particularly HIV prevention, to contribute to disease transmission reduction.

EP232

Utilizing human-centered design to explore HIV prevention and treatment dynamics among fisherfolk in Kalangala districts, Uganda: insights for targeted social and behavior change interventions

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Background: The Uganda Population-based HIV Impact Assessment reports indicate that Kalangala Island district exhibits the highest district HIV prevalence at 18.8% within the 15–49-year age category. Men on Kalangala Island infect women 3 or 2 times, with the net flow of HIV at 2.5 times greater from inland to islands. These findings emphasize the need for targeted Social and Behavioral Change (SBC) interventions to comprehend and address factors driving HIV transmission in island populations.

Methods: A participatory Human-Centred Design approach was used to conduct sessions with 18 community members aged between 18–60 years old including fisherfolks, business owners, female sex workers, people living with HIV, adolescent girls, and young women. For triangulation, rapid ethnographic observations were conducted at health facilities, bars, and lodges. Additionally, key informant interviews were conducted with bar and lodge owners.

Results: Action Media revealed that HIV knowledge varied among audience categories. Fisherfolk perceived low risk, while female sex workers, people living with HIV, adolescent girls, and young women perceived high risk. Negative attitudes, social norms, and subcultures facilitated low-risk perception. Observations and Action Media revealed emerging audiences for HIV/AIDS services included invisible fisherfolk and undercover female sex workers. High levels of stigma affected the uptake of HIV/AIDS services. Key informant interviews revealed that health facilities are unattractive to all audiences, potentially hindering service utilization.

Action Media further identified alternative media and interpersonal communication as potential messaging intervention approaches. Data revealed a need to leverage migrant labor movements, fish seasonality patterns, and the day-to-day life schedules of the community for effective community mobilization and service delivery.

Conclusions: Conclusively, participatory human-centered design helped identify two previously unknown groups – invisible fishermen and covert sex workers – that require

unique HIV prevention, care, and treatment. Targeted interventions should include leveraging migrant labor movements, fish seasonality patterns, and the day-to-day life schedules of fisherfolk.

EP233

HIV/AIDS knowledge in Albanian adolescents

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Background: HIV epidemic remains a serious public health issue, especially among adolescent girls. Knowledge about HIV/AIDS is a key component to prevent new infections of HIV/AIDS among adolescents.

As a consequence, the aim of our study was to identify the proper knowledge of Albanian adolescents regarding HIV/AIDS.

Methods: Our study was cross-sectional based on the data of the demographic and health study in Albania in 2022–2023. Two hundred adolescents aged 14–18 years old participated in this study. An anonymous validated online survey was administered to the participants of the study. An informed consent was taken from the respondents and an approval letter from the Ethical Committee of the University of Medicine. Data were analyzed using the statistical program SPSS 26.0.

Results: Nearly 45% of the youngsters participating in the study had whole knowledge related to HIV/AIDS. Almost 29% of the respondents were not aware that using condoms frequently may reduce the risk of HIV and 22% of the respondents believed that mosquitoes could transmit HIV/AIDS.

Multivariate logistic regression showed that having high education (AOR = 2.84, 95% CI: 2.30–3.80), being from the center and south region of Albania (AOR = 1.58, 95% CI: 1.38–1.76), and non-testing at least once in a lifetime for HIV (AOR = 1.83, 95% CI: 1.62–2.05) were significantly correlated with proper knowledge about HIV/AIDS.

Conclusions: Findings of our study revealed that complete knowledge regarding HIV/AIDS among adolescents in Albania are very poor. Various socio-demographic characteristics were related in a significant way to the entire knowledge concerning HIV/AIDS in this study.

Our results suggest that we should implement public health programs designed to improve complete knowledge about HIV/AIDS in Albania targeting to the girls with low level of education that live in the northern part of the country.

There is a need to focus on adolescents that have never been tested for HIV/AIDS to improve the complete knowledge about HIV and may raise the awareness about their health status.



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Predicting no-show at first PrEP appointment using routine demographics and appointment data in Tennessee (United States)

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Background: No-shows and cancellations at sexual health clinics in United States lead to wastage of already stretched clinical resources. Further, clients with no-shows or cancellations may not come back to complete a PrEP appointment and hence is a missed opportunity for PrEP care enrollment. We used a machine learning model to predict no-shows that could inform scheduling strategy of clinic to avoid wastage of resources or deploy interventions to potentially avoid that no-show.

Methods: We used data available at 340bwell.com - a custom software package that facilitates PrEP care continuum journey for a Tennessee based large sexual health service provider organization with multiple clinics. We used python to run Random Forest, Gradient Boosting, Gaussian Naive Bayes Classifier, XGBoost Classifier and Logistic Regression after dividing the dataset into standard 80-20 split for training and testing respectively, and then examined accuracy across models. We ran feature selection to understand the important features influencing the most accurate model.

Results: The dataset contained 7896 unique client records with 20 total attributes. The categorical and string columns were encoded to numerical columns using one hot encoding, resulting into 1524 columns. Random Forest Model yielded 66% accuracy, Logistic Regression gave 49% accuracy, Naive Bayes gave 48.4% accuracy, XGBoost returned 65.8% accuracy and gradient boost gave the highest accuracy at 66.8%. In gradient boost model, some of the most important features driving the model were waiting time, if appointment was Telehealth and Race.

Conclusions: Artificial Intelligence and machine learning can be successfully used to predict no-show at sexual health clinics which can be used to optimize scheduling and reducing those no-shows leading to saving resources and serving more people with same capacity.

EP235

Prevalence and related factors of symptom-based sexuality transmitted infections among people who inject drugs: a nationwide survey in Iran in 2023

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Background: Sexually transmitted infections (STIs) are a major public health challenge with an increasing trend globally. People Who Inject Drugs (PWIDs) are at a higher risk of STIs due to engaging in unsafe sexual behaviors. We aimed to determine the prevalence and associated factors of symptoms-based STIs among PWID in Iran in 2023.

Methods: This cross-sectional study was conducted among 2,379 PWIDs in 14 large cities from May to August 2023 using a respondent-driven sampling method. Participants were interviewed face-to-face and asked about their experience of STI symptoms in the last 12 months. Logistic regression was used to identify associated factors for reporting symptoms-based STIs.

Results: The prevalence of symptoms-based STIs among PWID was 10.03% (95% CI:8.75-11.42). Consistent condom use with casual partners (Adjusted odds ratio [AOR]:0.45, 95% CI: 0.25-0.79) and having a high school education (AOR:0.51, 95% CI:0.31-0.85) decreased the odds of reporting symptoms-based STIs in the last 12 months. However, being a woman (AOR: 9.66, 95% CI: 4.78-19.49), and having multiple sexual partners (AOR: 2.54, 95% CI: 1.23-5.25) increased the odds of reporting symptoms-based STIs in the past 12 months.

Conclusions: One out of each 10 PWID reported symptoms-based STIs in the last 12 months. Our findings highlighted the role of high-risk sexual behaviors in reporting STIs among PWID.

Integrating hepatitis B virus (HBV) and human papillomavirus (HPV) vaccination and STI screening tests in harm reduction services in addition to periodical educational interventions for safe sexual practices are powerful tools for reducing and controlling STIs among PWID.

EP236

Improving health outcomes for trans women living with HIV in Brazil: a qualitative investigation on challenges and strategies to enhance a peer navigation program

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Background: Transgender women (TGW) are a key population in the context of HIV epidemic. Despite their high prevalence of HIV, TGW exhibit low adherence to testing and treatment, influenced by factors such as pervasive stigma and inadequate healthcare services tailored to their needs. In response, our team launched the TransAmigas study, a peer-navigation intervention for TGW living with HIV and non-adherent to treatment.

This presentation aims to explore the challenges and strategies used by peer navigators (PNs), who are themselves TGW living with HIV and adherent to treatment, in engaging and retain of participants in the study.

Methods: From September to October 2019, seven in-depth interviews were conducted with PNs who navigated the care of 75 TGW living with HIV. These interviews, ranging from 75 to 120 minutes, employed a semi-structured approach to uncover the primary challenges encountered by participants and the navigators' own difficulties and solutions in delivering the program effectively. All interviews were audio-recorded, transcribed, and subjected to thematic qualitative analysis.

Results: The PNs identified the most significant challenges were navigating participants who were unreachable via telephone/social media, those struggling with substance abuse, or who lacked stable housing. In some cases, shared community ties or prior acquaintance hindered the development of trust due to concerns over confidentiality regarding HIV status or personal information. To enhance retention, PNs emphasized the importance of offering flexible meeting schedules and locations, sharing personal overcoming-barrier stories as inspiration, directing participants to community resources, and encouraging the development of personal autonomy through self-directed projects.

Conclusions: TGW struggling with basic survival needs, such as unstable housing, and other challenges like lack of access to communication tools or substance abuse, are highly vulnerable and show diminished program adherence. Addressing these barriers is crucial for assessing their obstacles comprehensively and providing effective support, including through peer navigation. Insights from these in-depth interviews are vital for evaluating the intervention's effectiveness and identifying areas for improvement in future research.

EP237

A success story on the linking strategies for HIV treatment in pregnant women – Guaianases, outskirts of São Paulo

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Background: Eliminating vertical transmission (VT) of HIV is a public health challenge in Brazil. Adequate treatment during pregnancy is essential to reduce the risk of VT. The sooner the pregnant woman reaches an undetectable viral load, the lower the risk of infection is for the baby. The city of São Paulo has been certified by the Ministry of Health since 2019 for eliminating TV and HIV.

Methods: In September/2022, healthcare supervision in Guaianases was called by a Basic Healthcare Unit (UBS) due to a case of a pregnant woman struggling to accept her HIV diagnosis. She was a black woman, 31 years old, 26 weeks pregnant, with basic education, no steady job and who was diagnosed with HIV in 2020, but did not start treatment. The pregnant woman reported feeling fear and stated that she would not start treatment at the Specialized Outpatient Service (SAE).

Interventions carried out:

Virtual consultations with a doctor from SAE and UBS;

At-home exam collection;

At-home delivery of antiretrovirals;

At-home delivery: antiretroviral for pregnant women at the time of delivery, medication to inhibit lactation, antiretrovirals for the baby's prophylaxis, and milk formula for the baby. A medical report describing treatment and guidelines for the delivery of the baby was also delivered.

Results: The baby was born at 39 weeks. They were monitored for 12 months and there was no vertical transmission. After birth, the postpartum woman began treatment at the SAE and continues to have good adherence to it.

The experience showed that it is possible for healthcare professionals to think about care alternatives, recognizing that each person is unique and deals with the HIV diagnosis in different ways.

Conclusions: The experience reflects the importance of regular testing of women of childbearing age and highlights the difficulties in linking more vulnerable populations to healthcare services. The case was disclosed by the STI/Aids Coordination of São Paulo on teleclinics for healthcare units in the city, aiming to raise awareness among professionals that it is possible to initiate HIV treatment even in delicate and complex cases.



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Client-initiated retesting among people with previous HIV positive status, Mozambique 2023

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Background: The World Health Organization recommends retesting for verification of HIV positive persons prior to antiretroviral therapy (ART) initiation to prevent unnecessary treatment. However, some HIV positive persons self-initiate retesting to reconfirm their HIV status. The actual HIV testing algorithm clarifies that retesting is not recommended for HIV positive persons on ART.

Whereas, this can result in serious negative individual and public health consequences. In Mozambique national level data was available on previous HIV positive diagnosis at HIV Testing Services (HTS) sites.

Methods: The Ministry of Health use HTS data tools to enable collection of previous HIV positive diagnosis from clients testing for HIV at all public HTS facilities (n = 1,634). Providers were trained to identify and record previous HIV positive status for persons testing HIV positive on HTS paper-based forms, which are aggregated into a national database.

We analyzed aggregated HTS routine program data from 2019 to 2023, and applied literature estimates on HIV testing costs and impact of ART on performance of HIV rapid tests, to understand the extent of HIV self-initiated retesting in the country and potential cost implications of unnecessary retesting.

Results: Nationally 11,118,341 testing was performed at HTS in 2023; 91% of tests were conducted at health facilities and 9% at community sites. During this time, 282,682 clients tested positive at health facility sites and 6,595 (2%) had received an HIV+ result previously in the past (retested). At community 65,517 were HIV positive and 2,754 (4%) retested.

Because clients testing HIV- were not asked about prior HIV diagnosis, we estimated that an additional 449 persons with prior HIV+ status self-initiated retesting with seronegative results compared with 914 in 2019. This unnecessary HIV retesting was estimated to have cost US\$117,910 compared with US\$219,443 in 2019.

Conclusions: This evaluation provides a first time compared estimate of client-initiated retesting among persons testing for HIV in Mozambique.

Although there is a decrease, non-disclosure of known HIV status by people living with HIV but undergoing HIV testing leads to waste of HIV testing. Improved screening of persons seeking HTS is needed to prevent unnecessary testing especially in community settings.

EP239

Centering Chicago youth to develop and implement PrEP4Teens: a PrEP social marketing and community mobilization project

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Background: Youth aged 13-24 account for 20% of new HIV diagnoses in the United States, yet few adolescent-centered PrEP awareness efforts exist. Youth-centered design and community engagement throughout research and implementation can ensure these efforts are tailored to diverse adolescents' needs and contexts. Social marketing campaigns that reach youth directly have potential to increase PrEP awareness and demand.

Here we describe the development of PrEP4Teens, a multimedia, educational campaign in Chicago -- the first of its kind in the country.

Methods: In 2021, we conducted focus groups with 50 LGBTQ+ adolescents and interviews with 30 adult stakeholders to assess preferences for youth-focused PrEP messaging. Then, youth recruited for a summer Think Tank translated the research findings into a Creative Brief with recommendations for campaign assets, implementation strategies, and mobilization approaches.

A community-based survey of 188 LGBTQ+ youth rated the acceptability and feasibility of initial campaign ideas. In 2023 after securing implementation funds, a community-youth-academic team assembled to realize the campaign.

Results: Findings revealed a desire for developmentally-tailored PrEP information delivered "direct-to-consumers" in adolescent-friendly ways. The Creative Brief illustrated how PrEP information could meet youth where they are by centering artistic expression, empowerment, and holistic health across creative workshops, youth-centered websites, and social media. The community survey indicated high acceptability and feasibility of the proposed campaign.

A consistent theme was that materials should be created collaboratively with youth; thus, following implementation funding, youth, artists, and the project team partnered to iteratively design campaign assets. PrEP4Teens launched in November 2023 at a Chicago organization serving Black LGBTQ+ youth where the website, social media, and a large mural was unveiled with the tagline "Let PrEP Be Your Safety Net". This was accompanied by a PrEP-themed "Mini Ball" and vogue competition. Initial feedback suggests the campaign is well-received by youth and adults.

Conclusions: Following youth's guidance and direction from research to implementation can ensure that PrEP social marketing and community mobilization projects are acceptable and successfully reach end-users. Research is needed to understand whether dissemination approaches for this campaign lead to increased PrEP awareness and uptake.

EP240

Impact of outreach strategies and contact categories on completing HIV testing services (HTS): lessons learned from a three-year implementation at a male-friendly clinic in Haiti

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Background: The Ministry of Health published the national guidelines for Index Contact Testing (ICT), a strategy to increase HTS efficiency in Haiti in 2018. HTS are offered to relatives and sexual partners of clients newly identified as HIV-positive or currently on treatment; They are reached either by the client (index), the facility or both depending on the client's choice. Social contacts of clients are mostly investigated by facilities working with key and priority populations and represent less than 1% of contacts tested nationwide. We present here the results of an outcome analysis of a three-year implementation of ICT at Klinik Er-itaj (KE), a male-friendly clinic in Port-au-Prince, Haiti.

Methods: A retrospective analysis using descriptive statistics was performed on ICT results at KE from March 2020 to December 2023 on the ICT app. A multiple linear regression analysis was performed to examine the influence of the variables Types of contacts and Outreach strategies on the variable completion of HIV testing.

Results: For the period, 1112 contacts were elicited (Males=581; Females=531) including 528 sexual partners (47%), 425 social contacts (38%), and 159 children (14%). A total of 1097 contacts were reached (99%): 87% by the index, 12% by the facility, and 1% using a mixed approach. A total of 1066 accepted HTS (97%) and 971 were tested (91%). Among the contacts: 82% of the sexual partners completed the HIV test compared to 85% of the children ($p=.455$) and 95% of the social contacts ($p<.001$); 88% of those reached by the client completed an HIV test compared to 82% of those reached by the site ($p=.041$) and 60% of those reached with a mixed approach ($p=.007$). Over 44% of those tested overall were positive and enrolled ARV: 54% of sexual partners ($N=234/433$), 49% of social contacts ($N=196/402$), and 1% of children ($N=2/136$). Only 6% of both sexual partners and social contacts tested HIV-negative were enrolled on PrEP.

Conclusions: Overall ICT strategy led to an increased HTS positivity rate at KE. The positivity rate and testing completion are high among social contacts. Including this contact category into ICT at all sites may further increase HTS efficiency.

EP241

HIV incidence and experiences for concurrent methadone and antiretroviral therapy use among injectors and non-injectors opioid recovering addicts in Kisauni Clinic, Mombasa, Kenya

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Background: Kenya adopted opioid substitution therapy (OST) program in 2014 as a harm reduction strategy to prevent HIV among opioid injectors. About 3.4% of OST clients tested for HIV in Kisauni were identified as HIV-positive in 2021. We aimed to determine HIV incidence, identify associated factors and explore experiences of mixing methadone and anti-retroviral therapy (ART) for clients who acquired HIV while on OST.

Methods: We conducted a retrospective cohort study involving quantitative and qualitative data on opioid users in Kisauni-OST-clinic. We reviewed records of clients enrolled between 2015-2019.

We analyzed HIV re-testing results as of December 2022, factors with a p -value ≤ 0.05 in the logistic regression model were considered to be independently associated with HIV-acquisition. We later held in-depth interviews with persons who acquired HIV while on OST. We conducted a thematic analysis of the qualitative data.

Results: Eligible records were 729/936 (77.9%) and contributed 3386.9 follow-up time. Fourteen (1.9%) clients turned HIV-positive at a rate of 0.4 (95%CI:0.2-0.7) new infections per 100 person-years(PY). Injectors had an HIV incidence rate ratio of 1.1 (95%CI:0.3-3.7) compared to non-injectors. Independent predictors for turning HIV-positive were being female (adjusted risk ratio (aRR): 8.0, 95%CI:2.6-24.3) and confirmed Hepatitis C (HCV) positive (aRR: 3.7 95%CI:1.1-12.4).

On qualitative analysis, barriers to concurrent OST and ART adherence included stigma from peers and community, transport costs, pill burden, and side effects of mixing ART and methadone.

Conclusions: There was no difference in HIV incidence rates between injectors and non-injectors indicating similar routes of HIV acquisition when on OST. We suggest enhancement of enrollment of both injectors and non-injectors to OST programs.



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EP242

Transmission of HIV drug resistance mutations in Central Asia

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Background: For the past decade, incidence of HIV has been on the rise in Eastern Europe and Central Asia, including the former Soviet Union (FSU) countries. Ineffective antiretroviral treatment (ART) administration leads to emergence of drug resistance mutations (DRM) leading to increased viral load. Since people living with HIV (PLWH) with higher viral load are more likely to transmit the infection, it is imperative to optimize the ART prescription to prevent further spread of the virus.

Methods: For this study, we analyzed 13,283 HIV sequences from FSU countries, including Armenia, Azerbaijan, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Tajikistan, Ukraine, Uzbekistan, Belarus and Russia. A total of 11,748 and 625 HIV *pol* sequences belonging to, respectively, subtype A6 and CRF_02AG were retrieved from the Los Alamos HIV sequence database.

Additionally, we included 563 A6 and 347 CRF_02AG *pol* sequences generated in our laboratory from Kazakhstani PLWH.

Results: Using the Stanford database, several major and accessory DRM were identified: the most prevalent DRM in A6 were A62V (39%), M184V (18%), G190S (11%), K101E (6%), and D67N (2%). Whereas for the CRF02_AG sequences, the most represented DRM were K103N (22%), M184V (19%), and S68G (9%). In a large number of sequences exhibited combination of multiple DRM known to confer high-level resistance to the currently prescribed ARV drugs.

The DRM A62V was predominantly found in Russia, Kazakhstan, and Uzbekistan, whereas the DRM M184V was most frequently observed in Belarus and Ukraine.

Phylogenetic analysis revealed a preponderance of the DRM A62V among earlier transmissions of subtype A6 in FSU region, involving multiple countries, whereas the DRM K103N appeared frequently in Kyrgyzstan and Kazakhstan.

Conclusions: Our findings provide insight into the origin and transmission of HIV DRM prevalent in the FSU countries, highlighting the importance of optimization of ART regimens to curtail further emergence of DRM in this region.

EP243

Determinants of accepting index testing services among MSM in Central America: an exploratory study

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Background: Low uptake of HIV testing is a salient barrier to curbing HIV transmission among men who have sex with men (MSM). To address this problem, the HIV index testing model has been introduced, whereby sexual partners of HIV-positive individuals may be anonymously notified and offered HIV testing.

The aim of this study was to explore determinants of participating in HIV index testing among MSM with HIV in Central America.

Methods: We employed an exploratory cross-sectional mixed methods study consisting of in-depth interviews (IDIs), a short semi-structured survey, and ego network analysis. Study eligibility included identification as MSM, 18 years or older, diagnosed with HIV in the past 18 months, and offered index testing services. Participants were recruited from HIV clinics in Panama City, Panama; San Salvador, El Salvador; Guatemala City, Guatemala; and Tegucigalpa, Honduras.

Results: The final sample included 58 participants across the four countries. Participant average age was 29 and 50% had university education. Approximately half (52%) accepted index testing services. Social network size was similar across groups, with an average of 8 members. Network density, a measure of social influence, was low (0.35 index vs. 0.27 not index, $p < 0.12$), suggesting that participant behavior was not highly influenced by network members. Individuals who did not accept index testing services had a higher proportion of network members who provided emotional support compared to those who accepted the service (0.40 vs 0.36, $p < 0.05$). Results from IDIs suggested that the main deterrents from accepting index testing services were not being emotionally ready at time of diagnosis, fear that anonymity would not be maintained, and lack of necessity as they themselves could communicate with their partner(s).

Conclusions: Participation in index testing services was largely driven by emotional readiness and confidence in the program to maintain their anonymity. Social network composition was similar across both groups, suggesting that social relationships and peer social norms may not be significant determinants of participating in index testing services in the study population.

However, less emotional support may facilitate acceptance of index testing. Further research is needed to understand factors driving or deterring participation in index testing services among MSM.

EP244

Door-to-door mobilization through Village Health Teams (VHT) structures and satisfied users to improve the Shang Ring method uptake in Eastern Uganda

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Background: Voluntary Medical Male circumcision (VMMC) is a proven prevention strategy against the spread of HIV. The World Health Organization 2016–2021 strategic framework on VMMC states that the use of Shang Ring (SR) is a safe and efficient innovation in the attainment of epidemic control. In USAID LPHS-E sites the SR performance for the first quarter (October–Dec 2022) was sub-optimal at 56% of the quarterly target. The team theorized that the underperformance was a result of low demand due to limited SR information and low coverage of trained sites (11%, 2/19). An RCA was conducted, changes tested, and outcomes observed on the uptake of VMMC services. The team shares the facilitators and barriers of the VMMC Shang Ring (SR) method.

Methods: Root Cause Analysis (RCA) using an online Kobo collection tool was undertaken to determine the overall satisfaction/acceptability of SR method. The target population was 251 circumcised SR clients (84% were 15–29 years and 7% were < 14 years. Responses of basis of choice, common dislikes for the method, main source of information and overall satisfaction/acceptability were collected. Data analysis was performed using Excel and Pareto charts to establish factors influencing SR uptake. Changes were tested at the implementing facilities.

Results: 83% (216/261) of the clients were satisfied with the SR circumcision because of the shorter procedure time, less bearable pain, and no needle injection anesthesia. 17% (45/261) were dissatisfied because of pain during ring removal and discomfort of having the ring. 99% said they would recommend SR circumcision to others. VHTs and satisfied users were the main source of information about SR.

Following the outcome of RCA, 18 health providers from three additional sites were trained and certified, and an intensified door-to-door mobilization with VHTs to create demand for SR was conducted. VMMC SR performance improved from 56% to 173% in three months to March 2023.

Conclusions: Satisfied users and VHTs are key influencers of SR and should be targeted for demand creation. Counselling and follow-up are critical to eliminating possible self-removals due to pain or discomfort. The high acceptability of SR means that more sites should be accredited to provide SR services.

EP245

Factors influencing reported PrEP use when offered as a study drug and non-study drug in a preventive HIV vaccine trial in Mbeya, Tanzania

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Background: The PrEPVacc phase IIb HIV vaccine trial enrolled participants likely to be exposed to HIV in Tanzania, South Africa and Uganda. Pre-exposure prophylaxis (PrEP) was provided as a study drug (Descovy or Truvada) for the first 6 months along with vaccines and thereafter, participants were encouraged to continue with non-study PrEP (generic Truvada) accessed at public facilities. In Mbeya, Tanzania 454 (99%) of 455 enrolled female participants took up study PrEP but only 14 (5%) have accessed non-study PrEP to date. Condomless sex within the last 7 days has been reported by over 88% of participants attending throughout. In this analysis we assessed factors that might explain the difference in reported PrEP use during the two PrEP phases of the PrEPVacc trial in Mbeya.

Methods: Qualitative data collection was embedded in the trial protocol and in-depth interviews were conducted from July 2021 to October 2023 with 30 participants at 2, 6 and 12 months of their trial participation. Participants were purposively selected according to study PrEP type (Descovy or Truvada), self-report of adherence and age. Perceptions and experiences of PrEP in the 3 rounds of interviews were compared and analyzed using a framework approach.

Results: Factors that promoted high study-PrEP use regardless of PrEP type were: perceptions that PrEP was a study drug and awareness that participants' urine was being tested for drug presence, understanding about PrEP and how it differs from antiretroviral therapy, perceived high HIV risk, trial team support and confidence in PrEP effectiveness. Low uptake of non-study PrEP was attributed to: choosing to take a break from daily pills, perception of reduced HIV risk, preference for injections over tablets plus negative attitudes towards accessing PrEP from non-study health facilities which are also HIV care and treatment centers.

Conclusions: Alternatives to daily pills that align with client lifestyles and preferences were needed for this population. These may include long-acting injectable PrEP, and diversification of access points other than HIV care and treatment centers.



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Leveraging community structures to improve mobilization for HIV testing services (HTS) and enhance case detection: lessons learnt from Uganda Episcopal Conference (UEC), Soroti region

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Background: UEC with funding from CDC is implementing Faith Lead Action to Sustain HIV Epidemic Control-FLASH Project in 12 health facilities in Soroti region.

Data reviewed for the first **8 weeks of October to December 2023** showed that **3,004 (58%)** HIV tests were conducted against the quarterly target of **5,317**.

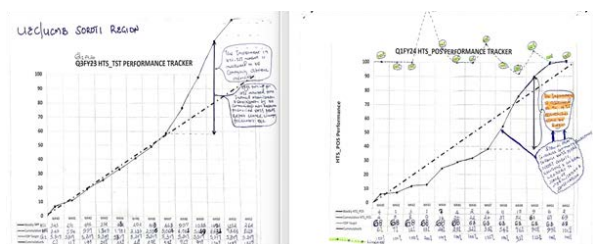
Additionally, compared to a quarterly target of **68, 26 (38%)** new HIV positives were identified and linked to care. However, the expected achievement for all indicators at review time is **67%**.

UEC's experience in Soroti region shares outputs from key interventions that contributed to closing the performance gap in the last four weeks of the quarter.

Methods: HTS data review was conducted and found that, more than **70%** of HIV tests were facility-based with limited community HTS.

Reliable community resource persons including VHTs, Linkage Facilitators, expert clients, peers, religious and faith leaders were identified, oriented and provided with talking points to integrate community sensitization and mobilization in their routines. Hotspots were mapped and targeted HTS outreaches were conducted. Data was collected, reviewed and reported weekly noting the number of people screened and tested for HIV, those identified positive and linked to care against the set targets.

Results: In four weeks (**Week 48 to Week 52**), **32** community HTS outreaches were conducted each averaging 100 tests. Overall total of **4,799** persons were tested and received results representing **90%** of the Quarterly target. Also, **41** persons living with HIV were identified and linked to treatment, a **60%** contribution of the quarterly target. Overall, at the end of the quarter, cumulative number of people tested was **8,125 (153%)** and **69 (101%)** new HIV positives were identified and all were linked to care.



Conclusions: Leveraging community structures represents a promising approach to enhancing mobilization for HTS and enhancing HIV case detection, thereby contributing to HIV epidemic control efforts.

EP247

Utilization of HIV testing, counseling and other related services at Africa's largest street party: a gender-trend exposition study

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Background: Large-scale HIV testing & counselling services in addition to related SRHR services are at the epicentre of HIV prevention efforts in resource-limited settings. Targeted outcomes are effectively achieved during the integration of the education, prevention, treatment and management in campaign formats conducted during periods of immense population convergence. However, there are observed gender disparities in service utilization.

This study aimed to determine the gender distribution in the uptake HIV and related services during a week-long duration at the largest Africa's Street party in Calabar, Nigeria.

Methods: A cross-sectional time-series descriptive study was carried out among 1,821 clients who utilised HIV and other related services at the #WiseUp Campaign centre during the #CarnivalCalabar festival between December 21 and December 27, 2023. Clients' register, following a purposive sampling technique, was utilised for data collection using Microsoft Excel. The quantitative data were presented in frequency, percentage and Chi-square analysis using SPSS 26.0.

Results: An analysis return rate of 99.6% (1,813) was recorded with Day 4 (23.7%) as the most-busy day. There were 1,355 (74.7%) males with an average age of 26. Only 95 (20.7%) of females accessed HIV risk assessment services with 246 (23.1%) representing the female-HTS uptake figure.

On a side-by-side gender-specific comparison, the distribution of females (231, 50.4%) who received HIV counselling services surpassed the males who, on the other hand, received more condoms and other contraceptives (1267, 93.5%). The females (31, 6.8%) notably accessed family planning services as compared to males 1 (0.1%). There was a strong relationship between clients' gender and HIV testing services, counseling services, condom reception, COVID-19 testing services and family planning services during the campaign ($p < 0.05$) with no significant relationship with the reception of risk assessment and tuberculosis testing services ($p > 0.05$).

Conclusions: Males participated more as clients in the campaign with a notable 3:1 ratio. However, the number of female clients that accessed these services offered were more receptive to HIV testing, counseling, and family planning services. Efforts towards exploring

the influencing factors on the gender participation gap identified during the delivery of essential HIV and other related health services in an open/festive setting should be made.

EP248

What motivated South African men to stay on PrEP? Interviews with a cross-section of men using PrEP in Buffalo City Municipality, South Africa

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Background: HIV related mortality is the leading cause of premature death for South African. South African men are more likely to delay HIV antiretroviral treatment (ART) and are more likely to have HIV related comorbidities when starting ART than their female counterparts. While PrEP has been recommended for rollout targeting cis-gendered, heterosexual men in South Africa, there are few studies investigating men's sustained use.

Methods: Adult men who had initiated PrEP at a community-based research site were interviewed after three months of initiating PrEP to understand resources that facilitated sustained use. We used the Network-Individual-Resources model (NIRM) to develop the interview guides, designed to explore resources that support continued PrEP use three months after initiation PrEP. Interviews were audio-recorded, transcribed, double-coded by two researchers, and analyzed using the NIRM.

Results: Twelve (median age=32 years, range 19-57 years) of twenty-two men who initiated PrEP three months prior were interviewed at their three-month follow-up visit. Men stated that condomless sex and multiple sexual partners motivated their continued PrEP use. Participants reported that they had, or would disclose PrEP use to their main partner, but were reticent about disclosing to casual partners. Partners and family members were key supporters for participants, and male friends were important sources of support for continued PrEP use.

All participants expressed positive perceptions of female PrEP users. Participants were supportive of PrEP access for men in their community, specifying preference for access at non-clinic locations at times that accounted for working schedules. However, participants agreed that the main barrier to accessing PrEP was the requirement for HIV testing, reasoning that men are generally fearful of an HIV positive test result.

Conclusions: In this study with South African men, continued PrEP use was supported by disclosure to a partner, a family member, and other male friends. Participants acknowledged high risk sexual activity as a motivator to sustain PrEP use. Men preferred accessing PrEP at community locations at times that would accommodate their working schedules. Men's uptake and sustained use may

be dependent upon convenience of access and perceived and actual social support from partners, family members, and male friends.

EP249

Strategies to expand HIV prevention engagement among transgender women in a research unit in São Paulo - Brazil

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Background: WHO has set the goal of eliminating AIDS as a public health problem, also aiming to reduce new cases through preventive strategies such as Pre-Exposure Prophylaxis for HIV (PrEP), recommended since 2015. In Brazil, PrEP was implemented as a public policy in 2017, but its distribution is heterogeneous, with limited access for travestis and transgender women (TrTW). Despite TrTW representing the group with the highest HIV prevalence in some regions of the country (16.9 - 36.7%), only 3.2% of PrEP users are TrTW, contrasting with the 82.2% of cisgender men who have sex with men. Stigma, discrimination, and socio-economic vulnerabilities are access barriers to HIV prevention for this population.

Methods: In 2018, the Community Education Program linked to Research Unit/CRT/AIDS - São Paulo was developed to provide ongoing education on HIV prevention and other STIs for the LGBTQIAPN+ community. Focusing on TrTW, sociological and peer education approaches were adopted, hiring TrTW to expand access to places frequented by this community. Educational activities were conducted in public service facilities such as shelters and citizenship centers, addressing different forms of HIV prevention, integral health, assisted hormone therapy by healthcare professionals and information on individual rights, such as the adjustment of civil registration and other needs pertinent to guaranteeing the dignity of this population.

Results: Following the implementation of recruitment and retention modalities tailored to the volunteers' needs, as described above, we observed a significant increase in recruited TrTW rates. In studies where these strategies were not used, 435 individuals were screened with 2.3% being TrTW, of whom 70.0% completed the follow-up. After implementing these strategies, 657 volunteers were screened, of whom 20.7% were TrTW, with a retention rate of 89.8% of those included.

Conclusions: Peer education conducted by TrTW, adapted to their specific needs, proved crucial in attracting and retaining this population in HIV prevention clinical studies. These strategies reached the target population more effectively than previous approaches based on social media, offering integral healthcare and with the volunteers themselves acting as multipliers to engage other TrTW in the studies.



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Access to harm reduction programs among sex workers who inject drugs: findings from a respondent-driven sampling survey in Namibia, Botswana, Eswatini, Mozambique and Zimbabwe

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Background: Over the past two decades, drug injection-related risk behaviors have been one of the major drivers of the HIV epidemic. Sex workers in most African countries are criminalized and using drugs or is as well HIV positive hinders most of them from acquiring services.

This study assesses access of sex workers who inject drugs (SWID) to harm reduction services (needle-exchange programs [NEP] and methadone maintenance treatment [MMT]) in Mozambique, Eswatini, Botswana, Zimbabwe, and Namibia in 2023, years after the large-scale implementation of these programs was rolled out.

Methods: 976 consenting SWID (>18 years old, ever injected in the past month) were recruited (24 seeds per country) into a zero-behavioral survey using a respondent-driven sampling method. Participants completed a face-to-face interview about HIV-related risk behaviors and access to harm reduction services. We calculated adjusted population estimates using RDSAT.

Results: 93.2% of the participants were female and male sex workers, 7.8% participants were LGBTIQ community, 46.3% aged between 18-29 years, 41.6% aged between 30 and 39 years old, 55.4% lived alone in the past year, 26.3% of the participants were female sex workers who are mothers and 18.8% lived in the outskirts of the towns and 70% lived in the urban towns. In terms of "awareness" and "use" of services among SWID, 62.8% and 54.8% were reported for NEP and MMT (respectively) and 19.7% for drug treatment services.

Similarly, (88.6%) SWIDs who lived with friends were more likely to be aware of and use (85.9%) services (vs. other living partners). 16.2% of HIV-positive SWIDs who are mothers have vertically transmitted HIV to their children. Overall, 17% of the participants were aware of but had not used any harm reduction services.

Conclusions: Programs should be incorporated or re-programmed specifically tailored for HIV-positive SWIDs and have breastfeeding children.

Despite a relatively high level of access to NEP among SWID in the five countries, a sizable fraction of the population remains without access to other services almost 8 years after their implementation. The use of harm reduction may be affected by certain SWID characteristics (e.g., living partners and geographical location). Ongoing surveillance activities are necessary to track change in access over time.

EP251

PrEP use and association with recent HIV infection among sexual contacts of Rwandan people newly diagnosed with HIV

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Background: In 2018, Rwanda implemented HIV recency testing as part of active case surveillance and introduced pre-exposure prophylaxis (PrEP) in 2019. We compared PrEP use among contacts of people with recent vs. long-term (LT) infection, and examined characteristics associated with PrEP use.

Methods: We studied HIV-negative sexual contacts of people newly diagnosed with HIV (index clients) during August 2021-October 2022 at 50 facilities in Rwanda offering PrEP. We defined recent infection as recent result on Rapid Test for Recent Infection and HIV viral load ≥ 1000 . We defined PrEP use as initiating PrEP any time before the end of the study.

We compared characteristics associated with PrEP use and index client recent infection using Fisher's exact or chi-square tests.

Results: We enrolled 586 contacts aged 18-74; 40 (6.8%) and 546 (93.2%) were linked to index clients with recent and LT infections, respectively. 84 (15.4%) contacts of LT index clients used PrEP vs. 1 (2.5%) contact of recent index clients ($p = 0.02$). 51 PrEP users (60.0%) were serodifferent partners, 26 (30.6%) female sex workers, 5 (5.9%) adolescent girls/young women, and 3 (3.5%) men who have sex with men. PrEP users were more likely vs. non-users to be female, aged <35, married/cohabiting with the index client, and received at an urban facility. Aside from age, contacts of index clients with recent infection did not share these characteristics.

	Total (n, %)	Used PrEP (n, %)	Did not use PrEP (n, %)	p value
Female	237 (40.4)	54 (63.5)	183 (36.5)	<0.01
Aged <35 years	361 (61.6)	63 (74.1)	298 (59.5)	0.01
Married or cohabiting with index client	181 (30.9)	54 (63.5)	127 (25.3)	<0.01
Received at urban health facility	373 (63.7)	65 (76.5)	308 (61.5)	0.01

Table. Comparison by PrEP use.

	Total (n, %)	Linked to index client with recent infection	Linked to index client with long-term infection	p value
Female	237 (40.4)	9 (22.5)	228 (41.8)	0.02
Aged <35 years	632 (61.6)	25 (62.5)	336 (61.6)	1.0
Married or cohabiting with index client	181 (30.9)	8 (20.0)	173 (31.7)	0.17
Received at urban health facility	373 (63.7)	21 (52.5)	352 (64.5)	0.18

Table. Comparison by index recency status.

Conclusions: PrEP coverage was low, and PrEP use less common among contacts linked to index clients with recent vs. LT infection. Characteristics of contacts linked to recent index clients were not aligned with contacts who had used PrEP; PrEP may not be reaching populations who need it. Increasing PrEP coverage, broadening eligibility, and ensuring program alignment with those at increased risk of infection are crucial steps in interrupting HIV transmission.

EP252

HIV testing Integrated service delivery for migrants and truckers population: results from Plan India's innovative One Stop Intervention project funded by Global Fund in 25 states of India

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Background: Though overall adult HIV prevalence remains low in India, as per data from HSS 2021, HIV prevalence was estimated to be at 1% among Long distance truckers (LDT). Complementing Govt. of India's effort to end AIDS by 2030, Plan India is implementing One Stop Center (OSC) project in 25 Indian states through community led Innovative strategy of One Stop Centre project (OSC) funded by The Global Fund.

Methods: The project is guided by three strategic objectives:

1. To reach out to and identify new & uncovered BP population through expanding service coverage beyond HIV prevention,
2. To provide enabling environment to the BP community and thus, reduce Stigma & Discrimination,
3. Empowerment of the BP communities by generating awareness and engaging in various skill development programme.

Project data of 52 thousand migrant and trucker registered during October,22 to September, 23 has been analyzed using SPSS 26.

Results: 77% of the total registered migrants (n=51,523) and truckers have received HIV testing. Total 112 clients were newly identified as HIV positive and 87% of them were linked to ART. With mean age remained as 34 years, HIV positivity remained higher in the older age group of >25 years (OR=1.705; CI: 1.089 – 2.671) compared to younger BP. With 20% client illiterate, 37% completed secondary education.

Most of the client is daily wage earner with 2 percent remained unemployed. 99% of the registered client received TB screening with 7.4% diagnosed with TB. 7% received viral hepatitis screening, with 54% received counselling on adherence, prevention & risk reduction, SRH & GBV, 6% of registered client received Drug De-Addiction and rehabilitation, Mental Health, Social protection, welfare scheme, livelihood, skill building etc., Legal Aids and Support.

Conclusions: Expansion of services beyond HIV testing is a vital strategy to respond to the unmet needs of Trucker and migrant population with varied sociodemographic profile.

While, Plan India's OSC project demonstrates a one stop solution for medical and additional services for the communities most vulnerable, it suggests that the service delivery needs to be prioritized based on sociodemographic profile of the client.

EP253

Beyond lectures: creative approaches for impactful HIV education

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Background: Creative approaches to HIV education and awareness campaigns have shown promise in engaging diverse audiences and promoting behavior change. Traditional methods often struggle to resonate with key populations like youth and sexual/gender minorities.

This literature review examines emerging evidence on the impact of novel strategies incorporating elements like crowdsourcing, digital storytelling, arts-based interventions, and community-driven media.

Methods: We conducted a comprehensive search in January 2024 for peer-reviewed articles published between 2015-2023 that evaluated creative HIV education programs and campaigns.

Data reported in this research article were obtained from reports, literature in peer-reviewed journals found in PubMed, PubMed Central, and ScienceDirect, grey literature, and UNAIDS database.

Studies were included to determine whether they employed non-traditional, arts/media-based methods and measured outcomes related to HIV knowledge, stigma, testing rates, or preventive behaviors.

Results: This review included 18 studies. Crowdsourced HIV testing promotion campaigns generated by community members increased home-based testing compared to standard materials. Interactive digital narratives like animated games improved HIV knowledge and self-efficacy among young sexual minority men.

Theatre-based and participatory arts interventions shifted attitudes, reduced stigma, and motivated testing across youth and adult audiences. Music video campaigns using hip-hop resonated with black young adults for HIV/STI prevention. Creative arts contests engaged college students in awareness efforts.



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Conclusions: Preliminary evidence suggests innovative, creative approaches leveraging digital media, performing arts, crowdsourcing, and community voice can enhance the reach and impact of HIV education initiatives. These methods show promise for priority populations like youth and marginalized groups who may be less receptive to conventional programs. Further research is needed on implementation, cost-effectiveness, and sustaining long-term effects.

EP254

A qualitative exploration of sexually transmitted infection and treatment seeking behavior of young men who have sex with men and transgender women who sell or trade sex in Thailand

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Background: Sexually transmitted infections (STIs) are common among young men who have sex with men and transgender women (YMSM/YTGW) who sell sex in Bangkok and Pattaya, Thailand. Assessing knowledge and beliefs regarding STI prevention and treatment in this key population could inform efforts to reduce STI incidence.

Methods: From July 2016 to July 2018, we conducted 62 key-informant interviews with 41 YMSM and 21 YTGW aged 18–26 years residing in Bangkok or Pattaya, Thailand who sold sex in the last 12 months. The interviews were conducted using Atlas.ti software, focusing on their history of STIs, treatment-seeking behavior, sexual decision-making during treatment, and STI prevention knowledge.

Results: The median age of participants was 23 years, of whom 79% reported completing primary/secondary school and 66% were full-time employed. During the past 12 months, 55% reported always using condoms during anal sex and 86% used a condom during their last anal sex.

Most participants reported a history of STI with symptoms (i.e., rash, genital pain, and urethral discharge); however, some participants who had screened positive for an STI reported no associated symptoms. Participant reactions to STI diagnosis varied by symptom severity and type of infection, and included searching the internet for treatment, seeking leftover medicine from peers, purchasing over-the-counter medicine, and visiting community clinics for prescribed medication.

Pain and discomfort increased the sense of urgency to seek medical care. Participants preferred to receive STI testing and treatment as part of a community STI pre-

vention campaign that compensated participants. During STI treatment, participants continued selling sex if lesions were painless or not obviously visible, believing they could not transmit the disease or were cured.

In addition to single condom use, participants endorsed these STI prevention methods as protective: simultaneous use of multiple condoms, rubbing ethyl alcohol on genitals after sex, and manually inspecting customers' genitals and anus to assess their cleanliness.

Conclusions: Thai YMSM/YTGW who sell sex demonstrated knowledge gaps and misconceptions about STI prevention and treatment. Providing this key population comprehensive sexual health education and physician-provided diagnosis and treatment could reduce STI incidence.

EP255

“We also need to become champions for this”: stakeholder perspectives on the introduction of new PrEP methods to AGYW accessing community-based services in the Johannesburg Health District, South Africa

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Background: Community stakeholders are key partners in HIV prevention programmes. Their participation can be strengthened to improve acceptability; particularly as new HIV prevention methods are introduced. Due to the novelty of long-acting PrEP methods (PrEP Ring and CAB PrEP), we assessed the perspectives of key community stakeholders in Johannesburg, South Africa, through the USAID-funded DREAMS PrEP Choice study.

Methods: The DREAMS PrEP Choice study is an implementation science study offering oral PrEP and PrEP ring to women 18 years and older at community sites across 36 sites in Johannesburg. We conducted eight focus group discussions (FGDs) between December 2023 and March 2024 with community stakeholders. Stakeholders were recruited purposely (based on prior knowledge) followed by snowballing. Data were transcribed and translated to English, and thematically analysed on Nvivo v.14. Participant demographics were captured on Redcap and descriptively analysed.

Results: Sixty-seven community leaders, parents, youth advocates, religious and traditional leaders, education and community development representatives participated. Eighty-two percent (n=55) were aware of PrEP, with lesser knowledge of the new PrEP methods. Stakeholders were eager and supportive of the introduction of long-acting PrEP methods, especially CAB PrEP, into their respective communities. However, some women were concerned with ability to maintain privacy during ring insertion in the gazebo model. Religious leaders stated lack

of collaboration, and access to PrEP services near churches. In higher learning institutions, the stakeholders mentioned that although AGWYs had high knowledge about PrEP, packaging and messaging of PrEP, as well as consistent service delivery were key for strengthening existing and new PrEP method delivery.

While acceptability of the new method was observed, differences regarding feasibility of delivering PrEP were observed by subdistrict. Specifically, limited knowledge, existing stigma and misconception around oral PrEP noted as barriers to scaling PrEP in some sub-districts.

Consequently, stakeholders recommended the appointment of community-based 'ring ambassadors' to debunk myths, stigma and misconceptions.

Conclusions: Community stakeholder views are important in informing key policy and implementation considerations for the scale up of existing and new PrEP methods. Multisectoral collaboration is needed to strengthen delivery, particularly involving the faith based sector, higher learning institutions and identification of community champions.

EP256

Qualitatively assessing factors associated with an increased need for HIV prevention among cisgender women in the United States

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Background: Cisgender women account for 20% of annual HIV diagnoses in the United States. Traditional demographic and behavioral risk factors have been insufficient to identify women who are most in need of HIV prevention. The purpose of this study was to qualitatively explore factors associated with increased HIV vulnerability from the perspective of cisgender women themselves and expert stakeholders.

Methods: Key informant interviews were conducted with cisgender women aged 18-65 years with a history of STIs or drug use, spoke English or Spanish. Participants who were stakeholders were experts in women's health. Data were collected using a semi-structured guide about factors associated with increased HIV exposure. Audio was transcribed then coded using directed content analysis in Dedoose.

Results: 120 interviews were completed from March 2023-February 2024. One-third of the women (n=40) were living with HIV, one-third were behaviorally vulnerable to HIV (n=40), and one-third were stakeholders (n=40). Participants were racially diverse with 3.3% Asian, 37.5%

White, 15.8% Hispanic, and 49% Black. Participants were from different regions of the United States, with 2% residing in US territories, 15% West, 24% Midwest, 24% South, and 35% in the Northeast.

Four key themes emerged as factors associated with increased need for HIV prevention: personal behavior, partner characteristics, inequity, and personal situation. Personal behavior included multiple partners and condomless sex. Partner characteristics included partner non-monogamy and partner drug use. Inequity included unstable housing, access to HIV prevention information, and access to HIV testing. Personal situation included experiences of intimate partner violence, coercion/abuse, mental health, alcohol abuse, drug abuse, and sex work. Stakeholders and women living with HIV more often discussed inequity and personal situation characteristics versus women living without HIV, who more often discussed personal behavior and partner characteristics.

Conclusions: Our study identified key factors associated with increased need for HIV prevention, positing intervention opportunities. Inequities in access to resources and personal situation such as intimate partner violence were highlighted by women living with HIV as key factors impacting the need for HIV prevention. Listening and acting upon the voices of key populations is a necessary strategy to decrease HIV incidence rates among vulnerable populations.

EP257

The impact of the COVID-19 pandemic on sexual health in a predominantly minoritized urban community

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Background: The impact of COVID-19 on sexual health and HIV prevention practices, particularly among minoritized populations disproportionately affected is largely unknown. We examined associations between sexual health and COVID-19 infection in a predominantly minoritized sample in New York City.

Methods: Individuals >18 years, living in the NYC area or accessing care at a large urban medical center in northern Manhattan were recruited online and in-person between September and December 2023. Participants completed an online survey on COVID-19 history, social determinants of health, and sexual health, including HIV/ Sexually Transmitted Infection (STI) associated behaviors, satisfaction with sex life [rated on 5-point Likert scale], and HIV perceived vulnerability [rated on scale of 0-10]. We conducted descriptive analyses and multiple logistic regression models to describe associations with sexual health outcomes.



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Results: Of 1,575 respondents, 948 were analyzed. On average, participants were 38.7 years (SD ±15.5), 56% female-born, 11% were non-Hispanic African American/Black, 28% Asian and Native Hawaiian/Pacific Islander, 46% Hispanic, and 50% foreign-born. The majority (72%) perceived themselves not at risk of HIV/STI acquisition; 47% had heard of PrEP, and 4% took PrEP.

Participants were somewhat/extremely satisfied with their sex life post-pandemic (60%). Participants likely to report somewhat/extreme satisfaction with their pre-pandemic sexual life (61% vs. 68%, $p=0.05$) had 0.64 (95% CI 0.49-0.84) lower odds of self-reporting COVID-19 infection.

Participants who had heard of PrEP had a 0.48 (95% CI 0.36-0.64) lower odds of self-reporting COVID-19 infection. The average number of recent sexual partners, condom use, or PrEP use did not differ statistically by reported COVID-19 status.

	N=948 (%)	COVID-19 Infection		Odds Ratio
		Yes	No	
HIV positive vs HIV negative before COVID-19 diagnosis or March 20, 2020	56 (6%)	38 (68%)	18 (32%)	1.16 (0.65-2.20)
STI diagnosis vs no STI diagnoses before COVID-19 diagnosis or March 20, 2020	36 (4%)	31 (86%)	5 (14%)	3.51 (1.34-11.68)
Somewhat or Extremely Satisfied vs. Neutral, Somewhat, or Extremely Dissatisfied with sex life after COVID-19	573 (60%)	363 (63%)	210 (37%)	1.15 (0.87-1.53)
Perceived STI/HIV Risk = 0	684 (72%)	177 (67%)	87 (33%)	0.86 (0.63-1.18)
Low HIV Vulnerability (<2 partners in the last 90 days AND =0 partners in the last 90 days OR Always uses condoms OR takes PrEP) AND no IDU (meth or heroin) in last 3 months)	479 (51%)	286 (60%)	193 (20%)	0.64 (0.49-0.84)
Knowledge of PrEP	436 (46%)	320 (72%)	116 (28%)	0.48 (0.36-0.64)
PrEP use vs Never use	37 (4%)	23 (62%)	14 (38%)	0.89 (0.45-1.76)
STI Diagnosis after COVID-19 diagnosis	9 (1%)	5 (56%)	4 (44%)	0.68 (0.18-2.55)
>2 partners in last 90 days vs ≤ 2 partners	81 (9%)	55 (68%)	26 (32%)	0.85 (0.50-1.42)

Conclusions: History of COVID-19 infection was associated with pre-pandemic sexual health satisfaction, STI history, and knowledge of PrEP, but not post-pandemic sexual health, or STI/HIV-associated behaviors. Understanding sexual health in vulnerable COVID-19-affected communities is critical to providing informed and targeted preventive care and resources.

EP258

'Is that it? That wasn't so bad!' Pain responses among the first clients to receive cabotegravir long-acting injections in Zambia

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Background: Despite the growth of the oral Pre-exposure prophylaxis (PrEP) program in Zambia, persistence remains suboptimal, with 50% of clients discontinuing at one-month. Zambia will introduce Cabotegravir Long Acting (CAB-LA) as a PrEP option in 5 districts in 2024. In October 2023, a rapid assessment was conducted to identify the possible facilitators and barriers to CAB-LA uptake among targeted populations, with pain being one of the main fears expressed by potential CAB-LA clients.

Methods: Focus group and in-depth interviews were conducted with 84 respondents. 43 were female, including FSW, and 41 were male, including MSM. 39% were aged 15-24, 54% aged 25-34 and 7% >35 years. FSWs feared HIV testing, while MSM feared possible stigma. Fears of undressing were predominant among male respondents. All respondents feared pain from the injection. At the start of implementation, clients opting for CAB-LA were asked to rate the pain from the injection using the Wong-Baker Faces Pain Rating Scale. This medical tool uses a combination of faces, numbers and words to help communicate the severity of physical pain, with '0' representing no pain and '10' representing the worst pain imaginable.

Results: Clients were counseled on possible pain to anticipate, compared to penicillin shots due to the similar consistency of the product. Between February 9 - March 15, 2024, 235 clients received CAB-LA injections at the first site to introduce CAB-LA in Zambia, Mwanjuni Health Post. 145 were females and 119 males, with 59% were aged 15-24, 30% aged between 25-34 and 11% >35 years. 152 clients (65%) indicated they felt no pain (0 on the pain scale), 78 (33%) reported a pain rating of 1, 3 (1%) reported a pain rating of 2 (hurts a little bit) and 2 clients reported a pain rating of >1% reported a pain rating of 3. In HPTN 083, 75% of participants in the CAB-LA arm who received at least one injection reported injection site pain.

Conclusions: CAB-LA is a gamechanger in HIV prevention. Countries introducing CAB-LA must provide comprehensive counseling to prospective clients that includes information on pain but take care not to dissuade possible clients by overstating expected pain.

EP259

Promoting routine HIV testing among young Black and Latinx MSM and transgender women through the HealthMPowerment (HMP) Stigma Digital Intervention

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Background: HealthMPowerment Stigma (HMP) is an app-based intervention designed to reduce intersectional stigma and improve HIV-related outcomes among young Black and Latinx men who have sex with men and transgender women who have sex with men (YBLMT). Among HIV-negative participants, we tested the impact of the HMP app on increasing HIV testing through a national randomized control trial.

Methods: 750 participants were enrolled and followed for 12 months. Eligibility criteria included: US residency, being aged 15 to 29, identifying as YBLMT, and reporting

condomless anal sex with men or transgender women. Participants were stratified by HIV status and randomized to one of three app intervention conditions: information-only control app (Arm 1), or an interactive app with content, forums, and activities (Arm 2).

Among 520 participants self-reporting HIV-negative or HIV status unknown at baseline, 258 (49.6%) were randomized to the information-only control app, and 262 (50.4%) were randomized into the interactive app.

Primary analysis compared routine HIV testing in the intervention versus control conditions. Sensitivity analyses assessed whether greater intervention engagement (e.g., time spent on app; total number of logins) was associated with more frequent HIV self-testing behavior.

Results: Participants' mean age was 24.17 (SD=3.45); 264 (70%) were identified as gay. 10% of the sample identified as gender minorities. 466 (89.62%) had ever tested for HIV. During the 12-month period, 68.8% of participants tested two or more times at least three months apart (routine HIV testing). There was no overall difference in routine HIV testing between intervention conditions (); however, greater app engagement was associated with more frequent HIV testing, as measured by time spent on app (61.1 vs. 28.5 minutes; $p<.001$) and total number of logins (24.6 vs. 10.6 logins; $p<.001$).

Conclusions: Participants with different versions of the HMP app did not differ in their rates of routine HIV testing, yet were higher than national estimates (10-40%) for routine HIV testing among YMSM/TW.

However, greater engagement with both versions were associated with greater routine HIV testing outcomes, suggesting the possible utility of HMP Stigma for supporting routine HIV testing.

EP260

Medroxyprogesterone acetate and norethisterone enanthate differentially regulate the hypothalamic-pituitary-gonadal axis: implications for clinical outcomes and HIV susceptibility in a secondary study from the randomized WHICH trial

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Background: Contraceptives modulate the hypothalamic-pituitary-ovarian (HPO) axis, which regulates multiple physiological processes, including fertility, behavior and the menstrual cycle. However, these mechanisms and differences between contraceptives are underexplored. The Women's Health Injectable Contraception and HIV (WHICH) trial conducted at two South African sites (2018-2019), randomized 521 women to intramuscular de-

po-medroxyprogesterone acetate (DMPA-IM) or norethisterone enanthate (NET-EN). Results showed decreased estradiol levels for both contraceptives but more amenorrhea and more risky sexual behavior for DMPA-IM than NET-EN one week after the 6-month injection at 25 weeks (25W).

Methods: Matched serum samples were taken at initiation (D0) and 25W (i.e. at peak study progestin levels) from 94-99 participants from each contraceptive arm in the WHICH trial. Serum was analyzed for gonadal steroids and progestin levels by UHPLC-MS/MS and for peptide hormones by ELISA/immunoassay. Progestin mechanisms of action were investigated in a pituitary cell line. Possible causal relationships were investigated by time-varying association analysis, including for select clinical outcomes.

Results: Differential effects were detected between contraceptives on gonadotropin-releasing hormone (GnRH) levels, after correcting for non-study progestin use. Both contraceptives decreased luteinizing hormone (LH) levels, DMPA-IM less so than NET-EN. DMPA-IM increased, while NET-EN decreased follicle stimulating hormone (FSH) levels. Both contraceptives decreased the levels of gonadal steroids substantially. *In vitro* data showed that MPA acts on pituitary gonadotrophs to increase FSH expression. Different time-varying associations between contraceptive arms were detected between several hormones and between hormones and select clinical outcomes.

Conclusions: Clinical and association data suggest that both contraceptives decrease gonadal steroids by progestins acting at the pituitary level to decrease LH levels. NET-EN may also regulate GnRH levels at the hypothalamic level or above. *In vitro* data suggest that FSH levels are modulated by direct effects of MPA on pituitary gonadotrophs.

The overall HPO hormone profiles of these contraceptive users are not comparable to each other nor to follicular or luteal phase hormone profiles of normal-cycling women, nor those in postmenopausal women.

Association data suggest that mechanisms affecting sexual behavior and amenorrhea are different between contraceptives, with a more protective effect of NET-EN than DMPA-IM on HIV acquisition.

EP261

Verbal TB screening among Transgender, PWID and Bridge Population in concentrated epidemics experience from One Stop Project implemented in 25 states funded by The Global Fund, India

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Background: Though overall adult HIV prevalence remains low in India, as per data from HSS 2021, HIV prevalence was estimated to be at 3.78% among TGs, 9.03% among PIDUs and 1% among Long distance truckers (LDT). Complementing Govt. of India's effort to end AIDS



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by 2030, Plan India is implementing One Stop Center project in 25 Indian states through community led Innovative strategy of One Stop Centre project funded by The Global Fund.

Methods: The project is guided by three strategic objectives:

1. To reach out to and identify new & uncovered Key population through expanding service coverage beyond HIV prevention,
2. To provide enabling environment to the KP community and thus, reduce Stigma & Discrimination,
3. Empowerment of the KP communities by generating awareness and engaging in various skill development programme.

Project data of 65 thousand key populations from transgender, PWID and bridge population during October, 22 to September, 23 has been analyzed using SPSS 26.

Results: More than eighty percent (n=65,658) client received HIV testing, with a varied positivity 2.4% among TG, 3.75% among PWID and 0.3% among BP. Ninety one (n=552) newly identified clients were linked to ART and followed up for adherence. Mean age of the registered clients remained as 32 years, with higher HIV positivity in the age group <34 compared to higher (OR=1.648; CI: 1.433 – 1.894). Ninety seven percent clients have received TB verbal screening, 553 were found to be TB symptomatic.

Ninety percent (n=496) out of the client found symptomatic received TB testing. Proportion of TB suspects diagnosed with TB on smear microscopy varied with 7.5% among BP, 10% among PWID and 1% in TG clients. With all the diagnosed cases linked to DOTS treatment and followed up for treatment completion.

Conclusions: Verbal screening for TB is an effective tool for early detection of TB among Transgender, PWID, Truckers and migrants' populations in concentrated epidemics setting.

While Plan India's One Stop Project shows the community driven intensive case finding integrated with HIV prevention programming this may be scaled up within HIV prevention and care programme in order to control TB/HIV diagnosis.

EP262

Msichana Salama: a pilot social network intervention for out-of-school AGYW in Tanzania

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Background: Out-of-school adolescent girls and young women (AGYW) in Africa are at increased risk for HIV. Nevertheless, large-scale HIV prevention programs, such as PEPFAR's DREAMS program, have faced challenges recruit-

ing out-of-school AGYW. A social network approach may be strategic for engaging out-of-school AGYW in HIV-related programs.

Methods: Using the PLACE sampling method, we identified social networks of out-of-school AGYW in Dar es Salaam, Tanzania. The networks were stable and cohesive, with an average of 13.7 members per network. Formative research with AGYW indicated high rates of self-reported HIV seropositivity (12.2%) and social norms supporting transactional sex.

Participants recommended economic empowerment as a strategy for avoiding transactional sex. Subsequently, we invited all members of 6 social networks (N=57) of out-of-school AGYW in Dar es Salaam to participate in the *Msichana Salama* program, comprising 16 HIV-protection social norms and "cash plus"/economic empowerment sessions.

The cash plus sessions mimicked Tanzania's social protection program. In-depth interviews were conducted after the sessions with a total of 38 participants; all analyses were conducted in Dedoose.

Results: 41 participants (72%) completed all sessions, despite a time lag due to the COVID-19 pandemic. Participants were given a cash transfer (100USD), livelihood and entrepreneurship training through the local government. All networks nominated leaders who promoted social norms change related to sexual health, and participants found the leaders' messages effective: "now I know how to prevent STIs, how to communicate with my partner and agree on condom use, and how to say 'no' to unsafe sex."

Furthermore, participants were trained in entrepreneurship and livelihood skills including cooking and make-up application. Participants reported being more financially literate and generating new income.

Some AGYW experienced challenges, such as problems receiving payment. Nevertheless, several were successful; as one with a cooking business said: "I was living with my mother, but now, I [live independently,] pay rent and support my family." Participants found *Msichana Salama* satisfactory and recommended improving it with more boosters, mentoring, and increased start-up capital.

Conclusions: A social network approach that combines social norms change and economic empowerment is a feasible and acceptable HIV prevention strategy for urban out-of-school AGYW.

EP263

Investing in HIV pays off: findings from the Kenya Program 2016-2023

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Background: Considerable resources both from in-country allocations and global health partners have been invested in Kenya's HIV response with the aim of ending AIDS as a public health threat by 2027. The transition of Kenya to a Lower Middle-Income Country (LMIC) has resulted in a significant decline in donor contributions, resulting in a shift of the national dialogue on HIV financing to sustainability, with questions on the cost effectiveness of continued scale up of investments for HIV programs despite epidemic control. There is need for empirical evidence on whether the epidemiological returns of investing in HIV programs warrant increased funding.

Methods: The Kenya AIDS Strategic Framework is the policy document that guides the national HIV response by mapping out strategic interventions by high-priority population groups and geographical areas. National data from the review of this strategic framework was used to analyze the relationship between level of investment in HIV programming as reported by the National AIDS Spending Assessment and reduction in new infections as measured by changes in HIV incidence and rates of mother to child transmission (MTCT) of HIV. Linear regression modelling was employed to measure the correlation between HIV expenditure and epidemiological change.

Results: Data from all 47 administrative units in Kenya was analyzed for the period 2016-2023. A statistically significant positive correlation was demonstrated between level of investment in HIV programs and reduction in new HIV infections as measured by decline in rate of mother to child transmission of HIV ($\beta=2.43$, $p=0.051$) and HIV incidence rate ($\beta=0.01$, $p=0.014$). The highest reduction was reported in regions with previously high prevalence who had achieved a degree of epidemic control as measured by HIV MTCT rate of $\leq 5\%$.

Conclusions: Ending AIDS as a public health threat is cost-effective, and merits continued financial support, as demonstrated by the reduction in new HIV infections in regions with significant investment in HIV. Innovative local solutions towards continued and sustained financing for HIV must be identified and implemented.

EP264

Strategies for enhancing effective use of event-driven pre-exposure prophylaxis among men who have sex with men as a method of HIV prevention. Qualitative results from a feasibility study

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Background: Event-driven (ED) pre-exposure prophylaxis (PrEP) may protect against HIV acquisition by about 90% or more when used effectively and as directed. ED-PrEP has been proven to be an effective method among men who have sex with men (MSM) (WHO 2019) at the time of study implementation. Pangaea Zimbabwe conducted an implementation science feasibility and acceptability study in preparation for the roll-out of ED-PrEP use as part of combination HIV prevention at public health facilities in Zimbabwe. Understanding perceptions around ED-PrEP effective use provides insights around the acceptability of ED-PrEP.

Methods: A prospective cohort study was conducted from November 2022 to April 2023 where mixed methodology data was collected to assess feasibility, acceptability, client and provider experiences and outcomes among MSM offered ED-PrEP. 177 eligible MSM were enrolled and offered oral or ED-PrEP, according to preference.

Each participant was followed up for six months, where patterns of use and outcomes were recorded. HIV combination prevention counselling and support was provided during the study. Key informant and focus group discussions were conducted with MSM and service providers, exploring insights around effective use of ED-PrEP.

Results: Strategies for effective use of ED-PrEP resembled a socioecological health model. Individual preferences and self-concept fostered effective use due to favorable duration of medication, easy dosage instructions and the autonomy to stop and start ED-PrEP as needed. Intrapersonal level networking, comprehensive counselling, and positive attitudes of service providers towards MSM and client follow up enhanced ED-PrEP effective use. At health systems level, reducing overall waiting time, PrEP commodity security and client centered, differentiated models of PrEP delivery enhanced uptake and effective use. Therapy related factors influenced behaviors around uptake with minimal side effects and reduced pill burden improving effective use.

Conclusions: Multipronged socio-ecological approaches and inferences from individual, provider, and health system levels, are critical for enhancing uptake and effective use of ED-PrEP as part of combination HIV prevention. Availability ED-PrEP in addition to daily PrEP enhances up-



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take and effective use in line with client preferences and changing HIV prevention needs over time. Lessons learned are critical as new biomedical prevention/ PrEP methods like Cabotegravir injection are being introduced.

EP265

Interaction of HIV and cannabis use on ECG abnormalities among people with or at risk of HIV

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Background: Cannabis is among the most common substances in the United States and its prevalence has been increasing particularly among people living with HIV (PLWH). Cannabis use association with abnormal electrocardiograms in PLWH has not been studied.

Methods: Cross-sectional data was obtained and analyzed from the MACS-WIHS Combined Cohort Study, the largest prospective cohort of adult people with and without HIV in the US. ECG findings were categorized as normal, myocardial infarction (MI), arrhythmia, or other abnormalities based on more than 50 clinical indicators abstracted from medical records. Cannabis use was self-reported from the participant's most recent study visit. We examined the association between cannabis use and ECG findings, stratified by sex, and HIV status.

Multiple logistic regressions were applied to evaluate HIV and cannabis use associations with ECG abnormalities, controlling for age, and sex.

Results: The study included 3,610 PLWH or at risk of HIV. 62.9% were HIV+ and 27.5% reported cannabis use since the last visit. Overall, 19.1% had evidence of MI on ECG, 0.5% arrhythmia, and 39.6% had other abnormalities. There was no significant association between cannabis use and ECG abnormalities in the full sample or by sex. HIV+ men had lower odds of having an ECG with evidence of MI (α OR=0.74, 95CI=0.55, 0.99) compared to HIV- men.

Among those reporting recent cannabis use, HIV+ men had lower odds of an ECG with MI (α OR=0.51, 95CI=0.32, 0.82) compared to HIV- men, whereas among non-cannabis users, there was no association of HIV status in men (α OR=1.07, 95CI=0.77, 1.49).

Among HIV- men, cannabis use was associated with higher odds of MI (α OR=1.63, 95CI=1.09, 2.44) compared to noncannabis users.

Among women, no significant association was observed by HIV status or by cannabis use.

Conclusions: Our findings show that among men reporting recent cannabis use, those with HIV had lower risk of having ECG evidence of MI compared to those without HIV. Among men without HIV, recent cannabis use was associated with greater odds of ECG abnormality sug-

gestive of MI compared to non-cannabis users. Our study highlights the important role of cannabis use and its differential impact on cardiovascular health by sex and HIV status.

EP266

Embracing unity: combating discrimination and advocating for HIV/AIDS prevention - Transcrições Art Project

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Background: Transgender women (TGW) face multifaceted vulnerabilities when it comes to accessing adequate healthcare services, particularly in the context of HIV/AIDS. Stigma and discrimination intersect to create significant barriers, leading to reduced access to HIV prevention, testing, and treatment services. To address these gaps, we established the *Transcrições* Project.

Methods: The *Transcrições* project, created in 2015, aims to establish connections and safe spaces, harnessing art to facilitate access to healthcare for TGW as well as increasing their research literacy, with a specific focus on sexual rights and health. Its monthly workshops are grounded in the principles inspired by Paulo Freire's Pedagogy of the Oppressed, the artist Lygia Clark's therapeutical propositions, and the Relational Aesthetics theory. Participants' demographics and perceptions are described in this abstract. The project is led by one transgender woman and two skilled art educators.

Results: Since 2015, 2600 individuals participated in 585 workshops, among which 35% self-identified as travestis, 45% as transgender women 3% as intersexuals, 7% as non-binary individuals, and 10% as trans men, 65% as Black/Pardo. Ages ranged from 17 to 60 years. Most workshops were in-person (55%), but 45% occurred remotely, especially during the Covid-19 pandemic. Participants referred that being part of the project improved their self-care, understanding of their rights, and increased their feelings of well-being and security, besides having a sense of community and belongingness.

The project also influenced health outcomes, as participants indicated the project as a support to PrEP uptake and retention, adherence to endocrinological and mental health care.

Conclusions: *Transcrições* workshops serve as pivotal mechanisms for ensuring equity and promoting diversity in HIV prevention and care clinical research. By integrating perspectives from affected communities, this project facilitates heightened inclusivity and breadth of demographic representation within studies, as well as strengthen trust and reduce HIV-related stigma.

EP267

High proportion of recent HIV infections among women, adolescents and young people; an analysis of Recency testing data in Zambia

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Background: Recency assays use one or more biomarkers to identify whether HIV infection in a person is recent (usually within a year or less) or longstanding. Recency assays have been used to estimate incidence in representative cross-sectional surveys and in epidemiological studies to better understand the patterns and distributions of new and longstanding HIV infections.

In Zambia the recency testing program was launched in 2020 and over 120,000 samples have been tested cumulatively. We analyzed recency testing data to better understand the transmission patterns of HIV across geographical areas and subpopulation and to monitor the proportion of the population living with HIV who are diagnosed early versus late in infection.

Methods: We extracted all recency tests data from the USAID supported regions in Zambia between 2020 and 2023. Records that were found to be recent by the screening test but did not have the confirmatory test result were excluded.

The PEPFAR Monitoring, Evaluation and Reporting version 2.7 definition was used to assign recency results as binary variables (recent or long-term) after the confirmatory test result came back. We further analyzed the results by sex, age category and testing delivery entry point.

Results: Recent infections were 1,747 (3.4 %) out of a total 51,749 tests done. Females were found to be having a recent infection in 3.8 % of samples as opposed to males (2.7 %). The entry point with higher percentage was PMTCT (4.6 %) and lowest was Index testing at 2.9 %. Young ages are associated with a higher proportion (15-19 yrs at 8.0 %; 20-24 yrs at 5.6 %, compared to 40-44 yrs at 2.2 % and 45-49 yrs at 1.8 %)

Conclusions: This analysis revealed that adolescent and young people as well females of reproductive age are found with recent HIV infection in Zambia. This data correlates with findings from the 2021 Population based HIV Impact Assessment that shows high HIV incidence among female, adolescent and young people. While further analyses are needed to better understand social demographic factors linked with HIV transmission.

In this population, findings from this study justifies the urge to scale up age specific HIV prevention interventions.

EP268

Quality of life and nutritional status of people living with HIV/AIDS in Buea and Limbe Health Districts

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Background: Evidence suggests that the nutritional status and quality of life of PLHIV significantly impact ART retention, treatment adherence, and survival, making it important for policymakers. However, there is paucity of data on this association in Cameroon, highlighting the need for this study, which aims to assess the association between quality of life and nutritional status of People Living with HIV/AIDS (PLHIV) in Buea and Limbe Health Districts, Cameroon.

Methods: This study was a hospital based cross-sectional study. The study period ran for 6 months, from December 1st 2022 to June 1st 2023. Body Mass Index (BMI) was used as an indicator for N.S. Sociodemographic factors, HIV related factors, weight, height and WHOQOL-HIV BREF answers were collected from the participants.

Descriptive analysis was used to estimate the prevalence of malnutrition and describe the QoL of participants. Logistic regression was used to assess the association between independent variables with quality of life and nutritional status, and equally BMI and QoL overall score.

Results: We recruited 500 participants. Ages ranged from 23 -73 years. From this study 184 (36.8%) participants with normal weight, 40(8.0%) participants were underweight, 165(33.0%) were overweight and 111(22.2%) were obese. Overall QoL was good (51%). There was a significant association between being single (AOR= 0.30[95%CI: 0.16-0.55], P=0.001), female (AOR= 2.09[95%CI:1.29-3.06], P=0.003), being in the lower wealth quintile (AOR= 2.14[95%CI: 1.26-3.6], P=0.005) and having a poor quality of life.

There was a significant association between ending school at the primary level (AOR= 2.80[95%CI: 2.01-3.35], P=0.002), staying alone (AOR=3.12[95%CI:2.26-4.23], P=0.001), having a detectable viral load (AOR= 2.12[95%CI:1.23-2.72], P=0.034), being in stage III and IV HIV (P=0.031) and being underweight.

Also, there was a significant association between being adherent to ART (AOR= 2.23[95%CI:1.67-2.92], P=0.030), having no viral load detected (AOR= 1.51[95%CI:1.01-2.60], P=0.043) and having a good quality of life. Our study revealed a very highly significant association between quality of life and nutritional status (P<0.001).

Conclusions: Malnutrition in PLHIV is common and directly affects their quality of life. Healthcare providers should prioritize monitoring and promoting good nutritional status, integrating nutritional support and counselling into HIV care programs to enhance the quality of life for PLHIV.



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EP269

Injectable contraceptives DMPA-IM and NET-EN differentially affect the number of HIV target cells in the female genital tract, but not systemically: implications for HIV acquisition

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Background: Observational data suggest a lower risk of HIV acquisition in women using the injectable contraceptive norethisterone enanthate (NET-EN), versus intramuscular depo medroxyprogesterone acetate (DMPA-IM). DMPA-IM and NET-EN are commonly used in sub-Saharan Africa and South Africa, respectively, both areas with high HIV prevalence in reproductive aged women. Extensive clinical data on the effects of DMPA-IM use on HIV target cells are inconsistent, while limited data are available for NET-EN users.

No data are available from randomized trials comparing head-to-head the effects of DMPA-IM and NET-EN, nor for any trials at peak progestin concentrations.

Methods: The Women's Health Injectable Contraception and HIV trial randomized 521 women to DMPA-IM or NET-EN at two South African sites (2018-2019). Cells isolated from blood and cytobrushes from 93 women, from one site, taken at baseline and one week after the 6-month injection (peak serum progestin levels) were analyzed by flow cytometry for effects on select CD4+ HIV target cells, expressing HIV co-receptors, an integrin and/or activation markers.

Results: Systemically, DMPA-IM and NET-EN use showed similar reduction in frequency and number of most HIV target cells, and expression of related CD4+ cell surface markers, with few significant differences between the contraceptives.

In contrast, DMPA-IM and NET-EN use showed different effects in the genital tract, with significantly different cell numbers for most populations between contraceptives. DMPA-IM tended to increase but NET-EN to decrease cell numbers, especially for CD4+ cells expressing HIV co-receptors, activation markers or the integrin $\alpha 4\beta 7$.

Few significant effects were detected in frequency or expression of surface markers on CD4+ cells for within or between contraceptives in the genital tract. Excluding for non-study progestins revealed additional significant increases in cell number and frequency of select HIV target cells in the DMPA-IM arm.

Conclusions: Our data suggest similar effects of both contraceptives on systemic CD4+ HIV target cell populations but differential effects in the genital tract.

The differences in numbers of HIV target cells in the genital tract between contraceptive users are likely to have implications for HIV acquisition. Results suggest that NET-EN use may be more protective in the genital tract than DMPA-IM use.

EP270

Persistent low-level viremia among pediatrics and adolescents living with HIV receiving antiretroviral therapy at the selected health facilities in Ondo, Southwest Nigeria. A retrospective cohort study

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Background: The increased risk of virologic failure, and HIV drug resistance associated with persistent low-level viremia among Pediatrics and Adolescents Living with HIV on HIV care is clinically becoming worrisome.

The aim of this study was to assess the persistent low-level viremia among HIV infected pediatrics and adolescents receiving antiretroviral therapy at the selected health facilities in Ondo, Southwest Nigeria.

Methods: In this retrospective cohort study, the longitudinal viral load results of the pediatrics and adolescents aged 0-19years enrolled into HIV care ≥ 12 months at 28 health facilities in Ondo Southwest Nigeria from January, 2021- December, 2023 was reviewed using electronic medical record. The persistent low-level viremia (≥ 2 last consecutive viral load measurements of 50-999 copies/ml taken six or more months apart), virological suppression (viral load results ≤ 50 copies per mL), and virological failure (≥ 2 last consecutive virological non-suppression viral load results) were used as an inclusion criterion, while deceased ones in these categories were excluded in the study. Log-binomial model was used to determine the relative risk for low-level viraemia and virological failure.

Results: The viral load results of 817 eligible clients was reviewed; (77) 9.4% had persistent low-level viremia, (677) 82.9% achieved viral suppression, and virologic failure occurred in (76) 9.3% of the participants.

The study also showed that male participants had a higher rate of persistent low-level viremia (PLLV) of (45) 58.4%, while participants with primary education and age band between 10-14years were implicated with high-

est PLLV rate of (77) 100.0% and (27) 35.1% respectively. Clients with persistent low level viraemia had an increased risk of virologic failure (adjusted relative risk 1.53, 95% C.I 1.30-1.81, p<0.000) at the next viral load test.

Conclusions: Persistent low-level viremia among the participants was significant. However, a targeted clinical attention and monitoring especially among pediatrics and adolescents is needed to break the HIV disease progression.

EP271

Enhancing HIV testing and treatment services among young bisexual men in Nairobi, Kenya

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Background: This abstract presents the findings of a study conducted between October and December 2022, aimed at amplifying HIV testing and treatment services among young bisexual men in Nairobi, Kenya, and especially those residing within informal settlements. Despite the high burden of HIV in Kenya, bisexual men face unique challenges in accessing and utilizing these services.

The study aimed to identify barriers and develop interventions to improve HIV testing and treatment uptake among the bisexual community in Nairobi, Kenya.

Methods: A mixed-methods approach was employed to collect data from a sample of young bisexual men in Nairobi. Quantitative data were obtained through a structured questionnaire administered to 300 participants, selected through a combination of random and convenience sampling.

Qualitative data were collected through focus group discussions and in-depth interviews with a subset of participants (n=30). Data were analyzed using descriptive statistics for quantitative data and thematic analysis for qualitative data.

Results: Quantitative findings revealed that only 45% of the young bisexual men had ever been tested for HIV. Among those who were HIV-positive, 30% were completely unaware of their status. The main barriers to HIV testing included fear of stigma and discrimination (62%), lack of knowledge about available services (48%), and concerns about confidentiality (37%).

The qualitative analysis revealed additional barriers, including fear of disclosure, lack of targeted information, and limited accessibility of testing facilities within their areas of residence.

Conclusions: The findings highlight the urgent need to improve HIV testing and treatment services among young bisexual men in Nairobi, Kenya. Interventions should focus on reducing stigma and discrimination, increasing knowledge about available services, and improving confidentiality.

Tailored information campaigns, peer support programs, and mobile testing units could enhance accessibility and encourage regular testing among this group of key pop-

ulation. Collaborative efforts between healthcare providers, community organizations, and policymakers are also very key for implementing effective strategies to address the specific needs of young bisexual men and mitigate the impact of HIV in this vulnerable population.

EP272

Utilization of community safe spaces for improving HIV PrEP uptake among adolescent girls and young women in Nyamagana Council, Tanzania: 2022-2023

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Background: Pre-exposure prophylaxis (PrEP) is effective against HIV infection when used consistently. As 77% of new HIV infections in 15-24-year-olds occur among adolescent girls and young women (AGYW) in sub-Saharan Africa, increasing PrEP uptake in this population is crucial. Poor access to facilities offering PrEP and stigma surrounding behaviors contributing to HIV are often barriers to PrEP uptake. We used AGYW-defined community safe spaces to support PrEP uptake in Nyamagana Municipal Council in Mwanza, Tanzania. We describe changes in PrEP uptake from 2022 when PrEP was available to AGYW only in health facilities, to the end of September 2023, when community safe spaces were fully implemented.

Methods: AGYW enrolled in Determined, Resilient, Empowered, AIDS-free, mentored, and safe (DREAMS) participated in a structured mapping activity. Trained peer educators (PE) used a community mapping tool to support AGYW to identify safe spaces. Venues frequented as safe and avoided as unsafe were evaluated for proximity to residence, accessibility, security, and privacy to construct a final list of safe spaces for community-based HIV prevention. Fifty-five health care workers (HCW) and 34 PE were trained to conduct PrEP outreach and education through community safe spaces. HCW and PE visited AGYW in established safe spaces weekly to provide client-centered education, PrEP screening, prescription drop-off/pick-up, referrals, adherence counseling, and side effect management. Service delivery data from 20 months of implementation were collected and analyzed using government health facilities registers that record initiation and refill.

Results: Through community engagement and mapping, we identified 50 venues to serve as safe spaces. The community safe spaces facilitated initiation of PrEP in 1,054 AGYW and refills for 1,842. On average 501 AGYW accessed



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PrEP services per quarter during the reporting period. The lowest and highest enrolment period were quarter July-September 2022 and January-March 2023 with 67 and 709 AGYW access PrEP services respectively.

Conclusions: PrEP services delivered in community safe spaces proved feasible and acceptable for AGYW who were able to access client centered sexual and reproductive health services away from stigma and discrimination. These safe spaces appear to be supporting both initiation and continued PrEP use by contributing to the de-medicalization of preventive services.

EP273

Enhancing adherence, emotional well-being, and psychological resilience: exploring expressive art therapy for children and adolescents affected by HIV

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Background: Children and adolescents living with HIV face unique challenges related to medication adherence, emotional well-being, and psychological health. Traditional interventions may not fully address their complex needs. Expressive art therapy offers a promising alternative by providing a creative outlet for emotional expression and communication.

Methods: During the 2023 school holidays (October-December), 100 children and adolescents (50 males, 50 females) living with HIV, aged 8-18, participated in a 12-week themed expressive art therapy program during support group sessions at the Kisumu County Referral Hospital and Lumumba health centre sessions focused on feelings, HIV education, adherence, disclosure, sexual health, and grief.

Led by trained therapists and counselors, activities included tie-dye, mask-making, friendship bracelets, letter writing, and performing arts. Pre- and post-assessments measured medication adherence, emotional regulation, and well-being. Positive outcomes included improved adherence (80%), emotional regulation (30% decrease in distress, 25% increase in coping), and well-being (85% reported higher self-esteem).

Results: The study's findings demonstrate significant enhancements among children and adolescents with HIV after participating in themed expressive art therapy. Medication adherence increased notably, with 80% reporting improved adherence post-intervention. Emotional regulation skills saw a substantial 30% reduction in self-reported distress and a 25% increase in coping strategies.

Psychological well-being notably improved, with 85% reporting heightened self-esteem and life satisfaction. Peer support and social connectedness also increased, with 90% expressing a stronger sense of belonging. Gender analysis revealed comparable improvements between males and females, while older participants (aged 13-18)

showed slightly greater gains. These results emphasize the efficacy of expressive art therapy in addressing diverse needs in this population, underscoring the importance of tailored interventions.

Conclusions: The study's findings carry significant implications for HIV prevention, treatment, care, and support for children and adolescents. Themed expressive art therapy demonstrates effectiveness in improving medication adherence, emotional regulation, psychological well-being, and social contentedness.

This holistic approach offers promising avenues for enhancing pediatric HIV care interventions, fostering resilience, and empowerment through creative expression and peer support. Integrating such interventions into healthcare settings could better support this vulnerable population, promoting well-being and quality of life.

Future research should explore the long-term effects and optimal implementation strategies of expressive art therapy in diverse healthcare settings.

EP274

Qualitative assessment on perceived barriers and facilitators to oral pre-exposure prophylaxis (PrEP) uptake among men who have sex with men and transgender women in Myanmar

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Background: HIV disproportionately affects men who have sex with men (MSMs) and transgender women (TGWs) in Myanmar. With funding support from USAID/PEPFAR and Global Fund, Community Partners International, collaborating with Population Services International (PSI) and Medical Action Myanmar (MAM), implemented a demonstration project that provided oral PrEP to MSMs and TGWs at two clinics in Yangon in July 2020. PrEP usage among them remains suboptimal despite introducing PrEP.

Therefore, we conducted a qualitative study to understand the barriers and facilitators to PrEP uptake among these populations.

Methods: We conducted a total of 31 qualitative semi-structured in-depth interviews (IDIs) with MSM/TGW PrEP users (restarted and current users) and non-users (declined and discontinued users) selected by criterion sampling from PSI-Lanpyakyl clinic and MAM-Tun clinic in Yangon. We explored their experiences and perspectives toward PrEP uptake. Interviews were conducted by telephone in April 2022. IDIs were audio recorded, transcribed verbatim, and coded using ATLAS.ti 7.5.1. We used a content analytic approach to define themes and key findings.

Results: 17 MSMs (4 restarted users, 4 current users, 5 declined users, and 4 discontinued users) and 14 TGWs (4 restarted users, 4 current users, 3 declined users, and 3

discontinued users) were involved in in-depth interviews. The most common barriers to using PrEP described by participants were low self-perceived HIV risks, concerns about daily pill burden and potential side effects, social stigma, fear of being misunderstood by others as taking ART, partner disagreement, and the requirement to use condoms while taking PrEP.

However, factors facilitating PrEP utilization included ensuring an HIV-negative status, supportive behaviors of PrEP providers, and travel expense reimbursement for clinic visits. Participants also indicated that social influencers and celebrities taking PrEP within their communities inspired them to use PrEP.

Conclusions: Findings indicated targeted interventions that address specific barriers faced by MSM and TGW populations are required to improve PrEP uptake among them. Celebrities and social influencers from key populations who are PrEP users could be used for PrEP knowledge distribution and encouragement through educational and social media campaigns.

Further research should investigate clients' preferred alternative PrEP options with different service delivery models to maximize PrEP uptake.

EP275

Lay providers in the frontline: an impact on HIV program service coverage in the Sudurpashchim province, Nepal

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Background: The lay providers-initiated HIV interventions including HIV testing were initiated in Nepal as well as in Sudurpashchim Province in 2018, it aims to support the National HIV Strategic Plan 2021-2026 (NHSP,2021) in achieving 95-95-95 strategic targets. The rationale for the introduction of HIV services by trained lay providers was to increase service coverage and overcome gaps in testing and treatment in resource-limited settings.

This abstract will investigate the impact of the HIV program with interventions delegated to the lay providers in 6 districts of the province.

Methods: Of the total 30,000 PLHIV estimates in Nepal, 17.3% (5,190) PLHIVs are estimated in Sudurpashchim province with 84.45% (4,383) knowing their status, and 83% (3,623) enrolled in treatment.

To support the service gaps and reach the goals of NHSP, since 2021 a dedicated team of lay providers has been catering the in-reach services with a package of behavior change communication (BCC) to mitigate risk behavior and HIV testing for triage for diagnosis of HIV for the migrant people, their spouses and People Who Inject Drugs (PWID) and link them for a continuum of services.

Results: With the in-reach program, 221,406 numbers of migrants and spouses and 967 PWIDs were reached for the BCC, 95% of them were tested to confirm their HIV status, 200 people were diagnosed with HIV and 94% of them were enrolled in ART. Furthermore, after 53 index tests, 14 people were diagnosed with HIV.

Since 2021, lay providers contributed to 90% of total testing, 35% of HIV case findings, and 34% of enrollment for treatment in the province.

Similarly, 16 children <18 years were diagnosed with HIV, 15 (94%) enrolled for ART, and 14 (88%) of them linked to nutrition, cash, and other support program (CABA cash transfer program).

Conclusions: Contributions of the lay providers in 6 districts of the Sudurpashchim province in attaining the goals set by NHSP by in-reach services with increased coverage in BCC, testing for triage, and linkages in treatment, care, and support programs are considerable. Its impact could be more pronounced with an expansion of these services to the remaining 3 districts of the province.

EP276

Willingness to use injectable PrEP among people at risk of HIV accessing services in community pharmacies in Kampala, Uganda

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Background: Long-acting injectable cabotegravir pre-exposure prophylaxis (LA-PrEP) is superior to oral PrEP and a significant development in HIV prevention efforts. Plans are underway to expand access to sub-Saharan Africa. Community pharmacies (CP) are a trusted healthcare site and could be an access point to populations at risk of HIV. Embedded into a CP study of sexually transmitted infection (STI) screening we asked people seeking care for STI syndromes and buying over-the-counter emergency contraception (EC) about their willingness to use LA-PrEP and their preferred access points.

Methods: In a prospective cohort study of 18 CPs in urban Uganda, study participants were tested for STIs and HIV using point-of-care diagnostics. Willingness to use LA-PrEP was assessed through a structured questionnaire. A bivariate and multivariable Poisson model was used to determine factors associated with willingness to use injectable HIV PrEP.

Results: Between May 2021-June 2022, 450 participants were recruited (female, 62.2%), median age 28 years (interquartile range, of 24-35). Of these, 235 (52.2%) were seeking STI treatment, 85 (18.9%) were seeking EC and 130 (28.9%) non-STI-related treatments. Transactional sex was reported by 62.4%, multiple (≥2) sexual partners by 23.8%, 55.6% never used condoms, 26.4% reported alcohol use in the last 12 months.



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Overall, 30.0% had a curable STI (syphilis, gonorrhoea, chlamydia, trichomoniasis) and 5.8% (26/450) were HIV positive. Of 424 who were either HIV-negative or unaware of their HIV status, 127 (29.9%) were aware of PrEP. Of these 386 (38/424; 91.0%) were willing to use PrEP and 226 (226/386; 58.5%) were willing to use LA-PrEP; 218 (44.8%) preferred to receive LA-PrEP at a CP, health facility (48.7%), or at home (6.6%). Those significantly associated with willingness to use LA-PrEP, were male gender (α PR,1.22; 95% C.I, 1.03-1.44, $P=0.024$), post-primary education (α PR,1.26; 95% C.I, 1.02-1.55, $P=0.030$), engagement in transactional sex (α PR,1.45; 95% C.I, 1.22-1.74, $P<0.001$), alcohol use (α PR,1.29; 95% C.I, 1.10-1.51, $P=0.002$), and STI symptoms (α PR,1.44; 95% C.I, 1.21-1.71, $P<0.001$).

Conclusions: Community pharmacies are an alternative venue to engage people not attending traditional health facilities. There was high acceptability in this group to use injectable PrEP. Prevention programs should actively engage CPs in their implementation plans.

EP277

The impact of program-level strategies on oral PrEP persistence among adolescent girls and young women at high risk for HIV acquisition in South Africa: an interrupted time-series analysis

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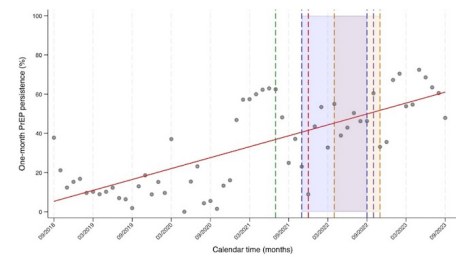
Background: Adolescent girls and young women (AGYW) in South Africa remain at high risk for HIV acquisition. Oral pre-exposure prophylaxis (PrEP) is an efficacious medication to avert HIV acquisition, but persistence remains a barrier to its effectiveness. Since research has shown a drastic decline in PrEP persistence by one month after initiation, we evaluated the impact of implementing program-level strategies at TB HIV Care, a non-profit organization in South Africa, on one-month PrEP persistence among AGYW.

Methods: We conducted an interrupted time-series analysis using an ordinary least-squares model to estimate the level change in the proportion of one-month PrEP persistence among AGYW associated with implementing five program-level strategies. We used routinely collected data from a prospective programmatic cohort of AGYW aged 15-24 who initiated PrEP across THC sites between September 2018-September 2023.

Results: A total of 90,853 AGYW initiated PrEP, of which 56% (50,649/90,853) were 19-24 years old. Overall one-month PrEP persistence was 44% (40,426/90,853). Persistence was higher among 15-18 years old (46%; 18,363/40,204) com-

pared to 19-24 years old (44%; 22,063/50,649). There was a steady increase in one-month PrEP persistence, from 10% (638/6,111) in the first year to 58% (13,197/22,624) in the fifth year (Figure 1).

Implementation of Strike Mobile was associated with a 14% relative decrease in one-month PrEP persistence (-14.2%; 95% CI: -25.2%, -3.2%). There was a relative increase in one-month PrEP persistence after implementing the Zimisele Membership (11.9%; 95% CI: -7.9, 31.8%); case management (10%; 95% CI: -4.3%, 25.2%); and Airtime Incentive (1.6%; -8.4%, 11.6%); however, we did not detect a significant difference.



	09/2018	03/2019	09/2019	03/2020	09/2020	03/2021	09/2021	03/2022	09/2022	03/2023	09/2023
Sites (n) [†]	2	3	3	4	4	5	5	5	5	5	5
AGYW (n) [‡]	-	334	644	1004	622	4,810	2,453	2,885	1,260	1,661	4,574

Results are from the interrupted time-series analysis. AGYW = adolescent girls and young women. PrEP = pre-exposure prophylaxis for HIV. Zimisele Membership: a unique identification card given for a structural intervention program. Strike Mobile: virtual case management. Dots are the proportion of one-month PrEP initiation. The solid red line indicates the one-month PrEP persistence trend modeled. Dashed lines indicate the implementation of the Zimisele Membership (green), Strike Mobile (blue), case management (red), airtime incentive (orange), and Le Kip Kip campaign (purple). The shaded region indicates the duration of implementation of the airtime incentive (orange) and strike mobile (blue). [†]Number of sites contributing data for each time point. [‡]Number of AGYW initiating PrEP the prior month for each time point. [§]Potential autocorrelation and heteroskedasticity were addressed using Newey-West standard errors with lag(1) and effects of the COVID-19 pandemic were controlled for using monthly COVID-19 cases per 100,000 residents.

Figure 1. Interrupted time-series analysis of the impact of the implementation of program-level strategies on one-month PrEP persistence among adolescent girls and young women in South Africa (September 2018 - September 2023)[‡]

Conclusions: Less than half of AGYW remained on PrEP for one month. Despite growing retention over time, strategies are not demonstrating significant impact. Assessments of implementation fidelity and adaptations may provide further insight into the tailoring needed to increase the effectiveness of strategies aimed at improving PrEP persistence.

EP278

HIV molecular epidemiology combined with *Neisseria gonorrhoeae* surveillance data highlight opportunities for HIV prevention

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Background: Clark County, Nevada, has a high incidence of HIV and *Neisseria gonorrhoeae* (NG), which is a potential facilitator of HIV acquisition and transmission.

We analyzed HIV genetic sequences and NG testing data to investigate whether a recent NG diagnosis is associated with being a part of a recent HIV transmission cluster.

Methods: De-identified HIV and NG surveillance data from 2018-2023 in Clark County were matched and analyzed; lifelong NG testing experience was recorded.

All reported HIV *prot/RT* genetic sequences were used to reconstruct Maximum Likelihood (ML) phylogeny using RAxML.

All clades of ≥ 5 sequences that had sequences with no NG testing information available were removed to improve computational efficiency; remaining sequences were then used to reconstruct molecular clock phylogenetic trees and estimate time to the most recent common ancestor (TMRCA) in BEAST1.10. HIV clusters with TMRCA between 2020 and 2023 were considered "recent".

Results: 1603 HIV genetic sequences were available for the ML analysis, 964 (60%) had an NG test result available, of those 408 (42%) tested positive. After removing larger clades without NG testing data, 1193 (74%) sequences were analyzed in BEAST (Figure 1).

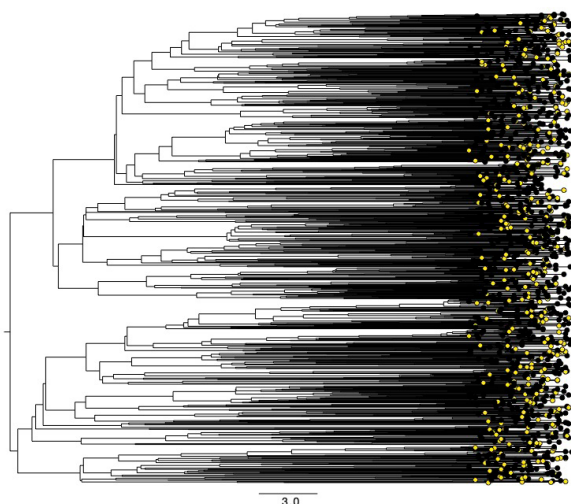


Figure 1.

Sixty-six recent clusters were identified (cluster size ranged 2-8). Of those, 35 (53%, comprising 86 individuals in total) included sequences sampled from patients who tested positive for NG in 2012-2023. Twenty-six of them (39%, comprising 68 individuals) tested positive for NG within 2 years of the HIV cluster TMRCA. *Figure 1.*

Time-tree of Clark County HIV *prot/RT* sequences; yellow circles indicate sequences sampled from individuals with a positive NG test result. The bar indicate timescale in years.

Conclusions: A large proportion of recent HIV clusters have an individual who received a positive NG test result within 2 years of the HIV cluster TMRCA. Universal HIV testing at sexual health clinics can present an opportunity to prevent HIV transmission.

EP279

Predictive machine learning approach for enhancing HIV self-testing willingness among at-risk populations in Sub-Saharan Africa

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Background: Given the significant HIV prevalence in Sub-Saharan Africa (SSA), broadening testing availability is crucial. HIV self-testing (HIVST) provides a discreet option, but its adoption among vulnerable groups is uncertain. The objective of the study is to identify key characteristics that influence the readiness to engage in HIVST among high-risk populations in SSA.

This study investigates the notion that machine learning might predict the predisposition towards HIVST, taking into account demographic and socio-economic factors.

Methods: This study retrospectively examined Demographic Health Surveys conducted between 2009 and 2019 in 24 Sub-Saharan African countries. The study encompassed a total of 594,000 participants between the ages of 15 and 49. It utilized the Classification And Regression Tree (CART) and Random Forest (RF) algorithms in the R programming language to create predictive models. The research thoroughly examined the impact of socio-demographic and socio-economic factors on HIV self-testing propensities by focusing on data preparation, visualization, and cross-validation.

Results: The RF model demonstrated a slight superiority over the CART model with an accuracy of 98.69% (Kappa: 0.9653) versus 98.43% (Kappa: 0.9584) for CART.

Age was the most influential predictor, with younger individuals (below 46.5 years) being more inclined to self-test. Gender (Male importance score: 146.64), wealth index (Richer/Richest importance score: 41.54), and country (Kenya importance score: 272.14; Gambia importance score:



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101.31) also significantly affected HIVST likelihood. Educational level and marital status were additional determinants with noticeable impact. AUC values stood at 0.97 for CART and 0.99 for RF, signifying the models' adeptness at distinguishing individuals likely to self-test.

Conclusions: The research confirmed that advanced machine learning tools could effectively discern impactful predictors of HIVST willingness, offering strategic insights for health interventions. The use of these models could facilitate the design of precise public health campaigns, fostering greater HIVST uptake, which is integral to combating the HIV epidemic in SSA.

EP280

Community engagement in the era of next-generation HIV vaccine development – identifying persistent challenges and co-creating innovative solutioning strategies across India and Africa

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Background: As the HIV vaccine quest is evolving with novel and experimental approaches, community engagement needs to be re-oriented to shifting needs, expectations, and ground realities. Towards this, resonating with World AIDS Day 2023 theme "Let Community Lead!", the South-South Co-learning and Exchange platform fostered essential dialogues between HIV vaccine researchers and grassroots communities across Africa and India.

Methods: Two workshops conducted in May and November 2023 cumulatively engaged 45 grassroots community representatives, peer leaders, advocates and 30 HIV prevention and vaccine science researchers across 10 Indian and 15 African organizations for cross-identifying community engagement priorities leveraging on regionally existing knowledge and new engagement practices in post-COVID scenarios. Key takeaways were delineated by structured thematic analysis of data.

Results: Two workshops cumulatively highlighted following critical community engagement priorities for next-generation HIV vaccine research and trials:

Addressing critical information need around unique value of products: Limited awareness around available prevention products were re-iterated along with need for contextualized and evidence-based messages communicating (a) relative benefit of upcoming vaccines and return on investments compared to currently available/expanding HIV prevention products; and (b) realistic differences in products at experiential and lifestyle level for the end-users.

Building credibility for sustained community interest: Early, consistent communication emphasizing scientific rationale behind HIV vaccine candidates and trial designs, and transparency around integrated national/regional/financial stakeholders' network with shared governance mechanism would be critical to reflect scientific integrity and promote community trust.

Pre-emptively managing mis/disinformation and stigma: COVID-19 renewed vaccine enthusiasm and destigmatized adult vaccination, although vaccine uptake remained affected by deep-rooted myths and misinformation. Identification and mitigation of mis/disinformation around new vaccine approaches and trial designs was emphasized for addressing stigma and hesitancy.

Ensuring effective dissemination channels: COVID-19 vaccination experience revealed fast-track vaccine related information transfer across trusted end-user peer networks, rather than from health-service providers. Also, internet-based digital platforms and social media were highlighted as principal source for vaccine related information.

Conclusions: A paradigm shift in community engagement, towards community partnership with co-learned and harmonized practices for enhancing HIV research literacy and building trust among communities will be essential for accelerating next-generation HIV vaccine development with community ownership.

EP281

Population level HIV -1 viral load suppression through enhanced viral load monitoring impacting undetectable = untransmissible strategy in India

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Background: HIV -1 viral suppression is critical to prevent sexual and perinatal transmission of HIV and improve overall health of People Living with HIV (PLHIV). India's National AIDS and STD Control Programme (NACP) launched routine viral load (VL) testing for treatment monitoring of PLHIV on ART in 2018. Ensuring universal access to VL testing requires a broader health system approach considering the rapid scale-up and improved coverage of ART in India.

This paper describes the approaches, and strategies adopted for Population level HIV - 1 viral load suppression through enhanced viral load monitoring in India.

Methods: The key approach was to establish and optimize a network of 64 public VL laboratories in public healthcare facilities across the country in 5 years to ensure uninterrupted services. The systematic approaches for establishing and strengthening this network included mapping linkages considering sample transport time and distance between ARTC and VL laboratory, assessment of lab utilization, forecasting testing demands, capacity building, implementation of quality management system, robust supply chain management system and comprehensive monitoring system. The approach also included establishment of treatment and testing standards and strengthening of lab clinical interface.

Results: This approach resulted in scaling-up annual VL tests from 16577 tests in 2018 to 1.2 million tests in 2023 in the 64 public VL laboratories ensuring equitable services

even to the hard-to-reach geographies and population. Parallely the proportion of annual VL tests progressed from 15% to 100% in public laboratories. The enhanced VL monitoring coupled with treatment interventions resulted in a gradual increase in VL suppression from 72% in 2018 to 93% in 2023.

Conclusions: The integrated health system approach resulted in rapid scale-up of HIV – 1 VL coverage and testing. Optimization of public VL laboratories maximized the efficiency and effectiveness of VL laboratories, leading to equitable access to VL monitoring that resulted in population level viral load suppression in India.

EP282

End user market segmentation, messaging and positioning for the dapivirine vaginal ring: a Lesotho case study

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Background: The dapivirine vaginal ring (DVR) marks a significant advancement as Lesotho's first approved long-acting, woman-controlled HIV prevention product. Understanding end-user perceptions and co-creating communication strategies for product usage are vital as implementation studies commence.

Methods: This study employed human-centred design to develop community-led communication strategies in Maseru and Berea across four phases:

1. Context Setting - literature review and development of user segments,
2. Co-creation workshops with 46 end-users aged 18-45 to design prototypes and a 7-person HCP workshop,
3. Prototype testing and validation with 59 end-users and 16 male influencers,
4. Findings dissemination in a stakeholder workshop.

Results: Phase 1 highlighted young women as most affected by HIV, with male partners often influencing sexual health decisions.

In Phase 2, HCPs identified reduced administration burden, minimal side effects, and collaboration as key motivators for DVR use. Barriers included counselling challenges due to misconceptions, stock availability, and cultural taboos.

End-user co-design workshops revealed method discretion, HIV protection, duration, self-administration and reduced stigma as motivators.

Barriers included discomfort, inability to self-administer, side effects and male partner disapproval. Phase 3 involved developing and testing 18 prototypes across 10 FGDs with end-users and male influencers.



Figure.

Key findings:

1. **Posters - male partner support** best received, effectively showed DVR endorsement.
2. **Testimonial posters** gave social proof, addressed concerns about DVR usage.
3. **HCP posters** instilled trust in DVR.
4. **Information Guides** had minimal impact due to text-heavy nature.
5. **Radio shows, trusted sources of information** targeting large audiences.
6. **Digital Chatbots** offer anonymous, convenient, and trusted information to women and partners.
7. **Talking cards** can be effective in choice counselling and garnering partner support.
8. **DIY Insertion Guides** bolster confidence in DVR use.
9. **Mobile Clinics** encouraged women to access DVR.

Conclusions: The government and community-led approach gained insights into end-user segments and developed tailored communication prototypes that ensured DVR messaging resonated with end-users and stakeholders' perspectives.

EP283

Understanding AGYW perceptions on the use of upcoming HIV prevention options

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Background: In Zimbabwe, adolescent girls and young women (AGYW) aged 15-24 years, face a significantly higher HIV incidence rate of 0.54% compared to their male counterparts at 0.20. Despite increased risk of HIV, there exists significant lack of understanding and awareness regarding the range of HIV prevention options currently in research and development (R&D).

Products in the research pipeline such as multipurpose prevention technologies and long-acting injectables could increase uptake of prevention of AGYW and meet their diverse needs.

Pangaea Zimbabwe (PZ) surveyed AGYW to understand their perceptions on HIV prevention products currently in R&D, including specific questions on lenacapavir, a twice-yearly PrEP injection currently in efficacy trials.





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Methods: 35 prevention champions in seven tertiary institutions (five per institution) were purposively sampled, targeting those within provinces with high HIV infections in Zimbabwe where PZ has been working. The survey was conducted through Microsoft Forms, an online platform that allows data to be collected electronically, to gather perceptions from AGYW on HIV prevention options currently in R&D. The survey intended to collect data on use, literacy, and barriers for current and future HIV prevention products.

Results: Despite the low uptake of PrEP products among AGYW, there's positive outlook towards lenacapavir, with 86% believing AGYW in their community would be interested in using it. Healthcare providers and peers emerged as influential factors in product uptake. Preferred access points included college clinics, community mobile clinics. Stigma, financial barriers, and stock-outs were stated as future challenges that new products need to overcome. 43% advocated for strengthened education on the HIV prevention pipeline. 94% were concerned about HIV drug resistance related to the use of lenacapavir. All the respondents advocated for a diverse toolbox of HIV prevention products to promote choice.

Conclusions: AGYW are interested in, and support, ongoing R&D to expand HIV prevention options. It is critical that future products, such as lenacapavir, address the preferences of AGYW for product introduction to ensure access. AGYW continue to affirm that choice is central to HIV prevention efforts, and offering choice honors their autonomy and is empowering. Community preparedness on future prevention options presents an opportunity to enhance HIV prevention service delivery.

EP284

Prevalence of HIV and associated sociobehavioural factors among men with urethral discharge syndrome in public health facilities in Kampala, Uganda

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Background: HIV and sexually transmitted infections (STIs) control in men is a major public health concern in Sub-Saharan Africa. Epidemiological data on HIV in male urethral discharge syndrome (UDS) are limited; national HIV prevalence in men 15-49 years is 3.6%. We describe the prevalence of HIV and associated risk factors among men with UDS in public clinics in Kampala, Uganda.

Methods: A cross sectional study of men with UDS was conducted from October 2019 to July 2022. An interviewer-administered demographic and socio-behavioral questionnaire was administered. HIV testing used point-of-care tests (Standard Diagnostics, Giheung-gu, Korea)

with confirmatory algorithmic testing. Bivariate and multivariable log binomial regression adjusted for age, alcohol intake in the past 6 months and antibiotics use in the past 2 weeks was conducted to determine the factors associated with prevalent HIV.

Results: Of 450 participants, 441 (98%) were included in this analysis; 9 declined HIV testing. Median age was 24 (IQR 22-32) years, 87% (N=384) reported a previous HIV test. Overall, 18% (n=81) were living with HIV; 33.6% and 4.7% in men aged ≥25 and <25 years respectively. Seven (8.6%) were new HIV diagnoses with over half diagnosed by the study team after completion of primary clinic visit. 94% with established HIV were on antiretrovirals, only 52% had suppressed viral loads by self-report.

Participants reported 'always' condom use (1.1%), transactional sex (45.4%), multiple partners (59.6%); 46.7% had notified their partners of symptoms.

Multivariable analysis demonstrated significant associations between HIV and older age (aPR, 6.06; 95% C.I. 3.29-11.17; P<0.01), alcohol use in past 6 months (aPR, 0.64; 95% C.I. 0.43-0.94; P=0.023) and antibiotic use in prior 2 weeks (aPR, 0.62; 95% C.I. 0.43-0.89; P=0.010).

Conclusions: Men aged ≥25 years seeking care for UDS in public facilities have a high prevalence of HIV and behaviors associated with STIs. There were missed opportunities for HIV prevention and treatment in public facilities. HIV was negatively associated with alcohol and antibiotic use prior to clinic visit. Men with UDS represent a key, previously untargeted, population for HIV testing, prevention and treatment services.

EP285

Factors associated with lack of post-exposure prophylaxis (PEP) awareness among Peruvian men who have sex with men (MSM)

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Background: Non-occupational HIV PEP has been available in Peru since 2008. However, little is known about PEP access or use among MSM in Peru, who remain disproportionately vulnerable to HIV.

Methods: We conducted an online survey from June to August 2023, recruiting MSM via social media ads. Following informed consent, respondents answered a survey on demographics, sexual behavior, and following a brief description of PEP, questions about PEP awareness, PEP use in the last 6 months, and reasons for not requesting PEP after high-risk sexual exposure.

For this analysis, individuals who self-reported living with HIV or currently using HIV Pr were excluded. We identified factors associated with lack of PEP awareness (defined as being unaware of PEP and/or being unaware of how to access PEP in Peru) using multivariate Poisson regression.

Results: Among 657 respondents, median age was 29yo (IQR: 24-35), 81 (11.6%) were unsure of their HIV status. In the last 6 months, 41 (6.3%) respondents reported requesting PEP in health centers; of whom 28/41 (68.3%) successfully obtained it.

Among respondents who did not request PEP, 42.3% believed they did not have an HIV exposure; and 53.7% lacked awareness of PEP (20% were unaware of PEP and 33.7% were unaware of how to access PEP).

Lack of PEP awareness was associated with monthly income <US\$540, being unsure of their HIV status, self-perceived HIV risk (yes or unsure), reporting <5 anal sex partners over the past 6 months, having sex partners with HIV risk (unknown HIV status or PLWH but not yet achieving viral suppression) past 6 months, inconsistent condom use, and PrEP background. (Table)

Factor	n(%)	PR (95%CI)	p
Monthly income <540 USD	217 (73.6)	1.37 (1.10-1.70)	<0.01
Being unsure of HIV status	54 (16.3)	1.29 (1.07-1.56)	<0.01
Self-perception of HIV risk (yes or unsure)	276 (83.4)	1.63 (1.23-2.14)	<0.01
>5 anal sex partner*	95 (28.8)	0.80 (0.67-0.95)	0.01
Any sex partner with HIV risk**	207 (72.1)	1.25 (1.03-1.50)	0.02
Inconsistent condom use	232(80.8)	1.43 (1.15-1.79)	<0.01

Poisson regression model adjusted by: age, university education, transactional sex, PrEP background, any STD*, and fear of acquiring HIV. *: In past 6 months; **: unknown HIV status or PLWH without viral suppression

Table. Factors associated with lack of PEP awareness among Peruvian MSM.

Conclusions: Despite increased HIV risk, very few MSM in Peru requested PEP and lack of awareness was high. These findings suggest informational barriers that need to be overcome.

EP286

Healthcare providers' experiences in the implementation of PrEP for MSM and TW in Peru: a qualitative study

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Background: Daily oral HIV Pre-exposure prophylaxis, shown to be highly effective for HIV prevention among MSM and transgender women, is finally being scaled-up in Latin America. PrEP scale-up could be improved if we learn from demonstration studies implemented in the region.

The experience of providers in those studies can be particularly helpful. Here we analyzed the perceptions and experiences around PrEP of healthcare providers in ImPrEP in Peru.

Methods: Qualitative interviews were conducted among users, potential users and providers in 3 cities where ImPrEP was implemented in Peru (2018-2021): Lima, Trujillo and Pucallpa. Here we analyzed 11 interviews with PrEP providers and used a thematic analysis to understand their experiences, challenges, and successes with PrEP provision in the Peruvian context.

Results: ImPrEP providers described positive experiences with PrEP provision; all expressed support for key populations to receive PrEP and their endorsement of PrEP as an important HIV prevention strategy. Providers also expressed concerns about their sites and the health system having too few human resources and inadequate infrastructure for PrEP provision, and about an increase in STIs among PrEP recipients.

Additionally, many considered that people who could benefit from PrEP did not have the discipline to be adherent. At least one provider described counting pills as a mechanism to reinforce PrEP adherence with participants. Providers often mentioned the need for 100% adherence and counseling with users to assure adherence, and indicated the importance of assuring experience with key populations, effective communication with these groups, and cultural empathy to facilitate PrEP provision in their services.

Conclusions: Despite the positive attitude toward PrEP among this sample of providers who were all part of the ImPrEP demonstration project, their concerns about PrEP and attitudes regarding adherence and risk may be problematic for users. ImPrEP did not see an increase in STIs among users, and pill counting was not a study procedure; providers' concerns and implementation of this type of adherence check could undermine users' desire to continue on PrEP if they feel judged rather than supported. Provider training and support is needed resolve questions that they have and continue to educate toward sex-positive, client-centered care.



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Tuberculosis incidence among people living with HIV in Israel: a 42 years follow up

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Background: Tuberculosis is a serious health threat for people living with HIV (PLWHIV). Early detection of tuberculosis and isoniazid prophylaxis are fundamental elements to improve prognosis.

This study aims to compare tuberculosis diagnosis before and after the introduction of potent antiretroviral treatment in Israel.

Methods: The national registries of HIV and tuberculosis were cross-matched to identify PLWHIV with tuberculosis diagnoses. Demographic data, CD4 count and tuberculosis treatment failure were compared between PLWHIV diagnosed before and after 1999.

Results: Between 1981 and 2023, 12,022 PLWHIV were diagnosed in Israel. During the study period, 565 (4.7%) had tuberculosis: 208 tuberculosis cases were detected among 2,506 PLWHIV diagnosed between 1981-1999, and 357 tuberculosis cases were detected among 9,516 PLWHIV diagnosed between 2000-2023 (8.3% vs. 3.9%, respectively, $p < 0.001$). PLWHIV between 2000 and 2023 were more commonly older than those diagnosed between 1981 and 1999, more likely to be non-Israeli citizens, originating in Eastern Europe, presented lower CD4 counts and had better survival (Table).

Characteristics	PLWHIV between 1981 and 1999 N (%)	PLWHIV between 2000 and 2023 N (%)	P
Age (median, IQR)	31 (27, 42)	36 (29, 43)	<0.001
Males	140 (67.3)	227 (63.6)	0.4
Non-Israeli citizens	10 (94.8)	136 (38.4)	<0.001
African origin	176 (84.6)	228 (63.4)	<0.001
Eastern European origin	9 (4.3)	97 (27.1)	<0.001
CD ₄ count (median, IQR)	348 (178, 281)	127 (52, 264)	0.9
Death	124 (59.6)	85 (23.8)	<0.001

Conclusions: Tuberculosis incidence among PLWHIV has decreased during the study period, and mainly affected migrant who originated in Africa or Eastern Europe - reflecting the tuberculosis burden in the source countries. This down trend is also associated with the declining incidence of tuberculosis in Israel during the study period. The relatively lower CD4 count among PLWHIV diagnosed between 2000 and 2023 compared with those diagnosed between 1981 and 1999 may be related to the higher rate of migrants and the late HIV-diagnoses.

Nevertheless, their survival was better, possibly because of the availability of more advanced treatment modalities. Earlier diagnosis of HIV and tuberculosis, initiation of antiretroviral therapy and close PLWHIV who are at increased risk of developing tuberculosis may increase their life expectancy.

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PrEP na Rua in prostitution houses: expanding sex workers' access to PrEP in the city of São Paulo, Brazil

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Background: In Brazil, the prevalence of HIV acquisition in sex workers is 4.9%, corresponding to one of the social groups most vulnerable to STIs, HIV and Aids in the country. Considering that, the Municipal Network Specialized in STI/Aids (RME) in the city of São Paulo was instructed and subsidized by the municipality's STI/Aids Coordination to carry out the project *PreP na Rua* in prostitution houses, offering pre- (PrEP) and post-exposure (PEP) HIV prophylaxes to the sex workers assisted.

The goal was to reduce access barriers to HIV and syphilis Rapid Tests (RT), as well as to expand access to PrEP as a prevention strategy against HIV for sex workers in the city.

Methods: From August/2022 to March/2024, 193 testing and prevention activities were carried out in prostitution houses in São Paulo. In them, PrEP was offered to the workers, along with registration, HIV RTs, point-of-care creatinine exams and distribution of prophylaxes on site. In 175 of these activities, syphilis RTs was also offered. The activities were carried out with reduced teams, of 2 to 4 professionals, aiming to adapt to the environments. These activities were carried out on dates and times planned with the locations, before or during their opening hours.

Results: RTs were carried out among cisgender women, transexual women and transvestite sex workers. 1389 HIV RTs and 1133 syphilis RTs were carried out, with 4 positive cases of HIV and 139 positive cases of syphilis. Of the total number of services provided by the RME during the activities that happened in these workplaces, approximately 60.8% (845) resulted in the initiation or continuation of PrEP usage by these women.

Conclusions: The population demonstrated significant interest in using PrEP as a form of HIV prevention. It became clear that it is necessary to go beyond the conventional care model, in which users go to specialized health-care units. By taking the services offered by the RME to sex workers in their work environment, it is possible to bring them closer to those healthcare units, allowing a comprehensive care for the individual.

EP289

Upholding equality: LGBTQI rights amid Uganda's legal landscape and access to HIV services

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Background: In Uganda's dynamic legal context, this study delves into the intricate interplay of political, legal, and societal dynamics influencing access to critical HIV services, with a specific focus on the LGBTQI community following the enactment of the Anti Homosexuality Act.

Methods: Recent data highlights the significant challenges faced by LGBTQI individuals in Uganda, where the HIV prevalence among men who have sex with men (MSM) is alarmingly high at 13.7 percent, as revealed by the Crane Survey. Despite this stark reality, governmental reluctance to integrate MSM into national HIV strategies persists due to the criminalization of homosexual activity.

A respondent-driven sampling survey conducted in Kampala unveils concerning trends among gay and bisexual men, with a notable proportion engaging in high-risk behaviours such as unprotected receptive anal sex and transactional sex.

Moreover, the study exposes a concerning lack of awareness regarding HIV risk among this population, underscoring the urgent need for targeted prevention efforts.

Results: Beyond statistics, the lived experiences of gay and bisexual men in Uganda reveal a complex tapestry of resilience amidst adversity. Despite hailing from diverse backgrounds, these individuals encounter systemic barriers in accessing HIV prevention and care services, highlighting the critical imperative for inclusion within local HIV programs and education initiatives.

Conclusions: Against this backdrop, this research advocates for a paradigm shift in policy and practice, urging the integration of LGBTQI rights within Uganda's HIV response.

By amplifying the voices and experiences of marginalized communities, this study seeks to catalyse a movement towards equity, dignity, and universal access to HIV services for all individuals, irrespective of sexual orientation or gender identity.

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End-user preferences for biomedical HIV prevention products: a mixed methods study with female university students in Zambia

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Background: Adolescent girls and young women (AGYW) in sub-Saharan Africa account for 63% of all new HIV infections globally despite being only 10% of the population. There are an increasing number of pre-exposure prophylaxis (PrEP) product options (e.g., daily oral pills, injection, vaginal ring) with more in development.

This mixed methods study sought to establish which PrEP products and delivery modalities are desirable among a sub-population of young women at risk for HIV in Zambia.

Methods: In 2022, we surveyed 846 female university students on PrEP product preferences (available and hypothetical products) and service delivery options. A sub-sample (n=34) of participants participated in 1 of 5 focus group discussions (FGDs) to elaborate on PrEP preferences. Survey data were analyzed descriptively. FGD transcripts were analyzed thematically.

Results: 498 (58.8%) participants reported having sex. Most sexually active students had heard about PrEP (80.7%), very few had used PrEP (4.6%), and almost none were currently using PrEP (0.8%). The most preferred PrEP products were monthly oral pills (34%); one-time vaccine (31%); 2-3 months injection (20%); once monthly injection (9%); and daily pills (8%).

There was a small minority of participants (<5%) who preferred the implant or vaginal gel or ring. Qualitative themes confirmed preferences for longer-acting PrEP options that reduced user burden. Most (52%) survey participants wanted to access PrEP in a non-clinical setting, including distribution from peers or local pharmacies. FGD participants explained barriers to receiving PrEP from a health facility were mostly related to HIV stigma.

Conclusions: Expanding PrEP choices, in particular longer-acting products, and service delivery options beyond the traditional health clinic are acceptable interventions among at-risk female university students in Zambia that may yield increased uptake and persistence of PrEP among AGYW.



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An innovative approach to improving HIV case finding in children and adolescents in Northeast Nigeria

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Background: Children and adolescents between the ages 0 - 17 years have historically lower HIV testing rates, compared to adults. This suggests that traditional HIV testing approaches may be unsuitable for these persons or may not adequately address concerns expressed by these populations, such as stigma and discrimination, that limit their access to HIV testing services (HTS).

This study describes an innovative model used to improve HIV case finding among children and adolescents in Northeast Nigeria, by the USAID-funded Integrated Child Health and Social Services Award (ICHSSA-4).

Methods: A retrospective cross-sectional study with a descriptive analysis of secondary data from ICHSSA-4, from October 2022 to September 2023, across 20 local government areas in Bauchi state, Nigeria.

The project engaged children and adolescents, using an intersectionality framework to recognize the experiences that limit their access to HTS. Then, to establish meaningful involvement and increase acceptance by this population, persons living with HIV, who doubled as caregivers of children and adolescents, and key populations, were trained to conduct HTS.

Furthermore, HTS was integrated into platforms used routinely for service provision to Orphans and other Children made vulnerable by HIV, to reduce stigma associated with isolated HTS. Participants were risk-assessed for HIV using a National HIV risk-assessment tool. Consenting persons, and caregivers for children less than 18 years old, were tested for HIV according to the National HTS algorithm.

Results: 2,817 children were tested and received HIV results. There were more females (51% - 1,439), than males (49% - 1,378) in the study. Overlapping causes of vulnerability included hard-to-reach areas (428; 15.19%), children of key populations (94; 3.34%), adolescents living in HIV-prevalent areas (1,395; 49.52%), and children of persons living with HIV (1,467; 52.08%). A total of 75 (2.66%) children tested positive through home visits (61; 81.33%), Peer-led testing (8; 10.67%), food demonstrations (2; 2.67%), parenting sessions (2; 2.67%), and gender meetings (2; 2.67%). Bivariate analysis revealed a significant association between HIV testing location and positivity rate ($p < 0.05$).

Conclusions: The study demonstrates the importance of tailoring HTS approaches to mitigate causes of vulnerability, thereby improving HIV case finding among children and adolescents in Northeast Nigeria.

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Real time geographic information system (GIS) to map community needle incidence in Regina, Saskatchewan, Canada, using reportneedles.ca for prevention education and rapid HIV testing and interventions of Naloxone training/peer support

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Background: In 2022, the national average rate of HIV was 4.7 per 100,000 people while in Saskatchewan, Canada, it was 19.0 per 100,000 people which is over 4 times the national average. The highest HIV incidence was reported among people who inject drugs.

AIDS Programs South Saskatchewan Inc. (APSS) operates one of the busiest needle exchanges in the province. Innovations in public health research are required to significantly reduce new HIV and HCV incidence in Canada, which are exceptionally high among people who use injection drugs in Saskatchewan.

APSS created reportneedles.ca, (1st of its kind in Canada) a real time geographic information system (GIS) to map community needle incidence in Regina, Saskatchewan.

This community-based, innovative method generates geo maps of hotspots in Regina where community needle incidence in public spaces is the highest to deploy targeted HIV prevention education and HIV testing and harm reduction interventions of Naloxone training and peer support.

Methods: People living with HIV/HCV/Syphilis are an endemic health challenge in Saskatchewan, Canada and injection Drug use (IDU) has been the most common mode of HIV transmission in Saskatchewan, accounting for approximately 65% new HIV diagnoses per year.

First Nations communities in Saskatchewan are disproportionately affected by high HIV rates, accounting for 65-80% of the province's HIV-1 incidence.

We will address the strong link between injection drug use and incidence of HIV/STBBI, generate geo maps of hotspots in Regina where community needle prevalence in public spaces is highest, and hold pop-up HIV, HCV and syphilis testing alongside prevention education including pre- and post-exposure prophylaxis (PrEP and PEP) and safe substance use.

Results: The proposed activities will study the feasibility and acceptability of the rapid assessment and response system, change in HIV/HCV/syphilis incidence, relationship between needle prevalence and access to care, change in knowledge regarding PrEP and PEP, and linkage to care for people with HIV/HCV and/or syphilis.

Conclusions: HIV education/prevention intervention will explore the barriers to assessing and utilizing pop-up risk reduction interventions, factors influencing engagement, perceptions and stigma.

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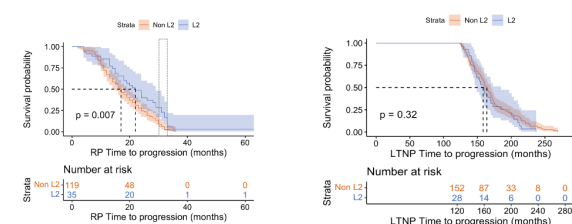
Mitochondrial L2 haplogroup association with pediatric HIV progression: insights from a Ugandan cohort

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Background: Pediatric HIV/AIDS remains a significant global health concern, with millions of children affected annually. Despite advancements in treatment and prevention strategies, understanding the factors influencing disease progression remains crucial. This study investigates the role of mitochondrial genetics in pediatric HIV progression, focusing on the association between mitochondrial haplogroups and disease phenotypes.

Methods: Utilizing Whole Exome/Genome Sequencing data from the Collaborative African Genomics Network (CAfGEN) study, comprising 1,107 perinatally HIV-infected children from Uganda and Botswana. These patients were at the extremes of HIV disease progression, i.e., Rapid Progressors (RPs), who develop AIDS within 3-6 months of HIV infection, and Long-Term Non-Progressors (LTNPs), who do not progress to AIDS even after ten years post-infection. Mitochondrial haplogroups were determined using HaploGrep2 and MToolbox software.



Cox proportional hazards
Covariates: Gender, Age at sample Collection

Figure. Within Ugandan RPs L2 haplogroup associated with progression.

Results: Within the Ugandan cohort only, results reveal an association between the L2 haplogroup and disease progression in the Ugandan cohort, particularly among RPs. LTNPs) did not show significant haplogroup associations, suggesting distinct genetic and environmental factors. Survivorship bias may explain the observed association with RPs.

Conclusions: Previous findings in adult non-Hispanic black individuals suggest lower baseline activated CD4 cells in L2 haplogroup subjects, indicating a potential immune regulatory profile. Our next steps will attempt to elucidate underlying biological mechanisms via gene-environment interactions and clinical implications, considering population specificity and environmental factors. The findings from this study contribute to advancing our understanding of pediatric HIV progression and underscores the importance of mitochondrial genetics in disease pathogenesis.

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Natural SARS-CoV-2 infection elicits cross-reactive immunity to OC43

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Background: The recent SARS-CoV-2 pandemic renewed interest in other previously discovered non-severe acute respiratory syndrome human coronaviruses. Among these, OC43 is a seasonal human coronaviruses widely diffused in the global population (90% seroprevalence in adults), mostly responsible for mild respiratory symptoms.

As OC43 protective immunity is short lasting, the aim of this study was to verify if systemic and mucosal SARS-CoV-2 humoral immunity elicited either by natural infection and/or vaccination confers protection against a new OC43 re-infection.

Methods: Neutralization assays using plasma and saliva samples of 49 SARS-CoV-2-vaccinated subjects who were never naturally infected and received three doses of BNT162b2 RNA vaccine (SV) and 25 SARS-CoV-2-infected and vaccinated subjects (SIV) were performed against "wild type" SARS-CoV-2 lineage B.1 (EU) and OC43 in VeroE6 cell lines.

Sampling was carried out immediately before (T0) and 15 days (T1) post third-dose administration (SV) or 15 days post-infection (SIV). SARS-CoV-2 anti-RDB NAbs were measured, as well, employing a commercial ELISA kit (Viazyme, Delft, Netherlands). Analyses on saliva at T1 were performed on a subset of SV (n = 18) and SIV (n = 15).



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Results: SARS-CoV-2-specific neutralizing activity (NA) significantly increased after third vaccine dose administration in plasma ($p < 0.0001$) and saliva ($p < 0.01$) from SV; however, this NA was not protective against OC43. Conversely, SARS-CoV-2 NA triggered by natural infection in plasma and saliva of SIV proved to be cross-reactive and protective against OC43 in both plasma ($p < 0.05$) and saliva samples ($p < 0.05$). A statistically significant difference was further confirmed by the anti-RBD Nabs assay in saliva samples at T1 ($p < 0.001$). Indeed, the SIV group showed higher levels than the SV group.

Conclusions: Overall, this study on immunity to SARS-CoV-2 suggests that compared to vaccine-induced immunity natural infection elicits a broader and cross-reactive immunity, which results in protection from viruses sharing sequence homology, at both systemic and mucosal level. As the oral cavity represents the main entry route for coronaviruses, these results support the development of a pan-coronavirus vaccine to prevent new infections and re-infections.

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Testing of simplified BBS-Lite bio-behavioral survey methodology in men who have sex with men in Georgia

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Background: We tested a simplified bio-behavioral survey (BBS-Lite) to assess HIV, syphilis, and viral hepatitis risks and prevalence among men who have sex with men in Georgia in 2023.

Methods: This cross-sectional study shared the implementation cities, recruitment criteria, sample sizes, and core questionnaire domains/items with the last IBBS (2018). Biological specimens were collected for testing on HIV, syphilis, HBV, and HCV in routine testing sites. However, unlike the standard IBBS, the BBS-Lite didn't utilize the standard respondent-driven sampling (RDS), and participants were enrolled through consecutive recruitment at the HIV prevention program sites and through "snowball" outreach.

Results: The study enrolled 653 MSM, (self-identified as 56% gay and 31% bisexual). 19.4% ($n=127$) were recruited through the "snowball" method.

The mean age of respondents was 27 (18-73) years. 63.1% reported receiving a standard package of HIV prevention service (condom distribution and IEC material or risk reduction consultation) over the past three months. 74.0% used condoms during the last sexual intercourse and 47.2% regularly during the last 12 months. 16.7% reported not using condoms during group sex. 17.6% of partic-

ipants reported taking PrEP during the last year. 24.2% of all respondents, reported using illicit drugs during the last month including 7.2% who reported using drugs through injection. The probability of having HIV infection was 53.4% greater among the participants who reported having group sex during the last 12 months (OR=1.534, 95% CI (1.205-1.952)). 98% of self-reported HIV-positive participants were enrolled in ART.

The HIV prevalence was 12.6%, anti-HCV and HBsAg prevalence 2.6 and 1.8%, and 16.5% of all participants tested positive for syphilis RPR test.

Compared to the IBBS considerably less time was required for data entry, data analysis and report writing for the BSS-Lite study and the budget was almost 2.5 times lower.

Conclusions: Our findings have demonstrated that if implemented regularly, the BBS-Lite can be a complementary source of systematic data collection for HIV programs for key populations. The methodology is recommended for testing in other settings and other key populations.

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Unlocking tomorrow: scaling-up of HIV oral pre-exposure prophylaxis uptake among adolescents and young people to enhance HIV prevention in three regions of Tanzania, October 2021 to December 2023

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Background: It is estimated that globally, 30% of new HIV transmissions occur among adolescents and young people (AYP) aged 15-24 years, warranting targeted prevention strategies. In Tanzania, awareness of pre-exposure prophylaxis (PrEP) is less than 15%. Among AYP, the awareness is even lower, at 7% for females and 8% for males. We implemented a peer-led strategy to scale up HIV PrEP services to enhance HIV prevention among AYP in Kigoma, Pwani, and Shinyanga regions in Tanzania.

Methods: In October 2021, we initiated a peer-led strategy to scale up PrEP services. We worked closely with the local authorities and the KVP Forum to recruit peers as per the national guideline for comprehensive package of HIV interventions for KVP selection criteria like community acceptance, trustworthiness, and non-discriminatory as defined by the community and good interpersonal skills. We trained 290 peer educators (PEs) over a 5-day period using the national guideline. The guideline provides a KVP-tailored combination package of biomedical, structural, and behavioral prevention interventions. PEs conducted weekly social and behavioral change communication (SBCC) sessions and delivered age-appropriate PrEP information. PEs used interpersonal communications, SBCC materials, and digital platforms like WhatsApp for dissemination. PEs also identified AYP hotspots, facilitated referrals, and supported demand creation, equipped with tools like job aides.

Additionally, we implemented flexible clinic hours, outreaches, multi-month dispensing, and PrEP pill cases to counter antiretroviral therapy-related stigma in all supported facilities.

Results: Between October 2021 and December 2023, we increased supported facilities from 108 to 245 and enrolled 8,324 new AYP PrEP users in Kigoma (2,665; 32%), Pwani (2,575; 31%), and Shinyanga (3,084; 37%). Among new users, 7,958 (96%) were females and 366 (4%) were males, and 22% (1,847) were aged 15-19 years and 78% (6,477) were aged 20-24 years.

Following the intensification of peer-led interventions in October 2021, we observed a consistent quarterly increase in PrEP uptake among AYP from 228 new users in October–December 2021 to 1,339 users in October–December 2023.

Conclusions: The scale-up of facilities, outreaches, tailored services and the engagement of PEs, support of SBCC tools, and demand creation activities spurred an increase in uptake of PrEP among AYP.

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Opt-out testing implementation and linkage to care for people living with HIV and/or HCV in a large urban correctional facility

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Background: Systems which prioritize syndemic approaches to testing for sexually transmitted infections (STIs) contribute significantly to reducing health disparities. Cook County Jail (CCJ), a large urban Correctional facility affiliate of Cook County Health, has reintroduced serologic testing in medical intake by implementing opt-out testing during processing.

In 2020, CCJ halted its opt-out testing program due to the SARS-CoV-2 public health emergency. Since that time, the health system and CCJ have collaborated in partner-

ship with Gilead, Frontlines on Communities in the United States (FOCUS) to screen and link people living with HIV and/or HCV to care.

Methods: Adults ≥ 18+ processed through CCJ are consented for HIV and HCV testing at time of medical intake. If the individual in custody (IIC) agrees, electronic medical record (EMR) automation kick starts the clinical testing workflow. A blood specimen is then collected, and HCV positive tests are reflexed to HCV RNA viral load. For clients who test positive for either HIV, HCV or both, FOCUS staff engage and provide health services (i.e. case management, post-test counseling, and referrals for linkage to care (LTC) and treatment) to IICs and those embarking on reentry.

Results: In a 9-month observational period, (N=19,430) clients were processed through CCJ and were tested for HIV and/or HCV test unless refused. Results from our testing and varying linkage modality of this population are found in the table below.

	HIV Testing (N=5261)		HCV Testing (N=5158)	
Test Result				
Positive	(N=35)*	0.7%	(N=175)**	3.4%
Negative	(N=5226)	99.3%	(N=4983)	96.6%
Linkage				
Linked to Care from FOCUS Testing	(N=22)	63%	(N=9/75)	12%
Out of Care	(N=13)	37%	(N=66/75)	88%
Known HIV Positive Patients/Not Tested (N=219)				
LTC via FOCUS	(N=91)	42%		
Out of Care	(N=128)	58%		

*11 New HIV Diagnosis, **N=75 (43%) HCV RNA Positive Table.

Conclusions: Leveraging a built-in infrastructure along with EMR automation has enabled CCJ to test nearly 30% of IICs for both HIV and HCV over a 9-month period. As the work of FOCUS programming expands, the infrastructure that supports this system will aid in tackling a syndemic approach to testing based on CDC recommendations for further STI screening and linkage. Larger implications from this work contribute to the macrolevel goal of Healthy People 2030 and reducing the transmission of infectious diseases amongst the community.



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Provider attitudes, perceptions, and the acceptability of offering PrEP choice in CATALYST study implementation sites in sub-Saharan Africa

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Background: Healthcare providers play a crucial role in counseling clients about new PrEP products and helping them initiate the product that best meets their needs. We describe provider attitudes and perceptions and the acceptability of implementing an enhanced service delivery package for PrEP choice through the PEPFAR/USAID-supported CATALYST study.

Methods: CATALYST is an implementation study delivering PrEP choice to women across public health sites in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe. Approximately six months after CATALYST trained providers to offer oral PrEP and the PrEP ring, a structured questionnaire was administered anonymously to a random sample of up to three providers per facility, assessing their PrEP attitudes and perceptions. Descriptive analysis was conducted using STATA version 15.

Results: From October 2023–February 2024, 74 providers were surveyed; 73% were female with a mean age of 40 years. Eighty-five percent had at least one year of experience offering PrEP services. Over 95% of providers viewed counselling adolescent girls and young women (AGYW) on sexual and reproductive health issues as part of their job, with high levels of comfort in providing oral PrEP and the PrEP ring to AGYW (100% and 97%, respectively). However, nearly all providers were concerned about clients' ability to return on time for resupply of oral PrEP (99%) and follow a daily oral PrEP schedule (97%). For the ring, providers were concerned about the ability of clients to insert/remove it independently (84%) and its efficacy (87%). On average, informed PrEP choice counselling took providers three additional minutes compared to oral PrEP counselling. Despite initial concerns, the majority (97%) of providers agreed that offering PrEP choice is appealing and a good match to their client's needs, as well as implementable in routine health settings (95%).

Conclusions: CATALYST providers are generally supportive of offering PrEP choice to clients. Implementing partners interested in adopting PrEP choice in their facilities must address provider concerns and ensure the availability of supportive counseling messages that speak to both the intrinsic characteristics of products and extrinsic factors affecting clients' ongoing health system engagement.

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High prevalence of adverse childhood experiences in adolescents and young adults with HIV in Kenya

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Background: Adverse Childhood Experiences (ACE) encompass stressful or traumatic events during childhood, with lasting implications for mental, emotional, and physical well-being. ACE experiences in Adolescents and Young Adults with HIV (AYAHIV) have not been explored. Our study aimed to assess the prevalence and characteristics of ACEs among AYAHIV in Kisumu, Kenya.

Methods: The study enrolled AYAHIV aged 14-24 years, participating in the Adapt for Adolescent study from April 2021 to March 2022 at three Kisumu County government health facilities. Demographic data including age, gender, education level, relationship status, employment, and living situation were collected at baseline. Concurrently, we administered the ACE- International Questionnaire, generating scores (0-12) based on affirmative responses. We used Poisson regression to analyze associations between ACE scores sociodemographic variables and mental health symptoms.

Results: Among 880 AYAHIV (14-17 years 37%, female 67%) the median ACE score was 6 (IQR 5-8). ACE scores were distributed as follows: 4-5 (26.6%, 95%Confidence Interval (95%CI) [23.7%-29.6%]), 6-7 (39.0%; 95%CI [35.7%-42.3%]), 8-9 (26.6%;95%CI[23.7%-29.6%]), and 10 or more (7.8%;95%CI[6.2%-9.8%]). In univariable analysis the ACE score Incidence Rate Ratio (IRR) was higher in females compared to males (IRR1.10, 95%CI [1.04-1.16]) and those 20-25 years compared to those 15-19 years (IRR 1.20, 95% CI 1.15-1.27) while it was lower in those who reported not being in a relationship at study enrollment (IRR 0.85, 95% CI 0.81-0.90). (Table 1)

Those reporting mild anxiety symptoms had a higher IRR compared to those with minimal or no anxiety as did those reporting mild, moderate, or severe depression compared to no depressive symptoms.

Conclusions: AYAHIV report a significant prevalence of ACEs, with nearly 75% experiencing 6 or more ACEs. Being female and older age were associated with higher ACE scores.

Additionally, ACE score appears to be related to mental health symptoms in AYAHIV in this cohort. This study highlights the high frequency of ACEs in AYAHIV and potential impact on later mental health symptoms demonstrating a need necessity for tailored interventions and support for vulnerable populations.

EP300

Can we self-test? Understanding the factors associated with the awareness and utilization of HIV self-testing kits among women in Ghana

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Background: Evidence shows that more than half of the new HIV infections are caused by persons who are not aware of their HIV status. Several factors such as stigma and privacy limit the uptake of HIV self-testing (HIVST) at the health facilities. To bridge the gap in HIV testing and to ensure a timely initiation of Antiretroviral Treatment (ART), the World Health Organisation recommended HIVST in 2016. Ghana has incorporated HIVST into HIV care and prevention. To ensure HIV care continuum, there is the need to monitor the use of HIVST. However, no study has used nationally representative data to examine the factors associated with the awareness and use of HIVST kits in Ghana since its implementation.

This study therefore examined the factors associated with the awareness and use of HIVST kits among reproductive women in Ghana.

Methods: This study used nationally representative cross-sectional data from the seventh round of the Ghana Demographic and Health Survey (GDHS) conducted in 2022/2023. The study was restricted to reproductive aged women yielding 12,143. Awareness and use of HIVST kits were measured by whether women have ever heard of HIVST and ever used HIVST kits respectively. Awareness of HIVST was categorized as "yes" and "no", while use of HIVST kits was also categorized as "yes" and "no".

Results: About 81% of women were aware of HIVST kit, while 15.5% had ever tested using HIVST kit. Women's age, ecological zones and educational level predict both awareness and use of HIVST kits in Ghana.

In addition, marital status, distance to health facility and heard of ARVs were associated with only awareness of HIVST, while NHIS was associated with use of HIVST kits.

Conclusions: Though awareness of HIVST is high, its usage is low in Ghana. There should be efforts through health promotion programmes to encourage women to use HIVST kits. Policymakers should target individual and structural level factors that predicts awareness and use of HIVST kits when designing interventions to promote awareness and uptake of HIVST kits.

EP301

Estimating PrEP usage amongst MSM using probabilistic techniques – (Kaplan Meier Method), a cohort analysis in Harare, Zimbabwe

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Background: Men who have sex with men (MSM) and other key populations present a substantively higher risk of acquiring HIV than the general population. Effective uptake and usage of HIV prevention methods like PrEP amongst MSM clients becomes a priority in reducing new HIV Cases and ultimately achieving epidemic control amongst this sub-population. PZAT implemented a prospective cohort study focusing on the feasibility and acceptability of event-driven PrEP (ED-PrEP) from October 2022 to May 2023.

In this abstract, the objective of the analysis was to estimate the number of days a client would use PrEP amongst MSM clients using scientific methods to guide program planning and implementation.

Methods: A probabilistic method of Kaplan-Meier (KM) was used to retrospectively estimate the number of days a unique individual would be covered with PrEP in a cohort of 196 MSM clients in the feasibility and acceptability study for ED-PrEP.

An event was defined as when a person stopped using PrEP as an HIV prevention method and clients who continued PrEP post the end of the study period were right censored. Cox's proportional hazard was used to test for differences in survival times on different factors.

Results: The mean estimated survival time was 121 days for 95%CI [112;129] meaning that an average client who is MSM exposed to ED-PrEP would be taking PrEP as an HIV prevention effectively for approximately 4 months (4.03 months). The presence of an STI did not provide any difference in estimating survival times for MSM PrEP clients. The client's age showed different estimates in the survival times for PrEP with the greatest mean survival time on 40-44 years (154 days) and the least being on the 15-19 years (78 days).

Conclusions: The available information is suggestive that offering ED-PrEP together with DO increase the likelihood of the client continuing on PrEP as program data for where DO was offered exclusively was indicative of only a 76-day survival estimate using KM. More bio-socio data on the clinical characteristics is required to investigate further the other factors that may have an influence on each client's survival outcomes.



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EP302

Piloting IMARA for Black Male Caregivers and Girls Empowerment (IMAGE) a family-based HIV prevention intervention

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Background: Black girls are disproportionately impacted by adverse sexual and reproductive health outcomes (i.e., early sex, sexual violence, and HIV/STIs), underscoring the urgent need for innovative strategies enhancing their protection. Engaging Black male caregivers may reduce sexual risk-taking and improve sustainability of protective behaviors for Black girls. Historically, Black male caregivers have been excluded from family-based HIV/STI programming due to structural factors (i.e., racism, poverty, and incarceration) reducing opportunities to protect.

This presentation describes the results of the IMARA for Black Male Caregivers and Girls Empowerment (IMAGE) pilot, an evidence-based intervention developed using community-engaged methods and a **3-Step Implementation Model** simplifying EPIS (Exploration, Preparation, Implementation, and Sustainability) into an accessible tool for community settings.

Methods: For the *Exploration* phase of EPIS, we partnered with LAMP, an urban community-based organization in Chicago, Illinois, to understand their needs and identify the most appropriate evidence-based intervention to address them. We identified and adapted IMARA closely aligning to LAMP's needs to develop IMAGE. For the *Preparation* phase, we identified barriers and facilitators of implementation, assessed adaptation needs, and developed an implementation plan. Consistent with the *Implementation* phase of EPIS, we completed an acceptability and feasibility pilot of IMAGE with 20 Black girls and male caregiver dyads (n=40). Dyads were surveyed at baseline and one month after intervention delivery to assess changes in HIV/STI knowledge, dyad relationship and communication, and sexual behavior.

Results: Girls were aged 13-18 years (M=16), and male caregivers 18-70 years old (M=29); 50% of caregivers were < 23 years old (i.e., brothers, cousins, mentors), 30% biological fathers. Black girls and male caregivers were actively engaged and satisfied with the program. The mean acceptability score (18 items, 1-5 scale) was 4.6 (SD=1.1) for male caregivers and girls. In open-ended responses, both reported learning new HIV/STI information and more effective communication about sex and condom use. 100% were retained at one-month post-intervention.

Conclusions: IMAGE, a promising behavior change intervention, meets the call for innovative approaches to address HIV/STI and sexual violence among Black girls. These

promising results led to a 5-year efficacy trial to test the impact of IMAGE on Black girls' sexual and reproductive health.

EP303

Enriching integration: Improving prep uptake among vulnerable populations through community-based models in Siaya county, Kenya

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Background: Vulnerable populations, such as discordant couples (DC) and men in high-risk settings (MHRS) in the context of HIV, face numerous risk factors contributing to higher HIV acquisition and transmission rates. MHRS includes individuals like gold miners, sand harvesters, cancutters, and boda-boda riders in Kenya. Factors such as inconsistent safe sex practices among DC, low PrEP uptake due to HIV status unawareness, limited HIV knowledge, low risk perception, and poor health-seeking behavior among men exacerbate vulnerability.

CMMB, in collaboration with the Kenya Red Cross Society, implemented community-led strategies, including community-based biomedical outreaches, sensitization campaigns, and peer-led demand creation, targeting vulnerable populations in Siaya County. These interventions aimed to improve access to HIV prevention services.

Methods: As of 2022, hotspot zones for MHRS and DC enrollment were mapped across wards and health facilities, respectively. Twenty-five MHRS and 22 DC peer educators (PEs) were meticulously recruited and trained in HIV education, sexual reproductive health, gender-based violence awareness, and demand creation for PrEP services. PEs facilitated community biomedical outreaches providing health education, HIV testing (HTS), antiretroviral therapy (ART) linkage, TB and STI screenings, and PrEP services.

Additionally, PEs conducted interactive sessions and referrals for MHRS peers. Quantitative data collected via service delivery forms and analyzed through Kobo-Collect app provided insights into health service access by vulnerable populations. Monthly PE feedback meetings were held to address field challenges and solutions.

Results: Between April 2022 and March 2024, significant improvements were observed in biomedical service uptake. MHRS showed a 56% increase (8,433) in HTS uptake compared to pre-2022 levels. DC identification and enrollment at health facilities increased by 62%. PrEP initiation among MHRS increased by 5.8% (396), and among DC, there was a 10% (203) improvement, highlighting the ongoing need for PrEP education and access. Qualitative feedback indicated enhanced knowledge, awareness, and access to services among both MHRS and DC.

Conclusions: Context-specific service delivery tailored to population needs has a profound impact. Leveraging community-based biomedical services improves PrEP up-

take by reducing travel time and costs. Community sensitization initiatives bridge knowledge gaps, promoting informed safe sex practices among vulnerable populations.

EP304

Empowering adolescent girls and young women: HER voice fund implementation in Uganda

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Background: This abstract presents the noteworthy progress and impact of the HER Voice Fund (HVF) implementation in Uganda, led by Peer To Peer Uganda (PEERU). HVF is executed through a consortium of six local civil society organizations, with PEERU serving as the country lead.

Since 2022, our initiatives have focused on advancing the meaningful engagements and leadership development of Adolescent Girls and Young Women (AGYW) in six districts of Uganda.

Methods:

1. Increasing Access to HIV/AIDS and GBV Services for AGYW: PEERU, in collaboration with local partners, has successfully expanded access to critical HIV/AIDS and Gender-Based Violence (GBV) services and projects to address the unique healthcare needs of this demographic.

2. Mobilizing and Advocating for Effective Implementation of HIV and AIDS Laws and Policies: Our efforts extend beyond service provision; we are actively mobilizing and advocating for the effective implementation of HIV and AIDS laws, policies, programs, and practices for AGYW in their diversity at both subnational and national levels through promoting equal access to HIV/AIDS services for AGYW, and supporting them engage meaningfully in key decision-making spaces by collaborating with district local governments to develop bylaws to protect and provide a favorable environment for AGYW living with HIV, disabilities or most vulnerable in their communities.

3. Supporting AGYW in Decision-Making Spaces: PEERU through strategic partnerships and capacity-building initiatives, we aim to amplify the voices of AGYW in shaping policies and programs.

4. Promoting AGYW-led Organizations and Domestic Funding: A key achievement has been the promotion of AGYW-led and serving organizations, empowering them to leverage domestic funding for activities that directly benefit AGYW. This sustainable approach aims to ensure the continued progress and impact of HER Voice Fund initiatives.

Results: Over 250,000 adolescent girls and young women have been reached through the HER Voice program in Uganda.

Conclusions: This abstract highlights the proactive role of PEERU as the country lead, along with the collaborative efforts of the consortium, in realizing the HER Voice Fund's mandate. The outcomes presented reflect a commitment to creating positive and lasting change for AGYW in

Uganda, particularly in the realms of healthcare access, legal advocacy, and meaningful participation in decision-making processes.

EP305

Usability and acceptability evaluation of two HIV self-test in general population of Argentina

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Background: In Argentina people acquiring HIV per year has slightly increased between 2018-2022 (4,937 to 5,629). Nearly half (44.5%) of people acquiring HIV in 2022 were detected at late stages, indicating the need for easily-accessible testing options. Lately there has been an expansion of HIV testing into non-clinical settings, including HIV self-testing (ST). This strategy has been legal in Argentina since 2022 (new HIV law 27,675); but there was no HIVST approved by our national administration of drugs, food and technology for commercial (CU) or public health uses (PHU). In this study we evaluated acceptability and usability of two ST (1 for CU and 1 for PHU) by non professional users (NPU).

Methods: Two complementary surveys were developed to evaluate HIVST acceptability: one designed to be completed by NPU (individuals using ST for the first time); other survey designed to be completed by professional users (PU-individual observing the tester), to verify NPU properly complete all required steps. 40 NPU were recruited in extramural testing devices to carry out one ST, either CU or PHU. Results from each survey were analyzed and separate descriptive analyses were performed.

Results: NPU survey: All NPUs who performed PHU and CU HIVST understood testing procedures, perceived they used them correctly, and would use similar devices at home. HIVST was found easy to use by 18/20 of NPU using CU ST and for 19/20 using PHU ST. HIVST was found easy to interpret by 17/20 of NPU using CU ST and for 18/20 using PHU ST.

PU survey: All valid results obtained for HIVST by NPU were correlated with those obtained by PU with 100% agreement. Only one invalid HIVST result was obtained in the PHU group. All HIVST steps were successfully performed by 17/20 of NPU using CU ST; and 19/20 of NPU using PHU ST. The common errors observed were: 1) depositing two drops of blood instead of one; 2) early reading of the ST.

Conclusions: Understanding of the HIVST procedure and actions following results interpretation was excellent. It can be concluded that both HIVST are easy-to-use, safe and reliable in vitro diagnostic products when used by NPU.



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EP306

Prioritization and barriers of mpox vaccination among gay, bisexual and other men who have sex with men (GBMSM) in Taiwan: 2023 HEART Survey

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Background: At the early stage of the mpox epidemic, limited vaccine availability necessitated public health authorities to immunize *vaccine priority groups*, including individuals with HIV and other vulnerable populations. Taiwan is the first Asian country to fully subsidize the two-dose mpox vaccine since March 2023. However, whether Taiwan’s prioritizing strategy effectively reached the intended recipients among GBMSM remains under-explored.

We sought to understand the characteristics of vaccine adopters and identify barriers for vaccine-hesitant individuals.

Methods: In November-December 2023, an online self-administered behavior survey comprising 65 questions was distributed to adult GBMSM in Taiwan using social networking applications. Multinomial logistic regression was conducted to compare sociodemographic and behavioral characteristics among those who were mpox vaccine-naïve, partially and fully immunized. We defined key barriers to vaccine uptake as items agreed by ≥ 25% of respondents.

Results: Of 1,656 survey respondents (mean age = 34.7 years, SD 8.2), 43% were vaccine-naïve, 13% received one dose, and 44% were fully immunized. Apart from people living with HIV (aOR = 5.19, 95% CI = 3.66-7.36), individuals currently using biomedical preventive strategies such as PrEP had higher odds of completion of mpox vaccines (aOR=7.68, 95% CI=3.66-7.36, see Table).

Having more than six sexual partners in the last 12 months and recent condomless anal sex were also significantly associated with vaccine uptake.

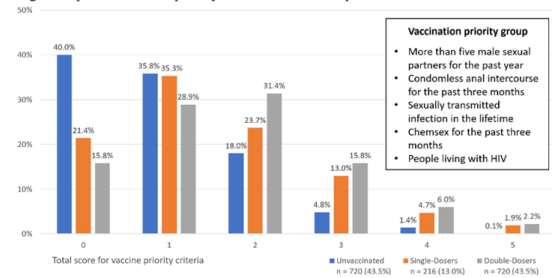
Among those men meeting two or more priority criteria, 26% (173/663) were mpox vaccine-naïve (see Figure). Key barriers for the unvaccinated *vaccine priority group* to uptake vaccines included a lack of perceived risk, low awareness, and inaccessibility of mpox vaccine.

Table. Multinomial logistic regression analysis comparing among men who were mpox vaccine-naïve, partially and fully immunized (n=1,656; referent outcome group: unvaccinated.)

	Single-dosers aOR (95%CI)	Double-dosers aOR (95%CI)
Sociodemographic and behavioral characteristics		
Age ≥ 34	1.25 (0.89-1.76)	1.63 (1.24-2.13)
Residency in major cities	0.96 (0.66-1.41)	1.21 (0.89-1.65)
Monthly income ≥ NTDS\$45,000	1.07 (0.75-1.51)	0.92 (0.70-1.21)
Numbers of sexual partners in the last 12 months ≥ 6	1.43 (0.98-2.09)	1.98 (1.48-2.65)
CAI in the last three months	0.98 (0.69-1.39)	1.44 (1.10-1.88)
Self-reported STI in the lifetime (any kind)	1.65 (1.02-2.68)	1.37 (0.92-2.05)
Chemsex in the last three months	1.26 (0.69-2.31)	0.89 (0.53-1.48)
HIV and PrEP (ref: HIV negative not on PrEP)		
HIV negative on PrEP	6.66 (3.97-11.15)	7.68 (4.99-11.82)
People living with HIV	4.17 (2.69-6.44)	5.19 (3.66-7.36)
Experienced Doxy-PEP	2.22 (0.64-7.68)	2.40 (0.78-7.40)
Had HPV vaccination experience (ref: unvaccinated)		
Single dose or two doses	3.00 (1.74-5.17)	3.11 (1.95-4.96)
three or more doses	1.86 (1.14-3.04)	7.30 (5.15-10.33)

aOR=adjusted odds ratio; NTD=New Taiwan Dollar; CAI=condomless anal intercourse; STI=sexually transmitted infections; HIV=human immunodeficiency virus; PrEP=pre-exposure prophylaxis; Doxy-PEP=doxycycline post-exposure prophylaxis; HPV=human papillomavirus. Bold values indicate significance at P < 0.05; Bolded behavioral characteristics indicate the five criteria for vaccine priority group eligibility.

Figure. Mpox vaccination priority scores and vaccine uptake



Conclusions: Integrating mpox vaccination into sexual health services that deliver biomedical HIV preventive strategies can promote vaccine uptake among eligible individuals.

Efforts should be made to enhance awareness of the mpox vaccine, tackle misinformation, and improve multi-channelled and equitable vaccine access among people affected by mpox.

EP307

Improving viral load testing coverage among recipients of care: results from intervention analysis Ndola, Copperbelt Province

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Background: The World Health Organization recommends viral load testing as the optimal way to monitor clients on ART to assess treatment success.

In Zambia, the national guidelines recommend one viral load (VL) test after six months of antiretroviral therapy (ART) initiation, and, subsequently, every twelve months for clients who are virally suppressed.

However, there has been a gap in VL testing coverage among the ART recipients of care (RoC) in Ndola district despite having the testing platform. In May 2020, the viral load testing coverage was at 66% due to a number of factors including low sample collection from the eligible clients, misaligned clinical, pharmacy and lab appointment dates, weak tracking system of sample movement from collection points to PCR laboratories.



The USAID DISCOVER Health project implemented by JSI structured interventions to respond to the above identified barriers in the supported facilities in the district.

Methods: The district implemented structured interventions to respond to identified barriers. Facility monthly due for VL list generated from electronic health records (EHR) and planned for proactive sample collection. Samples were collected both from facilities and in the community on all days including weekends. Targets were set for sample collection at facility level per day, week and month and designated staff was tasked to review implementation. Clinical and VL collection appointments were synchronized in EHR and facility appointment registers. The EHR was updated the same day results were received, including VL registers and client's charts. Use of a results holding folder at the facility was discouraged to reduce delays in updating registers and records.

Results: Viral load coverage improved from 66% in May 2020 to 95% in September 2023. The positive trajectory in viral load coverage was maintained through consistent implementation and close monitoring of the structured interventions.

Conclusions: Viral load coverage testing is critical in measuring treatment success of HIV treatment programs. Adoption of interventions aimed at optimizing sample collection, results transmission and recording in a proactive manner helps improve VL coverage.

EP308

The importance of male involvement in clinical trials involving pregnant and breastfeeding women-lessons learnt from MTN 042 study

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Background: Clinical research focusing on novel methods for HIV prevention are being conducted to ensure women have choices in HIV prevention. Pregnant and breastfeeding women require HIV prevention methods they know are safe for them and their babies. MTN 042 was a trial looking at safety of Dapivirine(DPV) ring and oral Truvada in pregnant and breastfeeding women. The PrEP methods were found to be safe and effective but more information was required in pregnant and breast feeding women. Male engagement is key in clinical trials involving pregnant and breastfeeding women in patriarchal societies like Zimbabwe.

It is against this background that we conducted a focused group discussion study to understand the importance of male involvement in clinical trials targeting pregnant and breastfeeding women.

Methods: To understand the importance of male involvement in clinical trials involving pregnant and breast feeding women, we conducted five male engagement meet-

ings with an average 40 men for MTN 042(DELIVER) study at St. Mary's, Seke and Zengeza communities of Chitungwiza.

The meetings were biased towards married and sexually active males aged between 18 – 60 years from MTN 042 catchment. Structured questions were used to unpack male perceptions and fears for their partners to participate.

Results: After our intervention we had an average of 2.5% males who remained skeptical about supporting pregnant and breastfeeding women to participate in clinical trials.

Although males indicated that culture contradicts with research, we learnt that pregnant and breastfeeding women participation in study cannot be done at individual level but needed to involve the male partner and significant family members.

Fear of the unknown life-threatening complications to the unborn child, the burden of responsibility associated with managing complications, skepticism of scientific approaches used in trials, science contradicting with culture and religious beliefs.

CAB and outreach teams to intensify on community education for research literacy on clinical trial processes. Trials involving pregnant and breast-feeding women should engage males and key significant other members of the family structure.

Conclusions: Formative consultations with stakeholders, community education and male involvement are integral in addressing fears and concerns for pregnant and breastfeeding women in clinical trials.

EP309

HIV risk perception, PrEP eligibility, and characteristics of women accessing public family planning clinics in Kenya

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Background: In Sub-Saharan Africa, family planning (FP) clinics are highly accessed by sexually active women and offer a great opportunity to reach women who could benefit from PrEP. Understanding the profile of women accessing these clinics could permit efficient integration of HIV and FP services.

Methods: We administered structured questionnaires to women without HIV accessing twelve public FP clinics in Kisumu, Kenya. The questionnaires assessed women's demographics, HIV risk factors and PrEP eligibility, HIV risk perception, confidence in FP providers, knowledge of partner HIV status and current HIV prevention services. HIV risk and PrEP eligibility was determined based on ep-



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idemiological and behavior factors defined by the Kenya PrEP national guidelines. Descriptive statistics were used to summarize outcome distribution.

Results: Of 1200 women surveyed, 79% were married or cohabiting with median age of 27 (IQR 23-31) years with 38% <25 years.

Overall, 62% (743/1200) did not know their partner HIV status, 23% (277/1200) reported multiple sex partners, 68% (771/1200) reported condomless sex with partner of unknown status or person living with HIV, and 76% (912/1200) had tested for HIV in the previous 12 months.

Among women with factors associated with elevated HIV risk, 61% (546/891) rarely or never felt at risk for HIV, 90% (814/907) were not using any HIV prevention methods, including no method while 72% (616/724) were not satisfied with their current HIV prevention choices.

A majority (>93%) reported FP clinics as an acceptable place to receive HIV prevention services and >69% reported they had full trust in FP providers to give correct information about HIV protection. Among PrEP eligible women with information on PrEP, only 8% reported to be using PrEP. Frequently reported reasons for not utilizing PrEP included need to consult partner/family (24%) or needed time to decide (38%) and concerns about side effects (20%), pill burden (20%), and stigma (17%).

Conclusions: Most women with elevated risk for HIV desired but were not using any prevention strategy. Integrating PrEP delivery in FP clinic has potential to reach diverse women who could benefit from PrEP but must be empowered to perceive risk and make informed choices about HIV prevention methods.

EP310

Challenges to biomedical trial participation among adolescent and young adult men: lessons learned from ATN 163

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Background: Young men who have sex with men (YMSM) continue to represent a disproportionately high number of new HIV cases globally. Their participation in biomedical trials is crucial for developing effective interventions tailored to their unique needs; however, their engagement remains limited. Understanding and addressing the specific barriers they face in participating in clinical research is essential.

Methods: As part of ATN 163, we interviewed 21 YMSM (ages 18-24) who were eligible at the in-person screening for enrollment in a Phase I trial, yet who declined to enroll in the clinical trial examining the safety, pharmacokinetics and

pharmacodynamics, and acceptability of a single-dose of a PrEP douche candidate. Through a video-based, semi-structured in-depth interview with a facilitator at a different site, we engaged participants in a conversation regarding the reasons and motivations that led them to not enroll in the trial. We used thematic analysis to analyze the de-identified interview transcripts.

Results: YMSM noted that their initial desire to participate in the study was motivated by the desire to benefit their community; however, participants experienced a multi-faceted set of challenges when considering whether to participate in the trial.

We identified three key themes: lack of awareness and familiarity with clinical trials, logistical hurdles to trial participation, and apprehensions about medical procedures. Participants expressed lack of awareness and understanding of the research process during their screening visit, contributing to apprehension and reluctance to participate. Participants also noted that logistical constraints, including scheduling conflicts with the hospital's schedule and transportation issues, further exacerbated participation barriers.

Finally, a few participants shared apprehension regarding the anticipated discomfort, embarrassment, and fear that could be associated with medical and laboratory procedures (e.g., biopsies, rectal exam). Participants recommended greater flexible scheduling regarding when clinical procedures could take place (e.g., evening; weekends), and audiovisual materials and supports to ease concerns about medical procedures.

Conclusions: Future biomedical trials focused on young populations must reimagine the traditional procedures and operations in hospital settings to ensure a holistic approach that increases the opportunities for youth to participate in biomedical research.

EP311

Intimate Partner Violence (IPV) and the HIV Pre-Exposure Prophylaxis (PrEP) care engagement among Sexual Minority Men: a systematic review

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Background: The engagement of HIV pre-exposure prophylaxis (PrEP) care among sexual minority men (SMM) can be influenced by interpersonal factors, including experiencing intimate partner violence (IPV). However, there is limited collective evidence summarizing this association. This systematic review aims to synthesize literature on the interplay between IPV experiences and PrEP utilization among SMM and identify critical gaps.

Methods: Following PRISMA guidelines, a systematic review was conducted to identify studies exploring the intersection of IPV and PrEP among SMM. Title and abstract were screened for eligibility and discrepancies in study screening, data extraction, and data synthesis were re-

solved through discussion with a senior researcher. A thematic analysis approach was used to qualitatively synthesize and summarize the key emerging themes and a meta-analysis was not performed due to the limited quantitative data available in the included studies.

Results: Only 10 studies met the eligibility criteria, most of which (n=8) were conducted in the United States while one study was conducted in China and one study was in South Africa & Namibia.

All studies were quantitative in design and utilized cross-sectional data. Two studies explicitly examined IPV and PrEP outcomes among Black SMM and one study was conducted among young Latino SMM in the U.S. Included studies utilized various measurements to assess different types of IPV across recall periods, and only one study assessed IPV perpetration and all the other studies only measured victimization. IPV victimization was found negatively associated with PrEP awareness and willingness, and it influenced preferences for PrEP delivery modalities, with notable impacts on oral PrEP and long-acting injectable PrEP uptake. PrEP adherence was negatively affected by IPV, with victims exhibiting lower adherence levels.

Conclusions: This review highlights the complex relationship between IPV and PrEP engagement among SMM. Despite limited research, existing evidence underscores the need for targeted interventions addressing IPV within PrEP programs. Longitudinal studies are recommended to assess the enduring impact of IPV on PrEP utilization and adherence.

Future research should also explore syndemic factors influencing IPV-PrEP dynamics, especially in low- and middle-income countries. Integrating IPV screening and support services within PrEP programs is vital for optimizing HIV prevention strategies for SMM.

EP312

PrEP: a new sensation. A case series of facial paraesthesia associated with PrEP in Australia

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Background: Tenofovir-disoproxil-fumarate plus emtricitabine (TDF/FTC) is widely used as pre-exposure prophylaxis (PrEP) to prevent HIV acquisition and is generally considered well tolerated.

Methods: We describe the presentation of a case report of facial paraesthesia associated with PrEP leading to a further 3 cases reported across Australia.

Results: The initial case, presented at the 2023 Australasian Sexual Health Annual Scientific meeting, was a 25-year-old cis MSM who reported a left-sided facial paraesthesia with onset within 60 minutes following ingestion of two TDF/FTC tablets. The symptoms lasted 3-4

hours. He described paraesthesia in the distribution of the maxillary branch of the left trigeminal nerve with possible ophthalmic branch involvement. There were no motor, systemic, visual, or skin changes. Following symptom resolution, a normal cranial nerve examination was elicited. He took no regular medications, rarely used MDMA and had no significant medical history. STI screening was negative. A full biochemistry and autoimmune screen were normal. Re-challenge with the same brand of TDF/FTC, a different generic brand and generic tenofovir alafenamide (TAF)/FTC all led to identical symptomatic outcome. Three other cases were subsequently identified at different Australian sexual health clinics. All cases were of young males starting TDx/FTC leading to facial paraesthesia occurring 30-120 minutes after ingestion. Two cases had taken a loading dose of 2 tablets, whereas the other two took one tablet. Symptoms resolved following cessation but for all recurred following re-challenge. All had normal neurological examinations and no other concomitant medications or history that could explain symptomology. Despite widespread use of PrEP, there is only three cases reported in the literature, and none within Australia, of similar phenomena.

Conclusions: This cluster of isolated reports highlights what was originally considered a rare event due to the limited published data, may be more common due to under reporting.

EP313

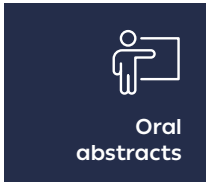
Tenofovir rectal douche for HIV prevention: a translational model-based approach to inform human pre-exposure prophylaxis dose selection

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Background: The DREAM (Development of Rectal Enema As Microbicide) Program has developed a rectal tenofovir (TFV) douche as an on-demand, behaviorally-congruent HIV pre-exposure prophylaxis (PrEP) candidate to prevent rectal HIV acquisition.

We used cross-species modeling to predict effective human dosing using macaque pharmacokinetic (PK) and simian/human-immunodeficiency virus (SHIV) rectal challenge pharmacodynamic (PD) data and human PK and ex vivo colorectal tissue HIV challenge PD data.

Methods: We built three models using a population approach (NONMEM v7.4): (A) macaque multicompartment PK, (B) macaque time-to-SIV-infection PKPD, and (C) human multicompartment PKPD.





Model A fit plasma TFV and colorectal tissue TFV-diphosphate (TFV-DP) PK data from single dose studies of macaques receiving iso-osmolar or hypo-osmolar high-dose (TFV 158mg; 5.28mg/mL) and low-dose (TFV 53mg; 1.76mg/mL) rectal douches (30mL) and human-equivalent high-dose (22mg/kg) or low-dose (5mg/kg) TFV disoproxil fumarate (TDF) oral formulations.

Model B fit macaque time-to-SHIV-infection events after weekly intrarectal SHIV challenges with an exponential hazard distribution model; using the average concentration at time of challenge as a covariate, a PKPD effect-per-matrix was estimated using an E_{max} relationship. Model C fit plasma TFV and rectal tissue TFV-DP PK data pooled from phase 1 human studies (DREAM-01/03) of iso-osmolar or hypo-osmolar high-dose (TFV 660mg; 5.28mg/mL) and low-dose (TFV 220mg; 1.76mg/mL) iso-osmolar rectal douches (125mL).

The combined translational model enabled simulation of human TFV rectal douche HIV protective efficacy across a 50-700mg dose range.

Results: The macaque time-to-SIV-infection model estimated TFV-DP EC_{50} (509 fmol/mg) and EC_{90} (4581 fmol/mg) in colon tissue; tissue TFV-DP concentrations were the most significant PK predictor of rectal SHIV challenge prevention. The human multicompartment PK model (plasma TFV and colorectal TFV-DP) estimated plasma absorption ($k_a = 1.4h^{-1}$) and clearance ($CL/F = 2360 L/h$), colon tissue distribution ($k_{pt} = 0.129h^{-1}$), and plasma/tissue ratio ($R_{pt} = 1300 [fmol/mg]/[ng/mL]$). Simulated tissue TFV-DP concentration-time profiles revealed doses higher than 450mg exceeded target EC_{90} concentrations.

Conclusions: Translational modeling using macaque SHIV challenge PKPD studies – unique to preclinical development – predicted clinically efficacious doses from clinical PK studies. Colorectal tissue TFV-DP was the matrix driving TFV douche protection. These data inform clinical dose selection for efficacy studies in humans.

EP314

Early user experiences with the dapivirine PrEP ring among women in Eswatini

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Background: With support from the PEPFAR/USAID-funded MOSAIC project, Eswatini is preparing for national introduction of HIV PrEP choice for women through a demonstration study introducing the PrEP ring in eight Ministry of Health-supported service delivery points.

Methods: HIV-negative, non-pregnant and non-breast-feeding women 18 years and older interested in PrEP received informed choice counseling for oral PrEP and the PrEP ring. We assessed reasons for method choice and

early experiences from ring users through enrollment and follow-up surveys completed during in-person PrEP visits and phone check-ins one week after initial method choice or switch. Data were analyzed descriptively.

Results: Between May 2023 and January 2024, 516 women enrolled in the study. Almost half (45%) previously used oral PrEP. Following choice counseling, 371 (72%) opted to use the PrEP ring. The median age of ring users was 29 years (IQR: 24-34). The most common reasons for choosing the PrEP ring at enrollment were ease of use (62%) and not needing to take a daily tablet (53%).

Over half of ring users self-inserted (52%) or had the provider (9%) insert the ring at the facility during the enrollment visit. Among the 39% who did not, 78% confirmed ring insertion by the one-week check-in.

Top reasons for not inserting the ring included completing STI treatment (27%), scared to insert (20%), and side-effect concerns (20%). In total, 190 (51%) women returned for at least one follow-up visit after choosing the ring at enrollment. Among them, 75% decided to continue the ring, 17% switched to oral PrEP, and 8% discontinued PrEP completely. Reasons for not continuing the ring include disliking side effects (19%), no longer needing PrEP (13%), ring discomfort (8%), not having time/money to return for resupply (8%), or pregnancy (6%).

Conclusions: The PrEP ring is an acceptable option for women to prevent HIV. PrEP choice counseling is important to ensure women can make an informed choice and understand benefits, limitations, and correct use. Ongoing support and management of side effects may improve product continuation. Expanding eligibility to allow ring use in pregnant and breastfeeding women will further expand access to PrEP choice.

EP315

Barriers to care engagement and viral suppression: a mixed-methods study of challenges to treatment as prevention for women in the U.S. South

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Background: The US Strategy for Ending the HIV Epidemic centers treatment as prevention (TasP). In southern US states in particular, low resources, economic disparities, and racial/ethnic dynamics present challenges to TasP among women. This study builds on extant research identifying factors independently associated with HIV care engagement and viral suppression among women, by examining the simultaneous interplay of psychosocial, behavioral, and structural factors, to prioritize targets for intervention.

Methods: This study analyzed qualitative data from virtual focus groups with women living with HIV and quantitative data from CDC's Medical Monitoring Project (2015–2021) in 6 southern US states. Focus group transcripts were thematically coded to identify primary barriers.

Quantitative analysis assessed the associations of race/ethnicity, psychosocial, behavioral, and structural factors with three TasP outcomes:

1. HIV care engagement (completed HIV care/viral load test in prior 6 months),
2. Viral suppression (viral load <200 copies/mL), and;
3. Biobehavioral transmission risk (condomless sex + viral load \geq 200 copies/mL).

Latent class analyses (LCA), stratified by racial/ethnic group, assessed syndemic conditions by identifying unique combinations of psychosocial, behavioral, and structural factors by race/ethnicity.

Finally, regression analyses tested whether emergent latent classes predicted the three TasP outcomes.

Results: Qualitative findings centered on basic needs (housing, food, employment, transportation) and time and caring roles (job and family caring responsibilities).

These results informed quantitative analyses. Preliminary quantitative results indicate high levels of several psychosocial factors—including depressive symptoms and violence, behavioral factors—including substance use, and structural factors—including housing insecurity and poverty.

Preliminary LCA by race/ethnicity suggest Hispanic, non-Hispanic Black, non-Hispanic White, and other/multi-racial women experience these in different combinations, and that they are differentially associated with outcomes.

Conclusions: According to syndemic theory, multiple psychosocial, behavioral, and structural comorbidities combine to drive the continued HIV/AIDS epidemic.

Findings suggest that in the US South, women of different racial/ethnic groups experience different syndemics and these vary in associations with TasP outcomes. Refined models (in progress) will help prioritize intervention strategies to address combinations of barriers experienced by diverse women in the South.

EP316

Combined prevention strategy for key population in the Dominican Republic

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Background: In Dominican Republic, 78,000 people are living with or affected by HIV. Our epidemic is concentrated in Key Populations (KP). According to the Fourth KP Serologically Linked Behavioral Surveillance Survey 2022 reported: Transgender Women (TRANS) 29.6%, Men who have sex with men (MSM)7.5%, Female Sex Workers (TRSX)4.9%, Haitian Immigrants (HI)4.8% and Persons Deprived of Liberty (PPL)4.8%.

Methods: As part of the National Response to HIV, in 2019 the country developed the Combination Prevention Strategy that includes: prevention education materials, condoms and lubricants, free HIV testing, Pre-exposure prophylaxis (PrEP), screening and referrals to treatment for positive cases of HIV, STIs, hepatitis or tuberculosis.

Voluntary index testing strategy is also offered. Information is collected through the Social Policy Program Application Form (FAPPS) of the National Health Service and services are regulated by the "Norm for the Prevention and Care of STIs, HIV and Hepatitis". The complete package is offered in 11 sites.

Results: As of September 2023, there were 3,386 registered PrEP users in the country (representing the third country in Latin America in number of cases on PrEP), 2,531 (74.7%) males, 780 (23%), females, 55 (1.6%) TRANS 20 (0.5%) not reported. 2,972 (87.8%) are Dominican, 137 (4%) Haitian and 265 (7.8) from others countries. MSM 2,205 (65.1%), TRSX 888 (26.25), Discordant couple 218 (6.4%). This shows that, despite the availability of drugs, the demand for PrEP remains low in KP, and much lower in the TRANS population. This could be attributed to the lack of friendly services in this population. In DC, it could be attributed to lack of knowledge of the HIV status of the partner.

Conclusions: DR has reduced new infections in the country by -7% since 2010, according to the UNAID 2023 report. However, coverage in KP remains low. Due to cost, injectable PrEP is not an option in the country.

We must create friendly services for this population, start in adolescents, include PrEP on demand and reinforce preventive education in these populations through advertising campaigns especially in social networks about PrEP and where it is offered.



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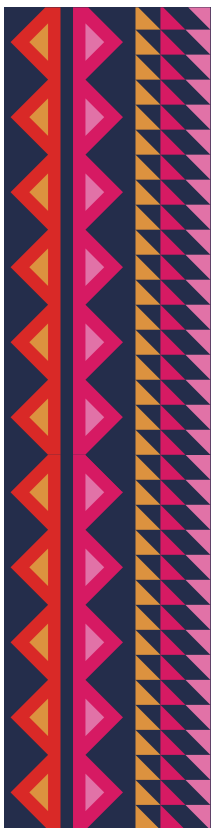
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EP317

Let's have a Kiki: incentivized vs. non-incentivized social network strategies for HIV services among MSM in South Africa

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Background: Social network strategies (SNS) are peer-based approaches that incentivize community gatekeepers or service-users to harness their social or sexual networks to reach hidden key populations. SNS are an evidence-based best practice for reaching MSM in combination with traditional outreach approaches. Funded by PEPFAR/ USAID, OUT LGBT Well-being's Engage Men's Health program (OUT-EMH) has provided comprehensive HIV services to MSM in Johannesburg, Buffalo City and Nelson Mandela Bay, South Africa since 2019.

Methods: OUT-EMH utilizes various SNS, including chemsex MSM groups, enhanced peer outreach approach (EPOA) and client-initiated peer (CIP) groups. In April 2020, OUT-EMH intensified SNS to reach high-risk MSM. MSM gatekeepers received incentives ranging from R200 – R500 per event and each new MSM attending received a snack (R60). In 2023, EMH-OUT redesigned its SNS to use committed peers and service-users rather than incentives. "Kiki (LGBTQIA+ slang for 'a gathering of friends for gossip/ chit chat') Groups" of ±5 MSM friends were established to provide safe, intimate, fun/social and convenient spaces for HIV services, peer support and ART/PrEP refills.

Results: Incentivized SNS were expensive and time-consuming to implement, with costs increasing year-on-year. In 2021, the incentive cost per new positive identified was R630 for CIP and R98 for EPOA. In 2022, costs escalated to R781 for chemsex and R486 for CIP.

Although SNS were effective in finding new positives ($n = 793$), adherence rates were sub-optimal (26% lower retention among SNS service-users than those initiated via outreach or facility modalities).

While still in pilot phase, between December 2023 and March 2024, 392 MSM attended Kiki Groups, resulting in the identification of 46 new HIV diagnoses (12% yield), 42 same-day ART initiations (91% uptake), and 316 PrEP initiations (93% uptake). To date, only one Kiki ART service-user has been lost to follow-up.

Conclusions: Incentivized SNS are not sustainable to ensure continuity of care for MSM, relying on the gatekeepers and creating dependencies that contradict the goal of fostering self-efficacy and agency. Non-incentivized Kiki Groups is a promising approach to reach and engage MSM in services. EMH-OUT will intensify, refine and evaluate Kiki Groups to harness the benefits of SNS without incentives.

EP318

Effectiveness of the *Le Kip Kip* social influence campaign on destigmatizing PrEP use and increasing PrEP awareness among South African women: a qualitative study

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Background: HIV pre-exposure prophylaxis (PrEP) uptake among adolescent girls and young women (AGYW) and female sex workers (FSW) has been a critical focus of HIV prevention efforts in South Africa. In response to HIV and PrEP-related stigma and low PrEP awareness, the *Le Kip Kip* social influence campaign was launched to shift social norms and create a more enabling environment for PrEP uptake.

We evaluated the effectiveness of the *Le Kip Kip* campaign in increasing PrEP awareness, attitude change and PrEP uptake among AGYW and FSW in South Africa.

Methods: In August-September 2023, we conducted in-depth interviews in Zululand, Ngaka Modiri Molema, and uMgungundlovu Districts with individuals involved in campaign implementation—PrEP champions, volunteer community mobilizers, and programme brand ambassadors ($n=30$)—as well as community members exposed to the campaign ($n=36$). We used rapid qualitative analysis to assess mechanisms of campaign effectiveness across three PrEP-related outcomes: awareness, and attitudes.

Results: The campaign was effective in increasing PrEP awareness, however, it encountered challenges in changing attitudes and ultimately increasing PrEP uptake. Most men had entrenched perceptions of PrEP primarily as a prevention method for women which deterred them from initiating on PrEP, despite their demonstrated interest in the campaign initiatives.

Additionally, some community members who expressed interest in starting PrEP experienced challenges accessing services due to PrEP programme outreach schedules. Nonetheless, the campaign facilitated the identification of local clinics offering PrEP services, thereby simplifying the process of accessing PrEP. Participants acknowledged the campaign's role in increasing PrEP awareness and accessibility, thus shifting men's and parents' attitudes toward women's PrEP use.

Conclusions: The *Le Kip Kip* campaign effectively broadened the understanding and perception of HIV prevention beyond traditional methods for AGYW and FSW pop-

ulations in South Africa. Further integration of campaign activities into existing PrEP services may increase campaign effectiveness by ensuring linkage into PrEP care occurs in real-time.

EP319

Prevalence of mental health disorders and pain and risk factors for viral load suppression among people living with HIV in Lima, Peru

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Background: People living with HIV (PLWH) are at higher risk for mental health (MH) disorders and pain than the general population, both of which can complicate adherence to HIV treatment. Co-morbid MH disorders and pain remain largely understudied in low-and middle-income countries (LMICs).

Understanding the relationships among pain, MH, and HIV in these settings is essential to tailored service delivery, particularly in the context of resource limitations.

Methods: From 2/2023 to 10/2023, we conducted a cross-sectional survey at a large hospital in Lima, Peru to quantify the prevalence of MH disorders and pain amongst PLWH receiving routine care and to explore risk factors for viral load suppression. Questionnaires on demographics, MH, and pain scales were completed during routine clinic visits. Data on treatment and viral suppression were abstracted from clients' electronic medical charts.

We calculated the prevalence of depression (PHQ8 \geq 10), PTSD (PCL-5 \geq 30), severe risk of alcohol use disorder (AUDIT-C \geq 8 for men, 7 \geq for women), and chronic pain (BPI-SF). We then used multivariate regressions to examine whether viral load suppression is associated with pain and MH distress.

Results: Among 397 study participants, 53% met criteria for probable chronic pain, 21% had probable depression, 22% had severe risk for alcohol use disorder, and 14% had probable PTSD. Among the subset of participants (N=109) with recent viral load data (2023 or later), MH and pain variables were not significantly associated with viral load suppression in multivariate regressions.

Even among the 89 participants with a recent suppressed viral load (<50 copies/ml) problems with pain and MH symptoms were common: 57% reported pain, 24% met the clinical cut-off for depression, 20% met the cut-off for severe risk of AUD, and 16% met the clinical cutoff for PTSD.

Conclusions: There were high levels of depression, PTSD, alcohol use disorder, and pain among PLWH receiving care at a large hospital in Peru; MH outcomes were not associated with viral load suppression.

These results suggest that screening for MH disorders and pain in PLWH is needed, even among those whose HIV is well controlled, and support the need for integrated MH services within HIV clinics in LMICs.

EP320

HIV benefits and risks of online social networks among female sex workers in Blantyre, Malawi

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Background: Globally, female sex workers (FSWs) exhibit disproportionately high prevalence rates of HIV, influenced by a myriad of socio-economic challenges such as poverty and stigma. Evidence from developed countries has shown that interventions based on digital social networks are effective in reducing the risk of HIV in this sub-population. There is limited evidence on the role of social media in influencing HIV risk within the context of sex work in sub-Saharan Africa. We explored FSWs use of social media in identifying and mitigating HIV risk through peer-support in Blantyre, Malawi.

Methods: A qualitative ethnographic methodology was employed involving daily in-person contact with eight FSWs and online group observations to explore social relationships and interactions with clients and people directly connected to FSWs. Data were collected between February and November 2023 in urban Blantyre, Malawi, and included eight in-depth interviews with FSWs and 20 key informant interviews with bar owners, barmen, and online group administrators. Data were analysed inductively to identify the most prevalent themes and coded using NVivo.

Results: Social media was found to be used daily by FSWs with WhatsApp and Facebook being the primary platforms to either solicit clients or for peer support. Online groups mainly consisted of bar-related and exclusive groups for FSWs. The groups served as forums for discussing gender-based violence through sharing information about abusive clients and promoting health practices, such as reminders to carry condoms and adhere to HIV treatment. Each group had set rules regarding confidentiality and participation. Failure to comply attracted disciplinary actions, including suspension or expulsion, potentially limiting access to beneficial health discussions and activities; and exacerbating social isolation and stigma.

FSWs reported that access to HIV prevention information from peers via social media had a strong influence on their actual sexual risk-taking behavior. However, some reported inconsistent condom use and treatment non-



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adherence despite this access. This discrepancy was usually disclosed to trusted friends within FSW networks or bar owners.

Conclusions: Social media is harnessed by FSW to help protect against HIV and violence. Further work should focus on understanding the potential of social media to contribute to HIV prevention strategies amongst FSWs.

EP321

HIV case-finding among the pediatric and adolescent sub-population through facility and community testing in Plateau State, Nigeria

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Background: HIV poses a significant public health challenge, particularly with a high incidence among children and adolescents. Achieving equilibrium between facility and community-based approaches for children and adolescents in Nigeria is crucial. Diversifying testing strategies is imperative to cater to varied demographics, aiding in the early identification of acquired HIV, timely care provision, and mitigation of HIV's impact especially for the children and adolescent age group (0-19 years).

This study analyzed the current HIV case-finding status among individuals aged 0-19. The problem being analyzed is the gender and age group with the highest case-finding status across 29 selected facilities and communities in 14 Local Government Areas in Plateau State, Nigeria.

Methods: This was a retrospective study using data from pediatric and adolescent HIV testing and case findings during 12 months (October 2021-September 2022) in health facilities and communities respectively and sourced from the DATIM across 29 facilities selected from 14 Local Government Areas in Plateau State. HIV testing efforts and positivity by age and sex across the testing settings were compared for any significant difference and association using the X²-test and a decision was made at $p \leq 0.05$.

Results: A total of 13,333 clients aged 0-19 years were tested during the reporting period, with facility and community test settings contributing 10,748 (80.6%) and 2,585

(19.4%) respectively. Positivity was found to be 1.8% (196) and 1.7% (45) for facilities and communities respectively with the difference found to be statistically significant ($pV = 0.04058$).

Positivity among male and female groups was 2.2% (108) and 1.6% (133) respectively with statistically significant differences ($pV = 0.005$), despite the higher proportion of females (63.9%) to males (36.1%).

Positivity rates were higher for the age group of 0-4 years in both settings with that of the community (7.4%) being higher than that of the facility (3.1%), with evident association between age and positivity rate.

Conclusions: The study reveals a relatively higher transmission rate among the age group 0-4 years in both settings, particularly in the community setting. It is advisable to focus collaborative efforts on early childhood HIV screening, especially within communities, to prevent pediatric HIV.

EP322

Cognitive behavior therapy for antiretroviral therapy adherence among people living with HIV: a systematic review and meta-analysis

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Background: Adherence to antiretroviral therapy (ART) is critical for the effective management of HIV. Cognitive behavior therapy (CBT) has emerged as a promising intervention to enhance ART adherence among people living with HIV (PLHIV). This systematic review and meta-analysis aimed to evaluate the efficacy of CBT on ART adherence, plasma viral load (PVL), and CD4 counts.

Methods: A search across five databases (PubMed, Embase, PsycINFO, Web of Science, and Cochrane Central Register of Controlled Trials) was conducted in August 2023, including randomized controlled trials (RCTs) that applied CBT interventions for PLHIV.

Assessed outcomes were ART adherence, PVL, and CD4 counts. Quality assessment was performed using the Cochrane Risk of Bias tool for RCTs. Meta-analysis utilized Cohen's d for effect sizes, considering a random-effects model, and risk ratios for HIV viral suppression. Heterogeneity was assessed via I² statistics, and publication bias was evaluated with funnel plots and Egger's test. The protocol was registered in PROSPERO, CRD42023465713.

neity was assessed via I² statistics, and publication bias was evaluated with funnel plots and Egger's test. The protocol was registered in PROSPERO, CRD42023465713.

Results: Twenty studies out of 1,234 reviewed met inclusion criteria and enrolled 1,739 PLHIV (17 measured ART adherence, seven measured PVL, and seven measured CD4 counts). CBT was associated with improved ART adherence (Cohen's d=0.28, 95% CI 0.06 to 0.50, p=0.01) with heterogeneity of 76% and no evidence of publication bias. The improvement was more pronounced for PLHIV aged 42 years and above, as well as for interventions lasting longer than 13 weeks, administered in more than ten sessions, enrolling PLHIV with psychiatric comorbidities, or implemented in low- and middle-income countries (Figure 1). No statistically significant findings were observed for the effects of CBT on PVL and CD4 counts.

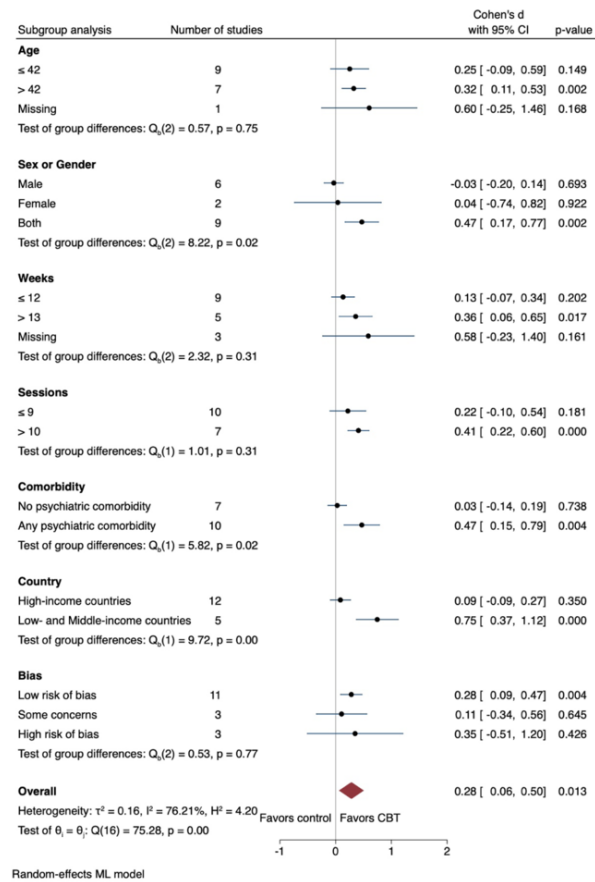


Figure 1. Subgroup analysis of the effect of CBT on ART adherence among PLHIV based on age, sex or gender, weeks and sessions of CBT, psychiatric comorbidities, countries and risk of bias.

Conclusions: These findings underscore the potential of CBT to improve ART adherence among PLHIV. The impact of CBT on PVL and CD4 counts remains inconclusive based on current evidence, necessitating further investigation.

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EP323

Guiding the public PrEP program for key populations in Peru: a mathematical modeling study informed by the ImPrEP demonstration project

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Background: In June 2023, free PrEP delivery to key populations was approved by the Peruvian public health system. This occurred after multiple PrEP studies among men who have sex with men (MSM) and transgender women (TW) in Peru, including the ImPrEP demonstration project, which recruited over 2000 participants in public sexual health clinics in Peru between 2018-2021 and gathered data on PrEP uptake, retention and adherence. To provide concrete guidance to the recently launched public PrEP program, we used mathematical modeling to estimate impact of PrEP delivery on HIV incidence among MSM and TW in Lima, also considering ART scale-up to achieve UNAIDS 90-90-90 and incidence reduction targets.

Methods: We used a dynamic compartmental model of HIV transmission among MSM and TW in Lima, parameterized with local data on sexual behaviors and HIV care, and calibrated to HIV sentinel-surveillance data from 1996-2019. The model reproduces the HIV epidemic, accounting for increases in condom use and ART coverage through time among four distinct groups based on differences in sexual behaviors, orientation, and gender identity: gay-identified MSM, bisexual/heterosexual-identified MSM, MSM engaging in sex work and TW.

We used ImPrEP project data to parameterize a PrEP intervention and considered three intervention scenarios between 2025-2030:

1. PrEP scale-up: 20% PrEP coverage,
2. ART scale up: three-fold increase in ART initiation,
3. Combined PrEP and ART scale up (using the same targets).

We estimated the proportion of infections averted in each scenario.

Results: Between 2025-2030, a 20% PrEP scale up led to a 22% (95%CI:17%-30%) reduction in new HIV infections, while a three-fold increase in ART initiation led to a 25% (95%CI: 23%-26%) reduction, and a combined PrEP-ART scale-up led to a 41% (95%CI: 37%-46%) reduction. The latter resulted in an 87% (95%CI: 81%-92%) reduction in incidence between 2010 and 2030, nearing the 90% UNAIDS incidence reduction goal.

Conclusions: While ART or PrEP scale-up alone will not achieve a 90% reduction in incidence among MSM/TW by 2030 in Lima, a combined strategy resulting in 90% of MSM/TW living with HIV receiving ART, and 20% of those HIV-negative receiving PrEP would near and potentially achieve this goal.

EP324

Maternal and infant predictors of mother-to-child transmission among HIV-exposed infants in Northeastern Uganda, a cross-sectional study

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Background: Despite Uganda making great efforts to eliminate mother-to-child transmission (MTCT) from over 20% in 2000 to 2.8% in 2021, the remote regions of north-eastern Uganda still have a high infant positivity due to long distances to health facilities, insecurity, and HIV stigma limiting access to HIV care and treatment services.

This study aimed to determine the maternal and infant predictors of MTCT (HIV infant positivity) among HIV-Exposed infants (HEI) less than 18 months of age in North-eastern Uganda.

Methods: This retrospective cross-sectional study was conducted at 12 public health facilities in northeastern Uganda. Data on the Sociodemographic and clinical characteristics of HIV-exposed infants (HEI) and their corresponding mothers was abstracted from the HEI register using a designed tool. Data was cleaned in Excel and entered in STATA version 15.0 for analysis. Data for birth cohorts of HEI and their mothers between April 2020 and September 2023 was collected. HEI who had the 6-12-week first HIV nucleic acid amplification test results were included in the study.

The primary outcome was the HEI testing HIV positive. Maternal and infant characteristics were analyzed using logistic regressions to determine the predictors of Infant HIV positivity. A P-value of less than 0.05 was considered significant

Results: A total of 223 mother-baby pairs (MBP) were included in the analysis with 52.91% (n=118) of the HEI being female, the maternal median age of 26 years (interquartile range 23-30), and Infant positivity of 2.24%(n=5/223). The odds of the infant testing positive was higher when the mother was non-suppressed (viral load greater than 1000) [adjusted odds ratios (aOR): 41.6, 95% confidence interval (CI):3.83-445.7, P=0.002], MBP identified from the community [aOR: 22.7, 95% CI: 1.72-2.99 P=0.018], Infant had mixed/complimentary breastfeeding [aOR: 12.3, 95% CI: 2.01-8.09, P=0.048], HEI did not receive Nevirapine prophylaxis [aOR:23.4, 95% CI: 0.83-653.9, P=0.064] and mother not being on antiretroviral therapy [aOR: 7.9,95% CI: 0.4067204- 155.4 P=0.172].

Conclusions: Maternal non-viral suppression, delivering with the community, and early mixed/complimentary breastfeeding were associated with higher infant positivity. Interventions to find pregnant mothers living with HIV within the community and supporting them to have viral load suppression could eliminate mother-to-child transmission.

EP325

The use of AI solution in the prevention and the response of re-emerging infectious diseases: a scoping review to identify the most recent use cases 2023

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Background: Infectious diseases continue to pose significant global health challenges, with their potential for widespread epidemics and pandemics. The COVID-19 pandemic has underscored the need for robust infectious disease control and management strategies. This scoping review explores the integration of Artificial Intelligence (AI) into healthcare systems to address infectious diseases. It assesses the potential applications of machine learning technologies in the diagnosis, monitoring, treatment, and control of emerging infectious diseases.

The objectives include identifying key use cases for AI in response to infectious diseases, by evaluating 2023 relevant peer-reviewed articles using PRISMA-ScR criteria.

Methods: The search strategy focused on the (PubMed [NCBI] database. The databases searched for only the 2023 published articles on the use of AI in the identification, control, or treatment of infectious disease and extracted all the relevant peer-reviewed literature, and a total of 113 articles were retrieved. Important AI applications were identified and highlighted for this scoping review.

Results: Machine learning (ML) and artificial intelligence (AI) are pivotal in healthcare. In antibiotic resistance, ML tools analyze phenotypic data and whole genome sequencing to pinpoint resistance patterns, guiding more precise antibiotic treatments. ML also aids in studying infectious diseases by integrating algorithms into simulation models to predict outbreaks and devise prevention strategies for diseases like AIDS and tuberculosis. Additionally, AI, notably Convolutional Neural Networks (CNNs), is transforming medical imaging diagnostics. For example, a study by Guimarães et al. (2023) showcased the potential of CNNs in diagnosing colitis by training them with real images and clinical parameters, though further refinement is needed for higher accuracy.

ML identifies biomarkers for critical conditions like sepsis. Ning et al. (2023) used ML algorithms to analyze gene expression data, revealing prognostic signatures such as the EVL gene, which has stable diagnostic value for sepsis, etc. Despite advancements, challenges persist, as seen in difficulties in achieving high diagnostic accuracy in colitis diagnosis studies.

Conclusions: The findings from this review contribute to our understanding of how AI can enhance infectious disease control and inform future research and development efforts. The integration of AI presents opportunities to strengthen healthcare systems' preparedness and response to infectious disease threats.

EP326

Increased emergency department utilization after HIV diagnosis in an urban, safety-net health system

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Background: Emergency department (ED) HIV testing programs are important for diagnosing persons living with HIV and may also serve to reduce ED utilization through care linkage. Our urban, safety-net ED utilizes routine, non-targeted, opt-out HIV testing. Healthcare seekers identified as living with HIV through our program are rapidly linked to care, and therefore may no longer need ED services. This could have great cost implications for the healthcare system, as well as improved health outcomes for people living with HIV.

We aim to characterize healthcare utilization before and after diagnosis, to better understand healthcare needs and opportunities.

Methods: A retrospective analysis was performed on hospital service use for six months before and after HIV diagnosis for all persons newly diagnosed in our ED (January 2016 – December 2017). Data was abstracted from electronic medical records, including number of ED visits pre- and post-diagnosis and demographics. The change in frequency of visits was evaluated using multilevel/mixed-effects regression.

Results: During the study period, a total of 287 people were newly identified as living with HIV. A majority (n=244, 84%) were Black, male (n=214, 75%) and mean age was 34.5 (IQR 26-49.5). With respect to HIV-related visits, healthcare seekers made an average of 0.02 visits in the pre-diagnosis period (0.004 [CI: 0.001 – 0.007] visits per month) and 0.21 visits in the post-diagnosis period (0.017 [CI: 0.012 – 0.023] visits per month), a significant increase (RR = 4.21, CI: 1.93 – 9.22). With respect to non-HIV-related visits, healthcare seekers made an average of 0.15 visits in the pre-diagnosis period (0.25 [CI: 0.016 – 0.035] visits per month) and 0.54 visits in the post-diagnosis period (0.045 [CI: 0.031 – 0.064] visits per month), a significant increase (RR = 1.80, CI: 1.29 – 2.53).

Conclusions: Healthcare seekers identified as living with HIV through our ED-based testing program showed a significant increase in ED service use post-diagnosis, despite access to alternative care services. Because EDs are well recognized to be a frequent source of care for people living with HIV, understanding health care utilization patterns of people living with HIV will be useful for improving service provision for this vulnerable population.



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Maintaining long-term saturation in DREAMS: minimum targets among adolescent girls and young women (AGYW) in Mozambique and Rwanda to ensure that successful DREAMS districts maintain their achievement through 2030

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Background: The PEPFAR DREAMS program aims to reduce the risk of acquiring HIV among HIV-vulnerable adolescent girls and young women (AGYW). As programs reach a point where 75%+ of vulnerable girls in a district receive services for their needs ("saturation") and are thus more protected against HIV acquisition, resource allocation ("targets") decreases as that district enters a saturated stage. Programs must ensure that ongoing targets are sufficient so the high percentage of previously-vulnerable AGYW served among the population does not fall as the population ages.

Among districts approaching saturation, there is uncertainty in how to establish adequate minimum targets to keep percentage of HIV-vulnerable AGYW who have completed protective services above 75%. We developed a method to produce minimum required 2023-2030 targets and compared actual 2024 PEPFAR AGYW targets to 2024 minimums to determine where targets were sufficient.

Methods: Population and HIV prevalence data from a variety of sources were used to produce estimates of the HIV-vulnerable AGYW population for each 5-year cohort (ages 10-24) to maintain saturation or achieve it within 5 years, starting with an assumption of 75% saturation. That common starting point was used to avoid complications between conflicting current methods of estimating saturation among countries.

For each year, we separate the incoming population to each cohort from the total population and apply two scenarios to estimate the number of incoming AGYW who would need to receive and complete at least the primary package of DREAMS programming to maintain 75% saturation. We conclude by taking actual 2024 targets and find where targets reached the necessary minimums.

Results: We produced minimum targets for DREAMS cohorts/age-bands and districts in both countries. 2024 targets were sufficient in 86.7% of Rwandan cohorts and

33.3-55.2% of Mozambiquan cohorts. Rwandan gaps were present for the 10-14 population (60% of cohorts sufficient). Mozambiquan gaps were present across all cohorts, from 18.8% to 87.5% sufficient depending on age and scenario.

Conclusions: DREAMS programming has contributed to reduced HIV incidence among AGYW. As countries reach saturation in DREAMS districts, they must ensure that minimum annual targets are aggressive enough to avoid losing this hard-won achievement.

EP328

"I am definitely smart enough to make this decision and I know what I'm doing": self-efficacy and HIV prevention education in the first US adolescent, CAB-LA PrEP study- HPTN 083-01

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Background: Comprehending HIV risk and protection options, paired with self-determining access to methods, empowers youth to make informed decisions about their risks for HIV. We sought to understand youths' personal motivations and experiences that influenced uptake of and persistence with long-acting injectable cabotegravir (CAB-LA) for HIV pre-exposure prophylaxis (PrEP) within the first adolescent CAB-LA trial in the US.

Methods: HPTN 083-01 investigated whether CAB-LA for PrEP was safe, tolerable, and acceptable for adolescents' assigned male at birth, including sexual and gender minorities. Nine males aged below 18 enrolled in Aurora (CO), Boston, Chicago, and Memphis from 2020-2022 and completed a series of five CAB-LA injections. Eight adolescents and four parent/guardians were interviewed near the end of the injection series about participant experiences of CAB-LA and motivations to join the study. Transcripts from the interviews were coded and analyzed using a thematic approach.

Results: The desire for independence and self-efficacy was a significant driver for participants to enroll, initiate and persist with CAB-LA injections. Four adolescents joined the study independently, self-consenting without guardian support, demonstrating exceptional self-efficacy and self-reliance. They felt smart enough to make decisions and did not expect parental permission or support. Their parents confirmed this experience, noting that their children often discussed the study in passing, arranging visits and transportation independently.

Additionally, majority of the participants reported strong motivation to adhere to the injection schedule after receiving appropriate sexual health education from clinic staff. Participants felt their new skills and knowledge al-

lowed them to protect themselves and others, utilizing the sex education they gained during the study. Parents/guardians also noted improved health education to be a notable benefit of their adolescent's study participation.

Health education	Participant	"I did wear condoms, but not enough. I was very overconfident and just not wearing it. I got help with education [from clinic staff] on it because my school did not really do that properly."
Health Education	Participant	"I enjoyed educating my friends on it because they don't really know anything about it. I feel like it's a very important thing to talk about, because it's a very taboo subject. I think talking about it is honestly the best way of prevention other than PrEP itself, is education."
Health Education	Parent	"At first, I thought for a minute he was like oh I get money with it [joining the study]. But I think it benefited him more with the education, because a lot of things he talk[s] about that I don't even know. And he tells me, „Mom, I'm really glad you put me in this because sometimes we can be reckless."
Self-Efficacy	Participant	"Just that it's a clinical trial, you never know. It's not approved. There's medical risks obviously. And they were just upset I didn't tell them, but obviously part of the reason I didn't tell them is because I didn't want to have to come out to my parents, because I honestly don't feel that my sexuality has anything to do with my parents in a way. It doesn't affect my day-to-day life like it does for a lot of other people. Which is why I wasn't outed by the study."
Self-Efficacy	Parent	"I mean, I have no impact because he's been really, I mean, I was kind of concerned about doing the study or doing this interview because I haven't been impacted by it much at all. He's been driving since he started, and I have never actually physically come in with him one time."
Self-Efficacy	Participant	I've talked to my best friend; I mentioned it to her, and I didn't tell my parents ever that I was participating in this until I had to tell them that I was coming in for the last appointment because they asked where I was going. So, I had to explain to them that I was going in for a study and then they searched all the studies on Fenway and found that this was the only one I could be in.

Conclusions: In HPTN 083-01, HIV prevention education and self-consent empowered participants to make informed decisions about HIV prevention options and remain adherent to their selected method. Providing youth with means and options to independently protect themselves promotes autonomy and, thus, ownership of their choices and sexual health safety.

EP329

Implications of correlates of engagement in commercial sex work among men having sex with men and transgender women in India: a warning bell for programme

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Background: Commercial sex work is prevalent among Men having sex with Men (MSM) communities worldwide, with varying degrees of engagement depending on cultural, socioeconomic, and local factors. MSM and Transgender Women (TGW) who engage in sex work are at higher risk of HIV transmission. Understanding of factors associated with commercial sex work among these key vulnerable populations is crucial for designing strategies

for HIV prevention. Our objective was to determine the correlates of commercial sex work involvement among MSM and TGW in the Indian context.

Methods: We present a baseline cross-sectional analysis of the prevalence of commercial sex work among MSM and TGW from a demonstration project studying the feasibility of daily oral Pre-Exposure Prophylaxis (PrEP) to MSM and TGW at Maharashtra, and Punjab, India conducted between December 2019 and July 2023.

The proportion of commercial sex work involvement was estimated and the correlates of engagement in commercial sex work were identified using binary and multivariable logistic regression models using STATA 16.1. Variables with a P value less than 0.05 were considered as independently associated factors with engagement in commercial sex work.

Results: Out of 865 screened participants [MSM=676 and TGW=189], with a median (Q1, Q3) age of 26 years (22, 30), 312 (36%) reported their engagement in commercial sex work with 122 (65%) TGW and 190 (28%) of MSM reporting it. Of the total 189 screened TGW, 11 (5.8%) were detected as HIV-positive. Participants having multiple partners (AOR=2.48, p=0.035), not using condoms with HIV-infected partners (AOR=2.57, p=0.001), recent anal sex (AOR=7.76, p<0.01), condom breakage/slippage (AOR=1.78, p=0.016), and requesting PrEP (AOR=3.8, p=0.004) reported increased odds of commercial sex in comparison with participants reporting no sex work involvement.

Conclusions: Commercial sex work was highly prevalent among TGW and MSM who voluntarily took PrEP in this study. MSM and TGW should be prioritized for assessment and PrEP delivery. High involvement of TGW in sex work requires continued access to condoms, lubes and lubricants. Denial about paid sex work among TGW who have multiple community and cultural level sanctions and prohibitions pose a challenge to HIV prevention program in India.

EP330

Early insights into PrEP choice counselling delivery from a community-based mobile site in Cape Town, South Africa

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Background: Oral, vaginal ring, and injectable HIV pre-exposure prophylaxis (PrEP) products necessitate the expansion of HIV counselling and testing (HCT) to include a PrEP choice component for interested HIV negative individuals. The PrEPared to Choose (PtC) study seeks to determine persistence on PrEP amongst adolescents and young people (aged 15-29 years) and their intimate partners (any age) when delivered as PrEP choice from a community-based mobile clinic setting in Cape Town, South Africa.





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Methods: A choice counselling script, informed by South African PrEP guidelines and constructed within a motivational interviewing framework, was co-created with PrEP providers (clinicians, HCT counsellors, peer navigators) and a Youth Reference Group. The final script, delivered by HCT counsellors, follows several multi-modal steps to convey PrEP information, contextualise product use, promote independent choice, and proactively identify barriers to use.

Participants' preferred PrEP choice, their level of interest (rated 0-10; 10 being high interest), their level of confidence in their ability to use the product (rated 0-10; 10 being high confidence), and the primary reason for their choice was recorded. PrEP was administered immediately after counselling, following clinical review.

Results: Of 145 participants, enrolled between 13 February - 18 March 2024, 53.10% were PrEP experienced. 76.55% (mean age 27; range 17-59) chose injectable PrEP, of which two went on to receive oral PrEP and one the vaginal ring, on clinical grounds. 22.76% chose and received oral PrEP (mean age 29; range 15-63) and one (age 22) chose and received the vaginal ring. 91.03% participants rated their interest in their chosen product $\geq 8/10$ and similarly, 95.17% felt confident ($\geq 8/10$) in their ability to use the product. 81.94% of those who selected oral and injectable PrEP chose the product due to compatibility with lifestyle, whereas the participant who selected the vaginal ring selected this product due to perceived safety over alternatives.

Conclusions: Early findings indicate high levels of PrEP interest and confidence after choice counselling. These ratings, along with reasons for choice and the discrepancy between choice after counselling and product initiated will be used to inform and interpret the primary analysis of PrEP persistence at seven and eighteen months.

EP331

From silence to celebration: how music and dance amplify operation triple zero (OTZ) clubs' impact in Kebbi State on the ACE 3 project

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Background: Adolescents and young persons living with HIV (AYPLHIV) often must contend with the fear and stigma associated with their diagnosis and usually without support from their community. Operation Triple Zero (OTZ) is a PEPFAR (President's Emergency Plan for AIDS Relief) Strategy targeted at achieving the UNAIDS 2nd and 3rd 95 goals, aimed at improving adherence and Viral sup-

pression among AYPLHIV between the ages 10-24 years who have gone through a complete disclosure of their HIV status. It focuses on fostering their health management skills to optimize their health outcomes.

Methods: The OTZ club is a curriculum-based program for adolescents, which consists of seven (7) modules led by trained OTZ Champions with support from Health Care Workers. It was initiated by the Project HOPE team in Kebbi State in 2022, with monthly meetings at two sites and currently at six treatment sites.

The sessions are facilitated in Hausa and English, and spiced with drama, music, and dancing competitions to make them engaging and interactive.

Results: The adolescents enjoy the dance sessions as some made requests for contemporary songs rather than the native songs. Expansion to additional treatment sites resulted in a 240% increase in attendance at OTZ meetings from 45 to 153, with 94% of the adolescents achieving viral suppression.

There is equal attendance among males and females, with adolescents within the age group 20-24 years having more participation than others between ages 10 -19 years.

Conclusions: Introducing the music and dancing sessions into the OTZ meetings has encouraged participation and promoted a sense of belonging. OTZ members, despite their health challenges, should be inspired to believe that they can achieve their dreams and fulfill their ambitions in life.

Increase in participation amongst the younger AYPLHIV will be encouraged to improve their suppression rate which is presently between 81 - 85% generally. The integration of entertainment into the OTZ curriculum and activities has fostered confidence, improved participation and viral suppression among the OTZ adolescents.

EP332

Curbing HIV transmission with PrEP: a modeling analysis of the impact of oral PrEP programming in Zambia

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Background: Zambia has one of the fastest-growing oral pre-exposure prophylaxis (PrEP) programs globally, with a 93% increase in annual new initiations from 2022 to 2023. However, in 2022, 33,000 people newly acquired HIV, reflecting significant unmet need for HIV prevention. To maximize impact, it will be critical to rigorously evaluate program impact and ensure PrEP programming targets those at highest risk of HIV. This analysis estimates acquisitions averted by age and sex to inform future prioritization and identification of gaps.

Methods: Oral PrEP program data was extracted for the period from January 2023 to December 2023 from DATIM. Oral PrEP initiations were disaggregated by age (5-year bands, 15-49) and sex at district-level. District-level HIV incidence estimates (disaggregated by age and sex) were gathered from Naomi Spectrum modeling for September 2023. To quantify the impact of oral PrEP, this analysis assumed a 74% HIV risk reduction associated with PrEP initiation, based on results from the SEARCH study. Based on the short time-period of focus (1 year), a static, excel-based model was used to estimate acquisitions averted by comparing scenarios with PrEP and with no PrEP among the number of initiators in each district and sex/age band.

Results: Based on analysis of 295,425 oral PrEP initiations, modeling estimates that between 945-3,078 acquisitions were averted in a single year with PrEP. The upper estimate assumes PrEP uptake was concentrated among higher-risk sub-populations within the overall age bands, while the lower range includes no adjustment for risk selection. Highest numbers of acquisitions averted were among females aged 20-24.

Estimated HIV acquisitions averted	No Background Incidence Adjustment	Moderate Background Incidence Adjustment (multiplier for higher incidence among MSM)	Key Population (KP) Background Incidence Adjustment (multiplier for higher incidence among MSM and FSW)	Full Background Incidence Adjustment (multiplier for all initiators based on risk selection)
	945	1,605	2,079	3,078

Table 1. Estimated HIV acquisitions averted by scenario

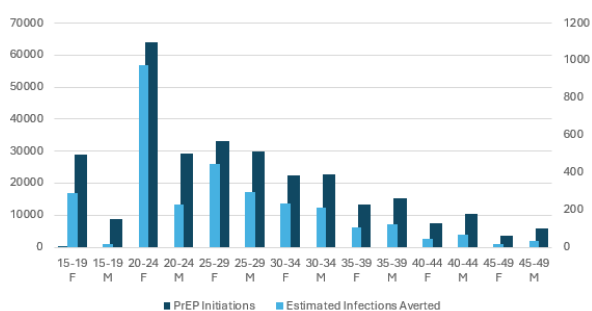


Figure 1. Oral PrEP initiations and estimated infections averted by population.

Conclusions: Oral PrEP made a substantial impact on the HIV epidemic in 2023. Reductions will be compounded when evaluating impact over a longer time period as background HIV incidence declines.

EP333

Breaking barriers: exploring HIV self-testing acceptance among vulnerable youth in Abuja, Nigeria

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Background: Out-of-school youth often face heightened vulnerability to HIV due to various factors including high-risk behaviors, economic hardship, gender norms, and limited access to structured information. Despite this, HIV testing rates among this demographic remain low, underscoring the necessity for innovative testing approaches such as HIV Self-Testing (HIVST).

This study aimed to assess the awareness, acceptability, willingness to pay, and preferences regarding HIVST among out-of-school youth aged 15-24years. Understanding these factors is crucial for designing targeted interventions to improve HIV testing rates and reduce transmission tendencies among this at-risk population.

Methods: A cross-sectional study was conducted across the six area councils of the Federal Capital Territory Abuja Nigeria, from October to November 2020. Time-location random sampling technique was adopted in this study, and a total of 363 respondents aged 15-24years were surveyed using an interviewer-administered structured questionnaire. Data analysis, comprising descriptive statistics and multivariable binary logistic regression, were undertaken using SPSS version23.

Results: A high proportion of respondents were single (72.1%), female (54.4%), unemployed (62.8%), and aged 20-24 (56.1%). Awareness of HIVST among respondents was low, at 29.1%.

Nonetheless, 71.9% expressed willingness to self-test using HIVST kits upon learning about the procedure. Moreover, 73.6% indicated a willingness to pay for HIVST kits, with prices ranging from USD1.38-USD4.16.

Preferences for accessing the kits varied, with 42.3% favoring pharmacies, 34.1% hospitals/clinics, and the remainder opting for local kiosks, supermarkets, or online platforms. Factors associated with acceptability of HIVST included older age (OR 1.2, 95%CI 1.1-1.3), being female (OR2.2, 95%CI 1.2-3.8) and a history of previous testing (OR 7.9, 95%CI 3.4-18.5).



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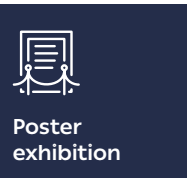


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Conclusions: Although awareness of HIVST among out-of-school young people is currently low, the study demonstrates a high level of acceptability for utilizing the self-testing kit. These findings suggest that with enhanced information dissemination and improved accessibility, HIVST could serve as a promising strategy to bolster HIV testing rates among this vulnerable population in Nigeria and improve our 95-95-95 agenda. Such insights are vital for designing targeted interventions aimed at curbing HIV transmission and promoting public health especially among younger males that have not been previously tested.

EP334

Impacts of the COVID-19 pandemic on sexual and gender minority people living with HIV in Thailand: a sequential mixed methods study

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Background: People living with HIV (PLWH) with intersectional marginalized identities experienced unique vulnerabilities and challenges in the COVID-19 pandemic. We explored the impacts of the pandemic and measures to control it on access to HIV care, gender-affirming care, and social determinants of health among sexual and gender minority PLWH in Bangkok, Thailand.

Methods: From March-November 2021, we conducted a web-based, cross-sectional, Thai-language (~45-minute) survey with sexual and gender minority PLWH recruited online via community-based organizations and HIV clinics in Bangkok. Questions examined pandemic-related challenges in access to ART/HIV care, gender-affirming care, and social determinants of health. From June-September 2022, qualitative semi-structured individual interviews (30-50 minutes) conducted online explored, in-depth, lived experiences of the pandemic. Survey data were explored using descriptive statistics. Qualitative data were transcribed verbatim, translated, and reviewed using thematic analysis. We merged and synthesized results across quantitative and qualitative data.

Results: Participants' (N=23) mean age was 34-years-old; range, 24-52 years. The majority (n=18; 78%) identified as cisgender (17 gay/bisexual men, 1 lesbian woman) and 5 as transgender (3 trans women, 2 trans men). Most (n=15; 65%) were single, with university education (n=17; 74%). Six (26%) were unemployed.

Four participants (17%) reported decreased access to ART ("It's really difficult; some medicines are in short supply") and one-fourth (n=6; 26%) reduced access to CD4/viral

load testing ("I'm not sure...I haven't tested because of the pandemic"). Ten participants (43%) reported past-year discrimination in healthcare. Trans participants reported reduced access to gender-affirming care: "I normally take hormones; just stopped during the pandemic because I was afraid..." and "I didn't have a job during the pandemic...it was because I had no money."

Several participants (n=6) who previously engaged in sex work reported financial hardship ("Your regular income is gone") and inability to qualify for government benefits due to ID cards based on birthnames/sex-assigned-at-birth and inability to verify employment/income. Nine participants (39%) reported food insecurity.

Conclusions: Pandemic-related decreases in access to ART, HIV and gender-affirming care, and unemployment, food insecurity, and inaccessibility of government benefits among sexual and gender minority PLWH indicate the imperative of community-engaged preparedness efforts and tailored interventions for COVID-19 and future public health emergencies.

EP334

Association between low-level viremia and advanced HIV disease at enrollment among clients', a risk for HIV transmission in Western Kenya

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Background: Low-level viremia (LLV) in HIV is associated with virologic non-suppression, a risk factor of HIV transmission. Few studies in Africa, have assessed the association between advanced HIV disease (AHD) at diagnosis and LLV. We analyzed the prevalence of LLV(51-999 copies/mL) at month 6 and 12 post antiretroviral therapy (ART) initiation and its association with AHD (CD4<200cells/mL), and the effect of 6-month LLV on 12-month viral load (VL) suppression (VLS:VLS<50 copies/mL) among clients aged ≥15 years enrolled under the Test and Treat strategy in 45 facilities in Kisii and Migori counties, Kenya.

Methods: A retrospective cohort analysis was conducted of clients enrolled in ART, October 2017-December 2021. clients with VL<50 copies/mL were considered fully suppressed. Clients with VL≥1,000 copies/mL or missing baseline CD4 count were excluded. The association between LLV and VLS excluded those with 6-month VL≥1,000 copies/ml. A complete case analysis was conducted, and five multiple imputations were performed to account for missing VL. Multivariable log-binomial regression models were used to estimate adjusted risk ratio (aRR) for all associations at 95% significance.

Results: Of 8,923 and 8,222 clients eligible for VL testing at 6 and 12 months, 7,838(87.8%) and 6,099(74.2%) had VL results with a median age of 30 (IQR: 23-38) years. The prevalence of LLV at 6 and 12 months was 9.7% (760/7,838) and 7.5% (460/6,099), respectively. Of those who had VL results, 3,344(42.7%) and 2,676(43.9%) had baseline CD4 count at six and 12 months, respectively. Clients with AHD had higher risk of LLV at six [$aRR=1.27$; $95\%CI:1.01-1.59$] and 12 months ($aRR=1.41$; $95\%CI:1.07-1.88$) as compared to their counterpart. With imputation, the association between AHD and LLV continued at both timepoints. Of 5,497 clients evaluated for LLV and VLS, 5,304(96.5%) achieved VLS and 597(10.9%) had LLV. Compared to fully suppressed, LLV was associated with decreased likelihood of VLS ($aRR=0.95$; $95\%CI:0.93-0.96$).

Conclusions: Clients with AHD were more likely to have LLV at six and 12 months, with those at six months less likely to reach VLS by 12 months following treatment initiation. Close clinical and adherence monitoring for clients with AHD is critical to improve VLS and prevent HIV transmission.

EP335

Effectiveness of m-Health technology in Improving HIV care continuity and service delivery among sex workers in Kenya

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Background: The delivery and results of health care can be enhanced by using mobile health technology, or m-health, which is the provision of health services and information via mobile phones through phone calls or messaging by addressing problems like accessibility to medical facilities, particularly in remote locations, Kenya's healthcare system's digitization holds the potential role to improve health outcomes.

This m-health innovation not only increases access to healthcare but also eases traffic and improves system performance overall. The main objective of this study was to assess the effectiveness of mobile health interventions in enhancing HIV continuity.

Methods: Weekly appointments were conducted using a longitudinal data gathering strategy for all sex workers in SWOP clinics in Nairobi Kenya through Making pre-visit calls, such as those for the seven, three, one, and actual dates of the anticipated visit, tracking forms, and putting in place a case management team to supervise the clients appointments and viral loads were ways this was achieved.

Results: Before the introduction of m-health appointment keeping was around 54% and a viral load uptake of 75%. After the implementation of m-health, appointment keeping improved by more than 86% and viral load uptake at 89%, enhancing health efficiency. Care clients were also free to disclose to the health provider any

health issues that might have prevented them from visiting the facility, such as being preoccupied at work, and receive assistance with medication at their convenience without having to visit the facility. These clients were also able to disclose obstacles to keeping appointments, and they would reschedule the appointment visit dates appropriately with the health providers improving HIV retention.

Conclusions: Reminders about viral load sample collection led to a rise in viral load uptake and an increased appointment-keeping rate, and the use of mobile health technology in conjunction with other retention strategies produced a noticeable improvement in HIV/care continuity and treatment outcomes in all swop clinics in Kenya.

To enhance the quality of care provided, it is necessary to increase the capacity of the health workers and provide clients with accurate health information on the need to provide accurate phone numbers for effective service delivery.

EP336

Additional services in HIV prevention services for effective hepatitis C diagnosis in people who inject drugs in Ukraine

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Background: War disrupts social environments and healthcare access, potentially increasing disease prevalence and the impact of risky behaviors. To address this, comprehensive strategies are needed that involve non-governmental organizations, healthcare workers, and other stakeholders in providing testing, counseling, and engagement activities. Collaboration with the public and local leaders is crucial to reach and involve vulnerable groups in disease prevention and testing initiatives.

Methods: Data were collected from the national registry "Syrex" of prevention programs for key groups. Based on the non-personal data, we were analyzed to determine the dynamics of the change in the yield of positive results of hepatitis C testing between 2020 and 2023.

Results: Non-governmental organizations (NGOs) received funding from state funding to implement programs for the prevention and treatment of hepatitis C among vulnerable PWID groups. The PHC center purchased 110,000 tests. This service has a significant impact on public health and contributes to reducing the incidence of hepatitis C among vulnerable PWID groups in Ukraine. In addition, social support and referral of clients for diagnosis and treatment of hepatitis C can provide individual support and assistance to patients at every stage of the treatment process.

The percentage of positive results decreased from 14.0% in 2020 to 9.3% in 2023. This may indicate some progress in reducing the effectiveness of programs for prevention and control of this disease.



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Year	Clients	Positive Clients	% Positive Clients
2020 pik	57225	7985	14,0%
2021 pik	38058	5399	14,2%
2022 pik	35167	5399	10,9%
2023 pik	39009	3641	9,3%

Conclusions: In November 2019, Ukraine joined the Global Hepatitis B and C Elimination Strategy by adopting the State Strategy for HIV/AIDS, Tuberculosis, and Viral Hepatitis Prevention until 2030. Within the framework of this Strategy, key goals and objectives aimed at eliminating viral hepatitis as a public health threat have been identified. According to the goals of the Strategy, by 2030, 90% of individuals with viral hepatitis are to be identified and treated.

Funding for the Public Health Center hepatitis C testing allows Non-governmental organizations (NGOs) to obtain necessary resources to implement programs among vulnerable PWDI groups, providing free access to services.

EP337

Decentralizing Uganda's diagnostic services to improve the efficiency of community HIV early infant diagnosis using point-of-care testing in Teso region: a pilot cross-sectional study

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Background: The Uganda Ministry of Health (MOH) established centralized early infant diagnosis (EID) by polymerase chain reaction (PCR) testing at the Central Public Health Laboratories (CPHL) in 2011 using dried blood spot (DBS) samples. The centralized EID PCR testing approach required establishing a national specimen transport system through the hub laboratory network to collect EID samples from across the country to CPHL for testing and dispatching results through the same mechanism. However, this had prolonged turnaround time (TAT) of results taking 14-30 days, thus delaying appropriate clinical decisions. We introduced and piloted point-of-care (PoC) EID PCR testing in Teso sub-region, Uganda, during 2019-2022 to improve TAT and linkage to care for infants identified with HIV. We then compared the TAT between the PoC and the non-PoC sites.

Methods: We piloted decentralized EID PCR PoC testing in 4 high-volume health facilities (Atatur, Kaberamaido, Katakwi and Soroti hospitals). Decentralization involved site assessment and validation, mentorship, and data management plans.

We documented the TAT for both the centralized and PoC EID PCR testing methods, and then conducted a comparative analysis of the TAT between the four pilot and five non-pilot health facilities. We extracted and reviewed data from the CPHL dashboard on EID TAT for October-December 2022.

Data were analysed using Stata version 15.0. Descriptive statistics and t-test were conducted to compare the differences in TAT for the two approaches.

Results: A total of 494 HIV exposed infants (HEIs) received PCR tests within the pilot period in the 9 health facilities, of which 40.3% (n=199) were analyzed using decentralized PoC. Average TAT was 16.6 (SD=12.7) days, 1.3 (SD=0.4) for EID PoC and 26.9 (SD=1.9) for non-PoC testing, and this difference was statistically significant (P<0.0001). All identified infants with HIV (n=5, 1.0%) were initiated on ART within two weeks of receiving results.

Conclusions: There was a significant reduction in TAT using EID PoC testing. Earlier scale up of the PoC in all the 9 hubs led to an overall improvement in TAT for the entire region to <3 days. Scaling PoC testing beyond the hubs might improve EID TAT across all health facilities to enable quick clinical decisions.

EP338

Stakeholder perspectives on a novel community-based peer-led biomedical HIV prevention intervention for women engaged in sex work in Uganda

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Background: HIV prevalence among Ugandan women who engage in sex work (WESW) is around 37%, yet uptake of oral pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) is suboptimal due to stigma and barriers to accessing healthcare. "Peer mentors" (peer leaders within WESW networks) could facilitate community-based PrEP/PEP delivery for WESW. We conducted formative research with key stakeholders to refine a potential community-based peer mentor-led PrEP/PEP intervention.

Methods: From July-August 2023, we conducted focus group discussions (FGDs) and key informant interviews (KIIs), informed by the Capability, Opportunity, and Motivation of Behavior (COM-B) model. Guides explored determinants of PrEP/PEP use, acceptability of hypothesized intervention components (monthly PrEP/PEP counseling, HIV self-testing [HIVST], peer delivery of PrEP refills, phone/SMS hotline for peer support, rapid PEP access), and ideas about additional intervention components. We recruited WESW, peer mentors, providers, and implementing partners in southwestern Uganda. FGD and KII transcripts were analyzed using a rapid qualitative analysis approach.

Results: We conducted 4 FGDs with WESW (N=20) and peer mentors (N=21) and KIIs with providers (N=4) and implementing partners (N=5). Most described substantial inter-

est in a peer-led PrEP/PEP model for WESW (Table 1). Community-based PrEP/PEP delivery with flexible hours and locations (e.g., bars, lodges) was suggested to address barriers to accessing health facilities. Peer mentors were perceived as trusted agents to increase PrEP/PEP awareness and deliver person-centered care for WESW, in partnership with clinicians. Participants emphasized the need for comprehensive and ongoing peer mentor training and supervision. Integrated PrEP/PEP and family planning products and HIVST provision were also described as key intervention components to empower WESW and support differentiated service delivery.

Kip, a social influence campaign to destigmatize PrEP use and create a more enabling environment for PrEP uptake among female sex workers (FSW) and adolescent girls and young women (AGYW) in South Africa.

Methods: We compiled social media metrics derived from the Le Kip Kip campaign alongside in-depth interviews (August-September 2023) with Le Kip Kip campaign implementers, specifically community mobilizers and PrEP champions (n=30), as well as community members (n=36) in three campaign-targeted districts: Zululand, uMgungundlovu, and Ngaka Modiri Molema.

We descriptively summarized social media views/followers and used a mixed methods approach to interrogate the reach of the campaign by strategies.

Results: Between Oct 2022-Sep 2023, a total of 899 100 unique people viewed the campaign page on Facebook and 70 696 from Instagram. Although young women were the campaign target group, messages also reached men and parents/older individuals (Figure), which aligned with campaign goals of changing PrEP social norms more broadly.

The Le Kip Kip campaign successfully disseminated de-medicalized PrEP messages and information to young women. Parents were reached through door-to-door interactions. Venue-based and face-to-face dialoguing from community-based PrEP champions and mobilizers were perceived by community members as critical to disseminating campaign materials to various audiences, allowing for personalized discussions and tailored information-sharing.

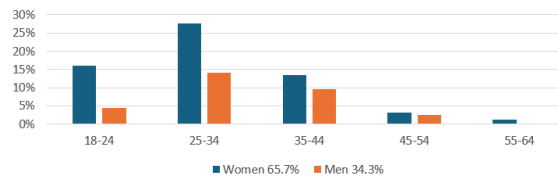


Figure 1. Le Kip Kip campaign Facebook page followers, segmented by age and gender demographics (n = 1937).

Conclusions: The Le Kip Kip campaign successfully leveraged social media to reach and engage target audiences. Moreover, the role of community teams proved invaluable in disseminating campaign materials and fostering meaningful engagement with the campaign. A holistic approach combining digital strategies with in-person communication is essential to ensure that HIV prevention information reaches all segments of the population.

COM-B construct	Barriers to PrEP/PEP use among WESW	Proposed peer mentor-led strategies to address barriers to PrEP/PEP	Representative Quotes
Capability	<ul style="list-style-type: none"> Misconceptions about PrEP and PEP (e.g., PrEP is the same as HIV treatment) Limited knowledge of PrEP Limited knowledge of how PrEP and PEP differ Concerns about side effects Confusion about how long protection benefit is sustained after stopping 	<ul style="list-style-type: none"> Community-based PrEP demand creation from peer mentors PrEP/PEP counseling from trained peer mentors who can speak from own experience Relationship building between peer mentors and health facility staff to troubleshoot challenges and learn about PrEP/PEP Peer ongoing support and reminders to address concerns that may arise 	<p>PrEP provider on peer mentors as PrEP champions: "Peer mentors of course are like our PrEP champions. They are the ones who teach the community about PrEP and they bring fellow sex workers for the services."</p> <p>Implementing partner on peer mentors to provide HIV counselling while disseminating their own experiences: "Communicating is about information sharing. For them (peer mentors) we shall not ask them may be medical counselling, but we shall ask them to tell people about their lived experiences, so they already know what they do. All we need to give them is the skill of communication."</p>
Opportunity	<ul style="list-style-type: none"> Community stigma about PrEP Inability to discreetly travel with PrEP Long lines at healthcare facilities PrEP/PEP stock-outs No money for transport to get to facility Lack of safe places to store PrEP/PEP Refills irregularly and infrequently offered at hotspots 	<ul style="list-style-type: none"> Peer delivery of PrEP/PEP at convenient community locations (e.g., bars, lodges, hotels, brothels, peer mentor's home) Phone/SMS hotline for WESW to request refills and report PrEP/PEP challenges Flexible PrEP refill options (1-month or 3-month refills) depending on ability to store pill containers and adherence PrEP/PEP counseling by peers, with potential for additional community or phone sessions as needed, to troubleshoot concerns 	<p>Peer mentor on importance of community-based PrEP/PEP delivery: "ensure PrEP and PEP services reach the hotspot and the sex workers are aware of the services and can easily access them, and ensure that the [peer mentor] is facilitated to deliver to them at their hotspots (community areas where WESW are based)... majority of the sex workers don't want to come to health facility to get their refills because of stigma that other people will think that they are HIV positive."</p> <p>Provider on WESW preferring PrEP from a peer in the community: "I believe peer mentors are going to work better [for PrEP uptake and also maybe with accessibility. I] know my peer mentor who is giving me PrEP - that can go to find her at hotel X or bar X - I may go there at any time I feel like, [rather than waiting for the schedule of the facility]."</p>
Motivation	<ul style="list-style-type: none"> PrEP/PEP use needs to align with one's own desires to prevent HIV Differing preferences around prevention options taken daily (PrEP versus over a shorter time [PEP]) Differing prevention needs for preventing HIV with romantic partners, clients, and in instances of sexual violence or rape Motivation depends on saliency of HIV (e.g., recent HIV test result) 	<ul style="list-style-type: none"> HIVST kits to empower WESW to know their HIV status and motivate PrEP/PEP use Integrated PrEP/PEP and family planning service delivery to address multiple health needs among WESW Rigorous peer mentor selection process by fellow WESW to ensure that peer mentors are trusted and respected community members 	<p>WESW on value of hearing about PrEP/PEP from a peer with similar experiences and HIV prevention motivations: "A peer knows what it means, when she is told that you have been exposed to HIV and when you ask her to deliver like PrEP. She may put on your shoulder and bring [PrEP/PEP] to you immediately because she would have experienced the same at some point and she can easily help... she will be there for us in case of any need for PrEP or PEP services."</p> <p>WESW on HIVST to facilitate PrEP use: "There are female sex workers who have never tested for HIV and do not know about their HIV status, and they may prefer that HIV testing kit because no other person will access their test results and when they test negative they will also be in position to start taking PrEP."</p>

Table 1. Barriers to PrEP/PEP for Ugandan WESW and opportunities for a peer-led approach, informed by COM-B.

Conclusions: A peer-led PrEP/PEP delivery strategy could address key barriers to biomedical HIV prevention use among WESW in Uganda. Subsequent research is needed to test whether this approach can increase PrEP/PEP use among WESW.

EP339

Reach of a social influence campaign to destigmatize PrEP and facilitate PrEP uptake among women in South Africa: a mixed method study

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Background: Pre-exposure prophylaxis (PrEP) has emerged as a highly effective HIV prevention method, but low awareness and uptake stymie HIV prevention efforts for marginalized women. We analyzed the reach of Le Kip

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Prevalence of sexually transmitted infections in healthcare clients with mpox in a large health center in Houston: a cross-sectional study

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Background: The 2022 mpox outbreak disproportionately affected men who have sex with men and people living with HIV (PLWH); groups at higher risk for STIs, and whose health needs are too often neglected. Testing for HIV in key populations remains suboptimal. We determined the prevalence of STIs in people with mpox who presented to a large health center in Houston, TX. This serves to target interventions aimed at screening, treatment, and prevention of STIs.

Methods: We conducted a retrospective cross-sectional study on adults aged 18 and above diagnosed with mpox with a PCR test between 6/1/2022 and 12/31/2023 in a large county health system in Houston, TX, United States. Data on demographics, symptoms, diagnostic testing, and treatment were collected from electronic health records, and analyzed performing descriptive statistics.

Results: A total of 111 persons with mpox were included, with a median age of 34 years (range 19-60), comprising 69 (62%) Hispanic, 33 (30%) Black, and 7 (6%) White individuals. Of those, 107 (96%) identified as male, two as female, and three as transgender.

Overall, 9 (71%) reported to be MSM, and 14 (13%) bisexual. There were 83 (75%) PLWH and 34% had an HIV RNA >200 copies/ml. Genital lesions were present in 79 (71%), and only 59 persons were tested for STIs. Among tested individuals, 17 (29%) had a new STI diagnosis. Of those, 12 tested positive for *N. gonorrhoeae*; 4 for *C. trachomatis*; and 8 for syphilis; 4 clients tested positive for 2 STIs. Of the 28 (25%) people who did not have HIV, 4 were on PrEP, and only 11 were tested for HIV, with two persons newly diagnosed.

Conclusions: STIs were considerably prevalent in people with mpox, and testing for these conditions was suboptimal. Clinical cues in this population warrant special consideration for testing and treatment.

We recommend the implementation of patient-centered comprehensive STI testing and counseling in people presenting with mpox. Healthcare practitioners' awareness of these findings will contribute to addressing the health needs of MSM and PLWH. It will also contribute towards the 95-95-95 goals set by WHO.

EP341

Identification of venues for HIV prevention interventions through overlapping HIV transmission and venue elicitation networks

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Background: The analysis of HIV sequences via molecular cluster detection can provide valuable insights into HIV transmission. These data are particularly useful for guiding the allocation of HIV/AIDS resources when analyzed in conjunction with information about venues where people meet sex partners. We assessed the overlap of HIV molecular and venue networks in the largest HIV clinic in Mexico City.

Methods: From July 2019 to December 2022 patients newly diagnosed with HIV and returning to care were invited to participate in a survey and donate a blood sample. HIV pol sequences obtained from all participants via Sanger sequencing were used to infer the molecular network, applying pairwise genetic distance methods with a 1.5% threshold using Seguro HIV-TRACE. Summary statistics were generated to describe and compare the study population overall and by cluster status using chi-squared tests or t-tests. Venues were classified by the clustering status of the individuals reporting the venue.

Results: A total of 7502 people living with HIV were included; 92% were men, 72% were sexual minority men (SMM), 52% used illicit drugs in the past 3 months, and 51% were clustered. Clustered participants were more likely to be male ($X^2=36.3$, $p<0.001$), younger $F=289.6$, $p<0.001$), use illicit drugs in the past 3 months ($X^2=22.2$, $p<0.001$), use more drugs ($F=8.7$, $p=0.003$), and use drugs during sex $X^2=22.2$, $p<0.001$ compared with non-clustered participants. A total of 1176 unique venues were nominated, with clustered participants nominating more venues than non-clustered (657 vs. 501), nominating nightclubs more often (16.5% vs. 13.8%) and their residences less often (2% vs. 4%) compared to non-clustered participants.

Importantly, 72% and 71% of nominations of one specific *cuarto oscuro* and one specific hotel (respectively) were mentioned by clustered participants.

Conclusions: This analysis combining molecular and venue network information identified venues in Mexico City where HIV prevention interventions could be administered to reduce future HIV transmission. Venues are important for HIV prevention interventions due to their role in shaping risk networks, facilitating transmission, and providing opportunities for targeted prevention strategies. Tailoring prevention efforts to specific venues and populations frequenting these settings is essential for effectively reducing HIV transmission.

EP342

High levels of vulnerability among adolescent girls and young women (AGYW) enrolled in a crossover pilot study of a dual prevention pill for HIV and pregnancy prevention in Harare, Zimbabwe

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Background: Oral pre-exposure prophylaxis (PrEP) is effective for HIV prevention, but uptake among adolescent girls and young women (AGYW) has been low due to multiple factors, such as power dynamics, economic status, stigma, and education. A dual prevention pill (DPP) combining PrEP with oral contraception (OC) could potentially increase PrEP use by addressing stigma associated with using Truvada for PrEP, since it is the same drug that is used for HIV treatment. We describe the characteristics of AGYW in a study evaluating the acceptability of an over-encapsulated DPP.

Methods: We enrolled 30 sexually active, HIV-uninfected, non-pregnant, 16-24-year-olds in a crossover study comparing a DPP capsule to PrEP and OCs taken separately (November 2023-September 2024).

Participants completed a baseline survey in Shona via computer-assisted self-interviewing including questions about HIV/pregnancy concerns, power, violence, and transactional sex.

Results: Most (97%) of participants (mean age 19 y/o) completed only primary education, 47% were married, 30% were divorced (30%), 97% had ≥1 child, and 37% sometimes/often went 24h without food. 37% reported multiple sexual partners, 86% had sex with ≥1 partner in the month before screening, 75% had not used a condom at last sex and 42% said their partner(s) would be angry if asked to use a condom. 46% said their partners have more say about important decisions, 27% stayed in a relationship for financial/material support, 21% experienced violence from partners; and 14% had been physically forced to have sex.

One participant knew her partner was living with HIV; 9 did not know their partners' status; 43% thought they were somewhat/very likely to have been exposed to HIV within 4w of screening; 83% were worried about getting HIV within 3m; and 90% said it was very important to avoid pregnancy.

Only 2 participants had used PrEP before joining the study. Assumed preferences at baseline were 53%, DPP; 17%, 2 pills (PrEP, OCs); 30%, either regimen, equally.

Conclusions: Baseline data indicate multiple risk HIV factors among AGYW, few of whom had ever used PrEP. Interest in the DPP indicates the potential that a dual prevention method may have to empower AGYW to prevent HIV and unintended pregnancy.

EP343

PrEP prescription bottleneck: a global analysis of provider cadres across the PrEP service delivery cascade

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Background: Oral pre-exposure prophylaxis (PrEP) delivery was slow to decentralize and become more accessible, due to monitoring requirements and doctor-dependence. As more PrEP products are introduced, it is vital to understand which service delivery approaches facilitate PrEP uptake. This analysis explores cadres providing PrEP services at three stages: counseling, prescribing, and dispensing.

Methods: AVAC's Global PrEP Tracker has collected data on 431 PrEP projects/programs from 2016-2023. A cross-sectional statistical analysis of 10 PrEP service cadres (doctors, nurses, community health workers (CHWs), NGO staff, pharmacists, medical officers, physician's assistants, family planning nurses, researchers) across counseling, prescribing, and dispensing was conducted on the 116 projects that reported cadres data.

Results: Of 116 projects, 47% were based in Africa, 22% in Asia, 21% in Europe, 8% in Latin America and the Caribbean, 2% in North America, and 2% in Oceania. They reported 362 counselors, 180 prescribers, and 210 dispensers (Figure 1). Primary cadres counseling on PrEP were doctors (21%), nurses (20%), and CHWs (14%); those prescribing PrEP were doctors (52%), nurses (21%), and medical officers (9%); and those dispensing PrEP were pharmacists (35%), nurses (21%), and doctors (16%). The prescription stage had the fewest total providers and lowest cadre diversity globally and in every region except North America. Regionally, in Africa, the primary cadres counseling, prescribing, and dispensing PrEP were nurses (22%), doctors (35%), and pharmacists (36%), respectively; in Asia, they were doctors (20%), doctors (83%), and pharmacists (37%), respectively. The greatest diversity in prescribers was in Africa (35% doctors, 30% nurses, 12% medical officers), and lowest in Europe and Asia (72% and 83% doctors, respectively).

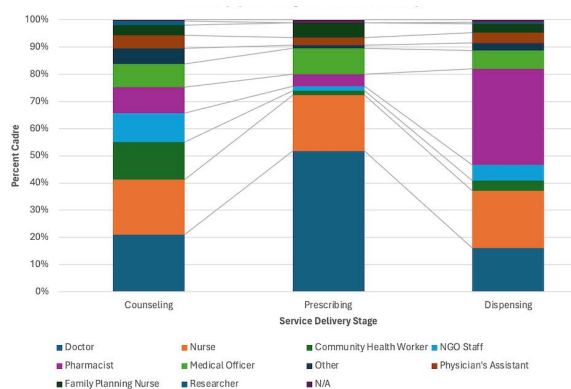


Figure 1. Cadres (%) delivering PrEP services globally.



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Conclusions: End users often encounter access barriers to doctor-provided services and obtaining a prescription from a provider other than counselors and dispensers can restrict access. Diversifying cadres authorized to prescribe PrEP, in alignment with counseling and dispensing cadres, could expand access.

EP344

Evaluating knowledge, practice and barriers to cervical cancer screening: a cross sectional study in women living with HIV, Northern Tanzania

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Background: Cervical cancer is the fourth most common cancer globally among women in incidence and mortality and one of the most common cancers affecting women in Tanzania. 8% of HIV-Positive women are disproportionately at a higher risk of developing the disease.

The aim of this study was to assess the knowledge, practices and barriers to cervical cancer screening among HIV- Positive women in Moshi Municipality, Kilimanjaro in northern Tanzania.

Methods: A cross-sectional study was conducted in the Kilimanjaro region among 215 HIV-Positive women attending care and treatment centers (CTC) at Mawenzi regional hospital and KCMC hospital between 8 July and 21 July 2021. A questionnaire was used for data collection using face-to-face interviews.

The study population were HIV Positive women aged 18 to 49. Data were analyzed using SPSS version 20.0. Frequencies and percentages summarized categorical variables and numerical variables summarized using median and interquartile range (IQR).

Results: 64.1 % of the participants had a good level of knowledge on cervical cancer risk factors. 52.2% women had poor knowledge on the signs and symptoms of the cervical cancer, 69.3% had good level of knowledge on cervical cancer preventive methods.

Over half, 64% of HIV-Positive women in this study had ever screened for cervical cancer. And among these 29.9% had their cervical cancer screening in the past 12 months. HIV status, advice from health care providers and screening campaigns were the reasons for undergoing cervical cancer screening. 85.0% received information on cervical cancer from health professionals and 47.7% from media and 20.1% of them from family/relatives.

Among the barriers to cervical cancer screening, afraid for the bad results was 71.5%, afraid for the test procedure was 59.8%, lack of disease symptoms was 46.7%, no reason for the test was 24.3%, never heard screening was 22% and not prescribed by the doctor was 20.1% of which commonly mentioned by the participants.

Conclusions: Women living with HIV demonstrate moderate screening rates, influenced by healthcare advice and campaigns. Health professionals are the primary source of information. Barriers to screening of cervical cancer suggesting a need for focused education and addressing psychological concerns to improve screening rates.

EP345

PrEP awareness and none- use among HIV high-risk adolescent girls and young women from fishing communities around Lake Victoria, Uganda: a cross-sectional survey

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Background: Adolescent girls and young women (AGYWs) have disproportionate HIV risk relative to the general population in Uganda. PrEP use among high-risk AGYWs from most at-risk fishing communities could reduce the HIV burden. We explored PrEP awareness and non-use to inform HIV prevention programming among AGYWs in fishing communities.

Methods: A cross-sectional survey was conducted between August 2023 and January 2024, as part of recruitment for a prospective observational multisite AGYW cohort study (the MAGY study) among three fishing communities along Lake Victoria, Uganda. 400 HIV seronegative AGYWs, at risk of HIV infection, aged 15-24 years responded to an interviewer-administered questionnaire on social demographics, PrEP awareness, and PrEP use. Awareness was defined as ever heard about PrEP, and could describe it. Use as ever taken or currently on PrEP. We employed logistic regression models to evaluate factors associated with PrEP awareness and use.

Results: Participants' median age was 19 (IQR 15-24) years, majority (n=329, 82%) were currently not in school, half (n=200, 50%) were a parent/caregiver, almost half (n=184, 46%) were currently caring for dependents, almost a quarter (n=99, 25%) were currently living with partner, slightly a quarter (n=101, 25%) were depending on their sexual partners as a source of income.

Overall PrEP awareness was high at 83% (n=330), with 17% (n=69) aware of PrEP but not able to specify any details, 27% (n=107) aware of its use, 38%(n=151) were aware of the oral pills and 1%(n=3) were aware of injectable options. Participants who were parents were more likely to be aware of PrEP relative to non-parents [AOR= 2.29, (95%CI 1.363 – 3.852)].

Most AGYWs were not currently using PrEP [68%, (271/400)]. Participants who were not parents were more likely not to use PrEP relative to parents [AOR= 0.38, (95%CI 0.199 –

0.724)]. Likewise, participants who had four to six people in their household were less likely not to use PrEP compared to those who had one to three people in their household.

Conclusions: We observed that majority of high-risk AGYWs were not using PrEP. There is an urgent need for targeted interventions to improve PrEP use among AGYWs in these communities.

EP346

Adapting an evidence-based group care model to create centering PrEP for Black women

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Background: Black women experience high rates of HIV acquisition but have not been adequately included in HIV prevention and Pre-Exposure Prophylaxis (PrEP) retention program development research. Community-empowered approaches are successful at reducing HIV acquisition among marginalized populations. Centering Health-care (Centering) is a group model of care that utilizes community empowerment to improve health outcomes and reduce health disparities. Centering involves regular group sessions (cohorts of 8-12 clients) with the same providers, integrating individual health assessments, service linkages, and interactive learning centered around clients' experiences. This innovative approach holds great potential for meeting the HIV prevention and PrEP care needs of Black women.

Methods: We utilized the Assessment, Decision, Adaptation, Production, Topical Experts, Integration, Training, Testing (ADAPT-ITT) framework a model for adapting evidence-based interventions to create Centering PrEP for Black women. We detail the application of ADAPT-ITT phases and the use of diverse qualitative methods. Data emerged from collaborative stakeholder meetings, individual interviews ($n=20$), focus groups with Black women ($n=12$) interested in or taking PrEP, and individual interviews with care providers ($n=5$). We partnered with the community to create a culturally adapted 3-session implementation and facilitator guide for Centering PrEP for Black women.

Results: Five themes emerged from qualitative analysis and were incorporated into the curriculum: 1) Black Love, 2) Providers lack of PrEP knowledge, comfortability, and communication, 3) Facilitators of PrEP include PrEP as protection, racially concordant PrEP providers, 4) Barriers to PrEP include assumptions about Black female sexuality,

fear of knowing HIV status, and 5) Perceptions of Centering include desire to center Black women's experience, empowered response to medical mistrust, and Centering outside of health systems.

We developed a 3-session implementation and facilitator guide for Black women on PrEP. Black women ($n=18$) and care providers ($n=5$) expressed interest in a group care model specifically designed to meet the needs of Black women receiving PrEP.

Conclusions: The curriculum and implementation plan are ready for theater testing so that the feasibility and acceptability of Centering PrEP for Black women can be assessed in preparation for an adequately powered implementation trial.

TUPE225

A discreet demand creation platform that educates MSM about HIV and the benefits of HIV prevention and treatment

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Background: While access to HIV services has expanded in South Africa, one key population remains underserved: men who have sex with men (MSM). The estimated HIV prevalence among MSM in South Africa is 48%, with an estimated range between 13.2%-58.4% across districts. MSM often face stigma and discrimination that prevents them from accessing respectful, relevant, and approachable HIV prevention and treatment services.

In 2021, financed by MSD Foundation, PSI, together with Matchboxology, the Aurum Institute & Pivot Collective, launched the Yim'Lo (meaning this is me) Project to expand access to HIV services among MSM in South Africa. Yim'Lo implements a two-pronged intervention co-created by MSM to address HIV service barriers:

The intervention addresses gaps around demand creation, friendly service provision, and poor engagement in HIV treatment services. Conducted in collaboration with targeted interventions for MSM run by non-government organisations, with linkages to public healthcare services. Healthy Men Project is a digital platform that aims to educate MSM about HIV and the benefits of HIV prevention and treatment. This platform enables MSM to access HIV-related services such as testing, and linkage to care.

Methods: Between June-August 2023, PSI and partners (Aurum Institute, Matchboxology, Pivot Collective) sought to evaluate the impact of the Yim'Lo Project among clients (referred to as 'players' in the programme) and coaches (MSM peers) through in-depth interviews conducted in Gauteng and KwaZulu-Natal.



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Results: Adverts were promoted on various social media platforms targeted to areas where programs and clinics were operating. Over a period of two months, adverts reached 690 male users [aged 18-49 years old], of which 54% accessed HIV information, 14% were linked to peer support, 5% engaged with HIVST services and 3% engaged with PrEP services. The topics that generated the highest traffic were traditionally taboo ones, such as anal douching.

Conclusions: Interventions that provide access to information or links to services whilst providing anonymity could enhance service uptake and improve access to and engagement with information on topics such as STIs and HIV.

Such tools reduce stigma and increase the awareness of HIV and benefits of treatment in a way that makes HIV more socially acceptable.

WEPE084

Patterns and predictors of HIV pre-exposure prophylaxis discontinuation and re-engagement in care at a safety-net healthcare clinic in Atlanta

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Background: Oral PrEP efficacy relies on sustained medication adherence over time. PrEP discontinuation is associated with increased risk of HIV acquisition.

The Grady Health System PrEP Program in Atlanta aims to enhance PrEP accessibility at a safety-net healthcare setting.

Methods: This post-hoc analysis evaluated the characteristics of PrEP discontinuation among individuals who initiated PrEP between June 1, 2018, and March 1, 2021, utilizing pharmacy refill data. PrEP discontinuation was defined as a medication gap over 120 days. Sociodemographic and clinical predictors of discontinuation were examined using logistic regression models.

Results: Of all 257 individuals, mean age was 33.7 years, 72.8% were Black, 78.2% were male assigned at birth, 47.1% were men who have sex with men (MSM), and 20.9% had a positive STI at PrEP initiation (Table 1).

The PrEP discontinuation group had lower proportion of MSM (34.8 vs. 64.9%). Of all participants, 63.4% had at least one PrEP discontinuation and 50.2% never restarted PrEP. Median time to re-engagement after each PrEP discontinuation was approximately 57 days.

Younger age, identifying as transgender women or, heterosexual men, and negative baseline STIs were associated with PrEP discontinuation (Table 2).

Variable	Total (N=257) n (%)
Age: Mean (SD) / Median (Min, Max)	33.7 (12.0) / 31.0 (15.0, 68.0)
Sex: Female/ Male	56 (21.8%) / 201 (78.2%)
Race and Ethnicity: Black White Hispanic	187 (72.8%) 42 (16.3%) 19 (7.4%)
Gender Identity: Cis-men/ Cis-women/ Queer*/ TGW/ TGM	152 (59.1%) / 54 (21%) / 2 (0.8%) / 47 (18.3%) / 2 (0.8%)
Mental Health Diagnosis: Yes/ No/ Missing	72 (28%) / 180 (70%) / 5 (1.9%)
Drug use in the last 6 months: Yes/ No/ Unknown/ Missing	81 (31.5%) / 132 (51.4%) / 38 (14.8%) / 6 (2.3%)
PrEP Indication: MSM/ TGW/ HSM/ HSW/ Other	121 (47.1%) / 47 (18.3%) / 24 (9.3%) / 45 (17.5%) / 20 (7.8%)
Serodiscordant Partner: Yes/ No	35 (13.6%) / 222 (86.4%)
STI at Baseline: Positive/ Negative	53 (20.6%) / 204 (79.4%)

*Gender queer or non-conforming

Table 1. Baseline characteristics

	Coefficient	Odds Ratio	Conf. Int (95%)	p
Intercept		46.79	0.70 – 3662.61	0.077
Age		0.97	0.94 – 0.99	0.018
Used Drugs in the Last 6 Months: Unknown		2.9	1.09 – 8.32	0.038
PrEP Indication: TGW		3.46	1.55 – 8.23	0.003
PrEP Indication: HSM		2.84	1.05 – 8.29	0.046
STI at Baseline: Negative		2.25	1.12 – 4.61	0.024

Table 2. Factors Associated with PrEP Discontinuation

Conclusions: This study provides valuable insights into PrEP discontinuation patterns in a high-incidence HIV area, with a focus on racial and ethnic minority populations. Utilizing pharmacy refill data enhances our understanding of real-world PrEP utilization, guiding efforts to optimize PrEP delivery and long-term engagement in HIV prevention. To address disparities, future implementation science studies should focus on innovative strategies for reducing PrEP discontinuation in vulnerable populations.

WEPE095

Migrants living with HIV/AIDS: the hidden epidemic in the Russian Federation

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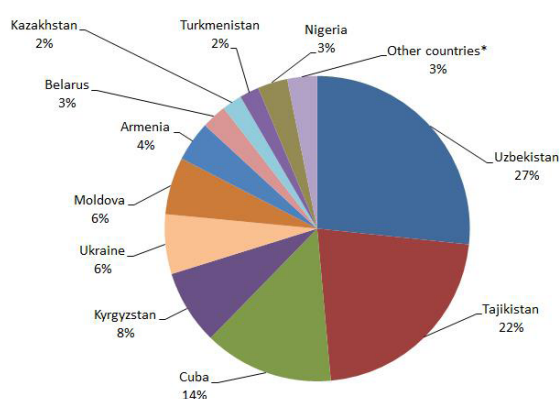
Background: Russia is one of 19 countries in the world that deport migrants living with HIV. As a result, most HIV migrants remain in the country illegally and are unable to seek social, medical and other assistance, which in turn aggravates the HIV epidemic in the EECA region. This marginalized group is also excluded from the Global Fund and other major international HIV programs.

Methods: Steps Charitable Foundation was founded on the initiative of people living with HIV in 2004, and it has been working with representatives of the most vulnerable groups: MSM, SW, PLHIV, PWUD, migrants, homeless, etc. In response to the crisis, in 2020, the "Step to Health"

program, unique for the country and the EECA region, was launched, intended to support migrants and other persons in mobility in need of assistance with HIV care and other public health challenges. Laboratory investigations, antiretrovirals, consultation by social workers and medical specialist are the available services in the foundation.

Results: There were 689 distinct benefactors from different nations between January and June 2023, the majority of them were from the EECA region and Cuba. Some of the benefactors had no identity documents (Table).

Distribution of migrants by key groups were as follows: MSM – 59.6%, SW – 38.5%, PWUD – 15%, TGL – 7.5%. Of the total key groups, 49% were HIV-positive. Rapid testing investigation at the foundation revealed 10% syphilis cases, 8.5% HIV, 4% HCV and 1.5% HBV cases. The foundation provided 243 antiretroviral regimens. By the end of the last year, 88% of HIV-positive beneficiaries achieved undetectable viral load and adhered to treatment.



Conclusions: The "Step to Health" program fulfils the provision of a full cascade of services in the context of HIV, from prevention to treatment. Representatives of key groups - migrants - who were not previously covered by HIV service programs were reached.

WEPE214

Breaking barriers: a model for PrEP provision to MSM in Lebanon

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Background: HIV is a concentrated epidemic in Lebanon, with the majority of diagnoses occurring among men who have sex with men (MSM), while comprehensive HIV prevention services remain largely inaccessible. A study in 2019 found that 40% of new HIV diagnoses were among individuals who had received education on prevention and had access to HIV testing and condoms, highlighting the importance of providing PrEP as part of prevention

services. The aim is to present a model of a PrEP provision service to the MSM community in Lebanon that alleviates barriers and reduces HIV acquisition.

Methods: In March 2023, a collaboration emerged between Lebanon's National AIDS Program (NAP), a community-based sexual health center, and an academic medical center aimed to provide free access to PrEP. The NAP secured the medication, while the sexual health center provided a safe space for MSM to receive free HIV tests, pre and post counseling, and medical consultations from an ID specialist who dispenses the PrEP to them directly upon completing their clinical evaluation. The recipients renewed their supply by a follow-up visit. During the consultation, participants were educated on prevention interventions and the different methods of taking PrEP.

Results: Between March 2023 and March 2024, 74 MSM were enrolled in the PrEP program. All were Lebanese, with a mean age of 31.4 years. 53% (39 individuals) presented for at least 1 follow-up visit. All 39 tested negative for HIV upon their follow-up visit(s) indicating zero sero-conversions. All 39 reported adherence to their preferred method of PrEP.

Conclusions: The presented model is unique in Lebanon and managed to alleviate barriers that have hindered access to prevention services for the population that is most vulnerable to HIV. In a country burdened with stigma and discrimination and a frail healthcare system, this partnership helped support MSM.

In addition to providing free PrEP, this program facilitates medical and social follow-up and ensures that MSM receive non-stigmatizing information and medical advice from professionals in a safe space.



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OA107LB

HIV trends in metropolitan U.S. cities from 2014–2022: baseline for the U.S. ending the HIV epidemic (EHE) initiative

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Background: The EHE initiative aims to decrease HIV incidence by 90% by 2030 in the 57 counties/states responsible for half the incident infections. EHE was announced in 2019 and phase I nears completion, our analysis provides a counterfactual comparator for future evaluation.

Methods: We used 2014–2022 Metropolitan Statistical Area (MSA) data to compare trends in HIV incidence rate between MSAs subsuming EHE regions (N=46) and other MSAs (N=73). A difference-in-difference analysis illustrated potential early-stage program effects.

Results: Across 119 MSAs from 2014–2022, 384,793 HIV cases were diagnosed with a mean change in MSA-level incidence of -4.94% (range:-55.14–333.3%) over the period. On average, MSA-level incidence changed by -19.70% (range: -55.14% to 19.30%) amongst MSAs including EHE regions and by 4.35% (range:-59.1% to 333.33%) in other MSAs over the study.

A difference-in-difference analysis indicated the incidence change among EHE MSAs was 2.07 cases per 100,000 people-years (p=0.03) higher than the base change rate in 2020–2022. These findings were robust to timeframe variations.

Measure	2014-2022	2015-2022	2016-2022
MSAs not targeted by EHE (n=73) (range)			
HIV incidence (period start)	9.55 (0.6 – 25.6)	8.52 (1.9 – 21.1)	8.76 (1.7 – 21.7)
HIV incidence (period end)	8.65 (2.1 – 22.2)	8.65 (2.1 – 22.2)	8.65 (2.1 – 22.2)
EHE Regions MSAs (n=46) (range)			
HIV incidence (period start)	21.22 (8.3 – 49.9)	21.22 (6.3 – 51.2)	21.22 (9.1 – 47.0)
HIV incidence (period end)	16.15 (7.2 – 38.3)	16.15 (7.2 – 38.3)	16.15 (7.2 – 38.3)
Model Outcomes (95% CI)			
Baseline annual change to HIV incidence	-0.73* (-0.91 – -0.56)	-0.72* (-0.92 – -0.52)	-0.83* (-1.07 – -0.59)
DiD Estimate: Difference in annual change to HIV incidence with EHE program	2.07* (0.68 – 3.46)	2.05* (0.73 – 3.38)	2.17* (0.88 – 3.45)

NOTE: DiD Estimate is for illustration only; we do not expect an impact of EHE programs in this time period.

Table: Summary of difference-in-difference (DiD) outcomes.

Conclusions: Although MSAs including EHE regions experienced greater HIV incidence reductions compared to other MSAs, high inter-regional variability requires exploration of program implementation and transmission drivers. These trend insights provide a baseline to aid future assessments of EHE program impacts.

OA0307LB

HIV BG505 SOSIP.664 trimer with 3M-052-AF/alum induces broad and potent ADCC-mediated antibodies

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Background: Adjuvants are known to play a significant role in the quality of immune responses elicited by a vaccine, but direct comparisons of adjuvants with the same immunogen in a clinical trial setting are rare. HVTN 137-Part B is a phase 1 clinical trial to evaluate the immunogenicity of the HIV-1 subtype A stabilized trimer, BG505 SOSIP.664 gp140, in combination with different adjuvants: the TLR9 agonist CpG 1018, the TLR7/8 agonist 3M-052-AF, both given with Alum, the TLR4 agonist GLA-LSQ, or Alum alone. The vaccine adjuvanted with 3M-052-AF+Alum was able to elicit autologous tier 2 neutralizing antibodies.

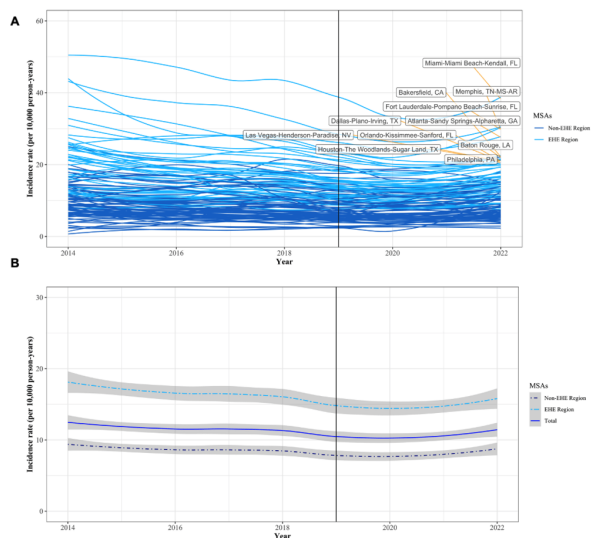


Figure. MSA-level HIV incidence from 2014 through 2022 by EHE classification (Panel A). Mean HIV incidence by EHE classification from 2014 through 2022 (Panel B).

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Methods: We measured antibody-dependent cellular cytotoxicity (ADCC) responses to understand the impact of different adjuvants using an ADCC Luciferase-based assay to quantitate killing of BG505 Envelope-Infectious Molecular Clone (Env-IMC)-infected target cells.

We subsequently assessed the breadth of ADCC responses in positive responders using cells infected against a panel of four Env-IMCs previously reported to have differing levels of susceptibility to ADCC (breadth panel).

Results: 3M-052-AF+Alum-adjuvanted vaccine elicited robust ADCC responses against BG505-infected cells in 6/16 and 11/16 participants two weeks post second and third dose, respectively, with the average magnitude of responses also increasing among positive responders after the third dose. In comparison, only 1/18 participants in the CpG 1018 group mounted detectable responses two weeks post second dose, and no other participants in the other groups had detectable ADCC activity.

Additionally, between 2 and 8 of the 11 positive responders in the 3M-052-AF+Alum group post third dose were able to mediate ADCC against the different Env-IMCs in the breadth panel.

Interestingly, vaccine-elicited responses could recognize Envelopes less susceptible to ADCC.

Conclusions: 3M-052-AF+Alum represents a potent adjuvant that can elicit broad ADCC responses in addition to neutralizing responses and represents a strong candidate for use in future HIV vaccine trials.

OA0507LB

Early virologic success on ART following breakthrough infection on CAB-LA PrEP

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Background: Long-acting cabotegravir (CAB-LA) PrEP could reduce HIV incidence globally. Breakthrough infections are rare but reported; the clinical consequences of acquiring HIV on CAB-LA are not well-defined. We report the first case series of treatment outcomes following HIV acquisition on CAB-LA PrEP.

Methods: SeroPrEP is an ongoing U.S. study examining HIV infection on PrEP. Clinical test results were obtained from participants' medical records. Serology was confirmed by BioPlex 2200 HIV Ag-Ab. Mutations in plasma HIV RNA were identified by single-genome sequencing (SGS) of

full-length *integrase*. CAB concentrations were quantified in plasma and segmented hair via liquid chromatography-tandem mass spectrometry.

Results: Among three SeroPrEP participants who developed breakthrough HIV infection despite on-time CAB-LA injections, median time on CAB-LA was 280 days before first detectable HIV-1 RNA. Two participants had negative point-of-care antigen/antibody testing with RNA required for HIV detection (PID1: RNA 3,940 c/mL; 6 injections; PID2: RNA 4,880 c/mL; 5 injections). One participant (PID3) had reactive laboratory-based antigen/antibody with HIV RNA 2,430,000 c/mL after 13 injections. In PID1, SGS revealed low-frequency (<5%) INSTI mutations E138K and N155K on separate dates not identified by commercial Sanger. No INSTI mutations were detected in PID2 by Sanger. PID3 had Q148Q/R by Sanger and additional low-frequency mutations: G140G/S, N155N/H, R263R/K by commercial NGS. CAB was detected in both plasma and hair in all participants. All participants initiated DRV/c/F/TAF; PID1 and PID2 had undetectable viral loads 35 and 47 days post-ART start, respectively. In PID3, HIV RNA declined from 248,103 c/mL while on DRV/c/F/TAF to 22 c/mL 28 days post-switch to BIC/F/TAF.

Conclusions: Among three individuals in the U.S. who acquired HIV on CAB-LA PrEP despite on-time injections and detectable drug levels, two required RNA for HIV detection. All achieved early virologic success on ART, with two of three on protease inhibitor-based regimens. One participant with multiple low-frequency INSTI mutations achieved early viral suppression on BIC/F/TAF.

Follow-up is needed to assess the durability of INSTI-based ART following breakthrough on CAB-LA PrEP.



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OA0607LB

Phase 1 dose-escalation trial to evaluate the safety, tolerability, pharmacokinetics and neutralization activity of PGDM1400LS in combination with VRC07-523LS and PGT121.414.LS in healthy participants without HIV (HVTN 140/HPTN 101)

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Background: Passive immunization with broadly neutralizing antibodies (bNAbs) presents a promising HIV prevention modality.

Studies suggest that bNAb combinations targeting multiple HIV-1 epitopes and clades are necessary for effective prevention. HVTN140/HPTN101 evaluated the safety, tolerability, pharmacokinetics, and neutralization activity of PGDM1400LS (V2 apex) administered in combination with VRC07-523LS (CD4 binding site) and PGT121.414.LS (V3 glycan) in healthy adults, without HIV.

Methods: The study was a multicenter, randomized, open-label study conducted in Africa and the United States. After establishing the safety of a single administration of PGDM1400LS in Part A (n=15), Part B (n=80) enrolled adults aged 18-50 years without HIV who received two doses of PGDM1400LS, VRC07-523LS and PGT121.414.LS four months apart. In the five bNAb combination groups, each bNAb was administered at weight-based doses of 20mg/kg or 40mg/kg intravenously, 20mg/kg subcutaneously or a fixed dose of 1.4g either intravenously or subcutaneously. Safety was evaluated through solicited and unsolicited adverse events.

Pharmacokinetic parameters were estimated using a two-compartment population pharmacokinetic model. bNAb serum concentrations were measured by anti-idiotypic binding antibody assays. Serum neutralization was assessed against viruses sensitive to each of the three bNAbs administered and a panel of recently circulating HIV-1 strains.

Results: Median age was 25.5 years, and 50.5% were assigned female sex at birth. Most participants reported mild-to-moderate solicited local and systemic symptoms. The median estimated elimination half-life of PGDM1400LS was 54 days, not significantly influenced by co-administration with VRC07-523LS and PGT121.414.LS. Compared to IV administration, the bioavailability of PGDM1400LS administered subcutaneously was 75.5%.

The median estimated elimination half-life of PGT121.414.LS was 66 days, with subcutaneous bioavailability of 77.7%. The median estimated elimination half-life of VRC07-523LS was 45 days, with subcutaneous bioavailability of 80.1%.

Weight-based and fixed-dose regimens showed similar pharmacokinetic patterns. ID80 neutralization titers aligned with predicted values, indicating sustained neutralization activity in vivo, with broad and potent neutralization against both bNAb-sensitive isolates and recently circulating HIV-1 strains. No treatment-induced anti-drug-antibody responses were observed.

Conclusions: The bNAb combination of PGDM1400LS, PGT121.414.LS, and VRC07-523LS was safe and well-tolerated, with no pharmacokinetic interactions or loss of complementary neutralization. These findings strongly support the evaluation of this triple combination in future efficacy trials.

OA0706LB

Transcriptional microenvironment of persistent SIV tissue reservoirs is associated with tertiary lymphoid organs in the colon and characterized by stress-induced decreased protein synthesis

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Background: Despite effective antiretroviral therapy (ART), HIV-1 persistence is the major obstacle to a functional cure. Thus, understanding the tissue microenvironment during ART of the reservoirs that lead to a rapid viral rebound after treatment failure or analytical treatment interruption (ATI) is key.

Methods: We have developed immunoPET/CT-guided spatial transcriptomics, combined with immunofluorescence detection of viral proteins and viral sequencing using the SIV/rhesus macaque model. With this approach, we can find and study foci of viral replication in tissues of all animals.

Here we compare the local neighborhood of the rebound eclipse-phase foci (4-6 days post-ATI) from animals initiating ART 4 days (early-seeded reservoir with short lifespan) or 10 weeks (well-seeded reservoir) after high-dose challenge, as well as early-seeded tissues from animals on ART for 3 or 7 weeks.

Colon tissues containing infected cells foci were identified with a ⁶⁴Copper-labelled probe against viral envelope. Subsequently, sections were validated by PCR for SIV DNA, evaluated by immunofluorescence to localize SIV proteins, and characterized by 10x Visium Spatial transcriptomics system.

Results: Overall, SIV presence in every condition is associated with higher transcriptional levels and up-regulation of genes related to SIV infection. Activation of innate immune responses is observed only in the eclipse-phase of the rebound for both types of reservoirs indicating the specificity of the analysis.

Notably, we also detect significant differences between early- and well-seeded reservoirs. Translation activation is associated with SIV presence in early-seeded but down-regulated in well-seeded reservoirs, while mitochondrial translation is activated in all cases. This is consistent with stress-induced decreased protein synthesis in well-seeded reservoirs.

Afterwards, we inferred frequencies of cell types per foci by transcriptional. SIV presence after ATI in well-seeded reservoirs was associated with epithelial cells, IgA plasma cells, monocytes, and cycling gamma-delta T-cells, while in early-seeded reservoir is associated with epithelial cells, IgG plasma cells, Th17 cells, and cycling DCs.

Conclusions: Our results indicate that persistent reservoirs are associated with tertiary lymphoid organs in the colon and might be characterized by a status of low translation consistent with stress responses.

This status could be favoring long-term viral persistence during ART and rapid rebound of robust viral populations post-ATI.

OA0802LB

Pharmacokinetic superiority of a 3-month dapivirine vaginal ring (100 mg) compared to the 1-month dapivirine vaginal ring (25 mg)

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Background: The dapivirine vaginal ring (monthly DVR), currently approved for use in eleven African countries, is a HIV prevention method for women for use over one month. An extended-use option, the three-month DVR (3-month DVR), offers several advantages over the monthly DVR, including reductions in cost, waste, and replacement frequency.

To bridge the efficacy data for the monthly DVR to the 3-month ring, we conducted a relative bioavailability study comparing PK profiles of the two rings.

Methods: We conducted a phase I, open-label, randomized, crossover trial (IPM-054) to investigate the relative bioavailability of monthly DVR, replaced every 30 days, to 3-month DVR for 90 days. We randomized healthy female participants to treatment sequence separated by a 28-day washout period. Plasma and vaginal fluid samples were collected at multiple timepoints over the two treatment periods and residual dapivirine levels in used rings were measured.

We compared the primary endpoints of plasma dapivirine concentration at Day 90 just prior to ring removal (C_{90}) and plasma exposure during the last 30-day use period (AUC_{0-90}) between the two treatments using mixed effects models with treatment sequence, treatment, and period as fixed effects, and participant within sequence as a random effect. PK parameters were log-transformed in the model so that the treatment difference provides ratio estimates when back transformed.

Non-inferiority for the 3-month to monthly DVR was predefined as the lower bound of the 90% confidence interval of the ratio (90% CI) exceeding -5% for both primary endpoints with superiority predefined as the lower bound of the 90% CI exceeding 1 for both primary endpoints.



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Results: 124 women (mean Age 28.8, range 19 - 45) were enrolled and randomized, with 104 completing all study visits. Criteria for both non-inferiority and superiority were met for C_{90} (90% CI of ratio: 1.06; 1.22) and AUC_{0-90} (90% CI of ratio 1.02; 1.15).

Conclusions: This study demonstrated that the 3-month DVR is pharmacokinetically superior to monthly DVR, suggesting that the efficacy of the 3-month ring will be at least equal to that of the 1-month ring. These data support the use of the 3-month ring as an alternative to the 1-month ring.

OA0803LB

Acceptability, adherence, preference and safety of placebo Long-Acting Pre-exposure Prophylaxis (LA-PrEP) injections and implants for HIV-prevention in South African men: the SAMURAI study

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Background: Globally and in South Africa(SA), cisgender men underutilize safe and effective HIV-prevention strategies. Early-stage research of new prevention modalities with male end-users offers the opportunity to assess attitudinal, behavioral and safety factors that may influence initiation and persistence with novel drug delivery platforms for long-acting (LA)-PrEP.

Methods: We conducted a 12-month crossover study called SAMURAI where men-who-have-sex-with-men (MSM) and men-who-have-sex-with-women-only (MSW) in Cape Town and Johannesburg, SA, used placebo versions of bimonthly injections and a six-month implant in randomized order. Acceptability, defined as satisfaction with, and future willingness to use, each product, was measured with 10-point rating scales (10=high).

Adherence was defined as initiation and persistent product use during their respective periods. Adverse events(AE) and social harms(SH) were monitored at all visits. LA-PrEP preference was assessed at study exit.

Results: From July 2022 through June 2024, 184 cisgender men (n =84 MSM, n=100 MSW) were enrolled, with 86% retention. More men initiated injections than implants (97.8% vs. 91.3%, p=0.009); 164(89%) used both products. 80.6% of men initiating injections were persistent users (35 missed bi-monthly doses). 91.1% of men initiating implants persisted with use (median 6.0, range 2.3-14.6

months); 15(9%) requested early removal. Persistent use was significantly higher for implant vs. injections (OR 3.11, 95%CI: 1.38, 7.03, p=0.006). The average user-satisfaction rating was 8.6(SD 1.8) for injections and 8.4(SD 1.9) for implants (p=0.44). Likelihood of future use was 8.9(SD 1.8) for injections and 8.7(SD 2.3) for implants (p=0.28). Among those who tried both products, injections were preferred by 48.4% and implants by 47.7%. All AEs (200 reported by 102 participants) and serious AEs (4 reported by 4) were unrelated to product use. Four participants (2%) reported study-related SH of physical or emotional violence, or stigma.

Conclusions: South African MSM and MSW were successfully enrolled and followed to use novel placebo LA-PrEP products. Each delivery form was highly acceptable and equally preferred, reinforcing the importance of PrEP choice, including within LA options.

Significant differences between product initiation and persistence suggest that familiarity with delivery form and frequency of clinic dosing visits influenced men's behavior, with implications for persistence in use of future LA-PrEP methods.

OA0804LB

Early implementation of long-acting injectable cabotegravir for HIV prevention in a safety net primary care center in U.S. South

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Background: There is limited data on the implementation of long-acting injectable Cabotegravir (LAI-CAB) for HIV Pre-Exposure Prophylaxis (PrEP) in real-world settings. We describe the early implementation and outcomes of our LAI-CAB program.

Methods: First, we described the clinical and logistical steps to integrate LAI-CAB into a primary care-based oral PrEP program. Through manual retrospective chart review, we described the sociodemographic, clinical, and social determinants of health (SDOH) of all patients referred to the LAI-CAB program from 12/1/2022 to 8/1/2023, and assessed LAI-CAB PrEP linkage, eligibility, enrollment, and initiation.

We also assessed reasons for interest or declining LAI-CAB, total numbers of injections administered, proportion of on-time injections, HIV seroconversions, self-reported adverse events, and discontinuation.

Results: To address known structural barriers to PrEP uptake, we applied a multidisciplinary team-based approach, streamlined our medication procurement process and HIV testing strategy, and adapted our integrated patient tracking system to minimize late injections.

Of all referred individuals, 77 (35%) initiated LAI-CAB. Their median age was 37 (IQR 29-42), and gender identities were cisgender man (63%), cisgender woman (26%), and

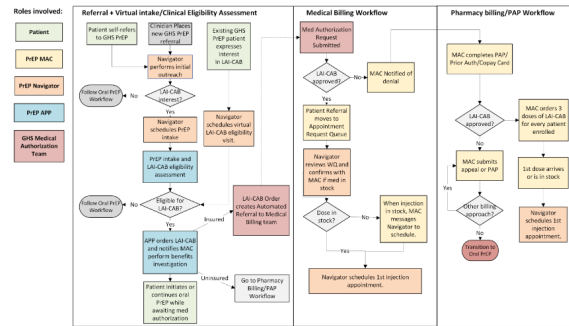


transgender woman (8%). Barriers to initiation included: scheduling delays for intake appointments (29%), individuals declining LAI-CAB (19%), and delays in medication procurement (16%). In total, 275 injections were administered, with 94% of subsequent injections delivered on time. Of patients who initiated LAI-CAB, 6 (8%) reported adverse effects and 8 (10%) discontinued LAI-CAB. There were no HIV seroconversions.

Methods: HIV RDT results were reviewed for people initiating CAB-LA in the PrEPared to Choose study, in Cape Town, South Africa, from February - June 2024. A 3-step HIV screening process was used, which included checking for signs and symptoms of AHI, ruling out HIV exposure in the past 72 hours (requiring postexposure prophylaxis) and a negative HIV RDT at point-of-care (POC). ONSITE Ab/Ag (4th generation) RDTs (at a mobile clinic site) and ABON HIV Ab (3rd generation) RDTs (at a government clinic site), were compared to NAAT (HIV RNA-1 viral load) results from the same day, done at an offsite laboratory. The Viral Load (VL) result was not known before CAB-LA initiation.

Results: 718 people (female 68,0%, (488/718), median age 23 years, IQR 15-29; male 32,0%, (230/718) median age 30 years, IQR 16-59) commenced CAB-LA following a negative HIV RDT. A 4th Gen HIV RDT was used in 68,1% 489/718 (female 62,2%, 304/489; male 37,8%, 185/489) and a 3rd Gen HIV RDT was used in 31,9% 229/718 (female 80,3%, 184/229; male 19,7%, 45/229). A total of 3/718 (0,4%) had a discrepant detectable VL: 1/489 (0,2%) 4th Gen RDT (>10 000 000 cp/mL) and 2/229 (0,8%) 3rd Gen RDTs (253469 cp/mL and 9251 cp/mL). There was no difference observed between those who received 3rd and 4th generation RDTs when stratified by gender, age, prior PrEP use and compared to VL positivity. Participants with detectable VLs were started on Tenofovir/Lamivudine/Dolutegravir treatment, within 5 days of CAB-LA initiation.

Conclusions: Acute HIV Infection was not detected by HIV RDTs in 3/718 (0,4%) people who were started on CAB-LA. Public health benefit must be weighed up against individual risk of same day RDT for CAB-LA PrEP where NAAT testing is not feasible.



Abbreviations: Grady Healthcare System (GHS), Long-Acting Injectable (LAI), Medication Access Coordinator (MAC), Patient Assistance Program (PAP), Pre-exposure Prophylaxis (PrEP)

Figure 2. Cabotegravir patient flow from referral to first injection.

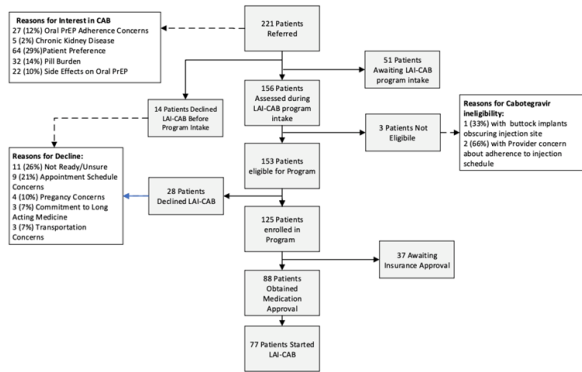


Figure 2. Cabotegravir referral to initiation care continuum.

Conclusions: We successfully implemented an LAI-CAB PrEP program in a primary care center designed to address structural barriers to PrEP uptake and persistence.

OA0805LB

Use of HIV rapid detection tests when initiating long-acting cabotegravir for HIV prevention, within an implementation science project

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Background: Viral resistance mutations may occur during acute HIV infection (AHI) if long-acting injectable cabotegravir (CAB-LA) is initiated concurrently. HIV rapid detection tests (RDTs) may miss AHI, while nucleic acid amplification testing (NAAT) is not feasible in many resource constrained settings. Data is needed to quantify the risk of third and fourth-generation HIV RDT use with CAB-LA pre-exposure prophylaxis (PrEP).

OA0806LB

Whole-genome sequencing of HIV in rural Kwa Zulu Natal does not support the role of age-disparate disease transmission underpinning the HIV prevalence gender-gap

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Background: Women aged fifteen to twenty-four years old carry a disproportionate burden of the new HIV infections diagnosed in Southern Africa. Whilst the causes of this HIV gender-and-age are unclear, one key hypothesis argues that age-disparate relationships with older men drives infection in younger women.





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Methods: We conducted whole-genome sequencing of HIV in a large phylogenetic study to model the transmission of the virus between demographic groups in the rural setting of KwaZulu-Natal, South Africa, utilising data from the Vukuzazi cohort. Samples with HIV viral loads >50 copies/ml were submitted for whole-genome sequencing. Adequate sequences were arranged into genomic clusters using a maximum likelihood phylogeny. Potential transmission pairs within clusters were analysed alongside the age and sex data of participants. The distribution of pairings between different age and sex groups was compared to a model in which pairs were drawn from the HIV positive population by chance.

Results: The Vukuzazi cohort enrolled 18025 participants, 6069 of whom were HIV positive, and 1232 of whom had viral loads over 50 copies/ml; sequencing of these samples yielded 1097 adequate genomes. Phylogenetic analysis produced 89 clusters containing a total of 205 individuals, and 73 possible linkages between men and women. Only 32 of these 89 potential transmission links (36%) were between men in an older age group than the woman. When compared to a model population in which pairings between men and women in different age groups occurs randomly in the within the sample, the number of pairs in all age-sex combinations was within the 95% confidence interval if pairs were drawn randomly.

Conclusions: Our data does not support the assertion that the gender gap in HIV prevalence is driven by older men pairing with younger women. This dogma has been used to influence public health messaging over the last 2 decades, based on previous research, and may be less true than initially thought.

Current work suggests that there likely is a contribution of age-disparity in transmission, though with significantly smaller age gaps than initially suggested.

OA0807LB

Bayesian methods provide a posterior probability by day for possible dates of HIV acquisition which is useful in clinical trials

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Background: Precisely identifying the time of acquisition is important to evaluate correlates and protective thresholds in HIV prevention clinical trials. However, estimating acquisition timing is often challenging due to relatively sparse visit schedules and variable biomarker detection during early HIV acquisition.

To address these challenges, statistical methods were developed to better estimate the time of acquisition from control cohorts (FRESH/RV217) for application to prevention trials such as the AMP trials.

Methods: Timing estimation methods utilized either diagnostic test markers or sequence diversity from HIV-1 GP (gag/Δpol) and REN (rev/vpu/env/Δnef) regions. For AMP, we used Bayesian methods to combine these estimators and thus obtain higher precision and accuracy. The resulting Bayesian estimator outputs posterior probability

distributions, from which we generated point estimates and credible intervals (CI) for the timing estimates, as well as date of diagnosable acquisition (DDA), with the goal of comparing them to the gold standard data from the accurately timed acute acquisition FRESH and RV217 studies. The "gold standard" estimator for DDA was computed as the mid-point between a participant's true last negative and first positive diagnostic tests, which is accurate and very precise (4 days, range 2-7 days) due to the frequent sampling in these studies.

Results: Overall, the 95% credible interval (CI) was smaller for the combined estimator (median width 6 days, IQR 4-21.5 days) than for the diagnostic estimator alone (median width 15 days, IQR 11-23 days). The overall coverage of the COB was lower for the combined than the diagnostic estimator (0.515 vs. 0.835, respectively) although the CI is more accurate for combined. The differences between the estimators were especially notable in antibody negative samples [median 95% CI width (IQR) 3 days (3-5 days) versus 12 days (7-14 days) for combined and diagnostic respectively].

Conclusions: Accurate timing estimators help evaluate the effectiveness of preventive measures and understanding time of HIV acquisition can help tailor intervention doses, in bNab studies such as the AMP and future trials. Acute infection data, as described here for the RV217 and FRESH cohorts, also provide valuable insights into viral dynamics associated with acquisition and establishment of infection.

OA1107LB

Assessment of infusion-related reactions after intravenous administration of HIV monoclonal antibodies PGT121.414.LS, PGDM1400.LS or VRC07-523LS (alone or in combination with PGT121, PGDM1400, 10-1074, PGT121.414.LS, PGDM1400.LS), in five phase 1 studies

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Background: Monoclonal antibodies (mAbs) are used to treat and prevent diverse clinical conditions, including infectious diseases, and hold promise for HIV prevention via passive immunization. Infusion-related reactions (IRRs) include a constellation of systemic signs and symptoms, that have a temporal and likely causal relationship to mAb administration. Knowing the frequency and characteristics of IRRs after mAb administrations is critical to establishing a safe and well-tolerated HIV prevention strategy.

Methods: This retrospective, cross-protocol analysis assessed five phase 1 randomized, multicenter studies conducted in the US, Switzerland, South Africa, Kenya, and Zimbabwe in people living without HIV. We assess the frequency and characteristics of IRRs among participants



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who received intravenous (IV) infusions of single mAbs and dual or triple combinations. The dosing range was 2.5 to 40 mg/kg of one mAb single dose or every 16 weeks. Additionally, mAbs were sequentially administered in dual or triple combinations at 20 to 40 mg/kg or 1.4 g per mAb every 16 weeks. HVTN127/HPTN087 (n=59), HVTN128 (n=24), HVTN130/HPTN089 (n=27), HVTN136/HPTN092 (n=20) and HVTN 140/HPTN 101 (n=57).

Results: 187 participants received 492 infusions. Median age was 27 years and 56% were assigned female at birth. Sixteen participants (9%) reported 21 IRRs (4% of infusions), all of which were mild (n=16) or moderate (n=5). Twelve (57%) occurred in participants who received VRC07-523LS alone and 9 (42,9%) occurred after a combination. The most common reported symptoms were fatigue, chills, myalgia and headache. Most reactions started within a few hours after the infusions were completed and resolved by 24 hours without intervention. Ten (47,6%) occurred after the first administration, and IRRs were not noted to be more severe after a subsequent infusion. IRRs led to permanent discontinuation in 6 (38%) participants, 3 after their second IRR.

Conclusions: IRRs after IV administration of anti-HIV mAbs in these trials were uncommon, mild to moderate, and most were self-limited. These findings support the safe administration of these mAbs combinations by IV infusions in future HIV prevention clinical trials.

OA1207LB

HIV BG505 SOSIP.664 trimer with 3M-052-AF+alum induces a lasting IFN signature that correlates with the development of HIV-1 antibodies

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Background: HVTN137 is a phase 1 trial evaluating the safety and immunogenicity of HIV-1 BG505 SOSIP.664 gp140 (BG505SOSIP), a stable soluble envelope, with distinct adjuvant formulations, including 5mcg of TLR7/8 adjuvant 3M-052-AF+alum, and alum alone. During dose-escalation testing (Part A), BG505SOSIP+3M-052-AF+alum generated autologous tier 2 HIV-1 neutralizing antibody responses in 3 of 5 vaccinees.

In comparisons with other adjuvants (Part B), we studied immunological signatures of blood and rectal tissue to identify how these adjuvants activate innate responses, potentiate antibody responses, and return to homeostasis.

Methods: Participants received placebo (n=6), BG505SOSIP+alum (n=6) or BG505SOSIP+3M-052-AF+alum (n=8) at months 0, 2, and 6. Blood was collected at baseline, days 1, 3, and 7 post-first immunization and 2.5 weeks post-third vaccination (2.5WPTV); with cells evaluated by flow cytometry and differentially expressed genes (DEGs) assessed by bulk RNA-seq. Optional rectal biopsies were collected at baseline and 2.5WPTV for DEG analysis. Serum binding Abs (bAbs) against BG505SOSIP were measured by binding antibody multiplex assay at 2.5WPTV.

Results: Innate immune responses after BG505SOSIP+3M-052-AF+alum, but not placebos or BG505SOSIP+alum, peaked at days 1-3, showing a strong IFN type I signature, increased activated CD86+ monocytes, and transient depletion of neutrophils, NKs and CD4+ T cells

from blood. Although cellular responses returned to baseline by day 7, 96 IFN DEGs remained upregulated at 2.5WPTV, 25 of which were also increased in rectal tissue, including MX1, IFIT1, TRIM6, IFI44, IFI44L, CMPK2, HERC5. At 2.5WPTV, 5/6 BG505SOSIP+3M-052-AF+alum recipients had developed a high magnitude of BG505SOSIP bAbs (>3000 MFI), 1/8 for BG505SOSIP+alum, and 0/6 were seen in placebo. At 2.5WPTV in blood, but not rectum, the cumulative expression of the IFN module (M127) positively correlated with the magnitude of bAbs ($r=0.942$ $p=0.017$).

Conclusions: IFN signaling pathways in blood of BG505SOSIP+3M-052-AF+alum vaccinees peaked 1-3 days post-immunization, and mostly returned to baseline by 2.5WPTV.

However, both in blood and rectal tissue, a subset of type I IFN DEGs persisted only in BG505SOSIP+3M-052-AF+alum vaccinees, indicating a 2.5-week-long TLR7/8 response in blood and mucosa. This IFN signature in blood correlated with BG505SOSIP bAbs, suggesting it may support the development of a strong B cell response.

OA1307LB

Observed adherence-concentration benchmarks for emtricitabine/tenofovir alafenamide pre-exposure prophylaxis for African women

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Background: Tenofovir diphosphate (TFV-DP) thresholds in dried blood spots (DBS) derived from US populations for emtricitabine/tenofovir alafenamide (F/TAF) pre-exposure prophylaxis (PrEP) helped to interpret F/TAF efficacy for men who have sex with men. No study has yet defined TAF benchmarks for African women or whether US population-derived benchmarks apply to them.

Methods: Between March to December 2023, we conducted a randomized pharmacokinetic study of oral F/TAF PrEP in DBS and peripheral blood mononuclear cells (PBMCs) among 54 Kenyan women without HIV.

Women were randomized to 2, 4, or 7 oral F/TAF PrEP doses/week (clinicaltrials.gov: NCT05140954). Dosing was directly observed for 10 weeks. TFV-DP was quantified in DBS and PBMCs using validated LC-MS/MS assays at the University of Colorado. Observed median concentrations were compared between dosing groups using the Wil-

coxon test. Geometric mean ratios of steady-state PBMC TFV-DP concentrations from F/TAF were compared to respective concentrations from a contemporaneous Women Benchmark study of emtricitabine/tenofovir disoproxil fumarate (F/TDF).

Results: Median (IQR) age and creatinine clearance at baseline were 23 years (21-25) and 126 mL/Min (110-149), respectively. Overall, >99.9% of expected doses were observed. Observed median (IQR) week 10 DBS TFV-DP concentrations were 432 (407-504), 1214 (930-1377), and 2345 (2063-3006) fmol/punch for 2, 4, and 7 doses/week. These thresholds are comparable to the respective 25th/75th percentiles from the US TAF-DBS study (432-657, 952-1449, and 1980-2962 fmol/punch). TFV-DP from F/TAF concentrated in PBMCs with median (IQR) steady-state concentrations of 70 (55-94), 229 (159-278), and 680 (462-864) fmol/10⁶ cells for 2, 4, and 7 doses/week.

In contrast, median (IQR) steady-state PBMC TFV-DP concentrations from F/TDF were 9 (7-19), 28 (21-34), and 49 (36-63) for 2, 4, and 7 doses/week ($p<0.001$ for all). Notably, 2 doses/week of F/TAF generated TFV-DP levels 1.41-fold (1.04-1.89) higher versus daily dosing with F/TDF ($p=0.027$).

Conclusions: We have established F/TAF PrEP adherence benchmarks for African women and show they are within range of historical benchmarks from US populations. F/TAF PrEP produced more than seven-fold higher PBMC TFV-DP levels versus F/TDF across adherence groups. These data reinforce the strong intrinsic potential F/TAF PrEP potency and pharmacologic forgiveness for African women in the PBMC compartment.

OA1407LB

Tackling HIV through teen pregnancy prevention: results from an innovative intervention among African American teens

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Background: African Americans bear a disproportionate burden of the HIV epidemic in the U.S. Deep South, yet tailored socio-ecologically-based interventions focused on addressing the underlying factors in this epidemic in this region remain sparse. One of the overlooked factors of HIV vulnerability in this population is teen pregnancy. Despite declining rates of teen pregnancy nationally, teen pregnancy remains high in Georgia. African Americans are disproportionately affected by teen pregnancy in Middle Georgia. Between 2018 and 2022 the average teen pregnancy rate was 46.5 for African Americans and 11.5 for whites.

The continued progression of these dual epidemics in this population calls for context-based interventions that challenge cyclical factors that perpetuate teen pregnancy.





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Methods: We designed an innovative curriculum: Un-trapped: Teen Pregnancy Prevention Curriculum for African American Teens ages 11-19. The multi-layered, co-educational intervention. It targets four main aspects of the social ecology of the teenager: cognitive growth through didactic instruction, intra-personal growth through journaling, interpersonal peer growth enhanced through collaborative development of a problem tree, and socio-structural influence through a problem tree display in the learning space.

Results: The curriculum was pilot-tested among middle-school and high-school students at an after-school program in a mid-sized city in Middle Georgia. A pre-intervention and post-intervention survey was administered, with individual interviews at the program's conclusion. Results were analyzed quantitatively and qualitatively. Results showed a change in the ideal age for sexual debut. The age at which one should start having sex was higher after the intervention. Sixty-nine percent (69%) reported that having a child as a teenager was a problem post-intervention compared to 47% pre-intervention. When the program concluded, 85% reported high confidence in their ability to prevent pregnancy compared to 26% pre-intervention. Qualitative responses revealed that the teenagers enjoyed the interactive nature of the program. Several reported appreciating how it allowed them to voice their opinions. Post-intervention problem tree activity revealed a more versatile understanding of the various factors that shape teen pregnancy.

Conclusions: The intervention was effective in addressing overlooked aspects of risks associated with teen pregnancy and instrumental in raising critical awareness about factors that shape teen sexual choices and attitudes about teen pregnancy.

OA1607LB

Drug-agnostic transcutaneously-refillable subdermal implant for ultra-long-acting delivery of antiretrovirals for HIV prevention

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Background: Long-acting sustained antiretroviral (ARV) release systems for protection against human immunodeficiency virus (HIV) could improve and maintain adherence, a longstanding global health challenge. Drawing parallel from contraceptives, having options that enable personal preferences could increase uptake, acceptability and efficacy of HIV pre-exposure prophylaxis (PrEP).

These long-acting delivery systems include oral tablets, injectables, and implants. Here we present a drug-agnostic transcutaneously-refillable subdermal implant for ultra-long-acting controlled delivery of potent ARVs, with a primary focus on islatravir (ISL) and MK-8527.

Methods: The subdermal implant comprises of a bio-compatible titanium casing acting as the drug reservoir, internally mounted with a silicon nanochannel membrane to control release. Constant and sustained ARV release occurs through constrained diffusion of drug molecules across the nanochannels. Subdermal ISL-eluting implants were evaluated in nonhuman primates (NHP) for a 29-month pharmacokinetic study as well as PrEP efficacy against repeated rectal and vaginal simian HIV (SHIV) challenges in males and females, respectively. Long-term safety and tolerability to the implants were evaluated. Further, the implants were evaluated for in vivo release of MK-8527, lenacapavir (LEN), bicitgravir (BIC), and other hydrophobic ARVs.

Results: Sustained ultra-long release of ISL from the subdermal implant was shown through stable plasma and peripheral mononuclear blood cells drug levels for over 29 months in NHP without fluctuation or implant refilling. More importantly, 100% protection against rectal and vaginal SHIV exposures in NHP substantiated PrEP efficacy of the ISL-eluting implants.

Further, safety and tolerability demonstration in NHP validated feasibility of long-term implant deployment. Additionally, sustained release and tolerability of MK-8527 was also achieved in vivo. Further, release of hydrophobic ARVs, namely LEN, BIC, and DTG highlighted drug-agnosticity of the implant.

Conclusions: Our ultra long-acting subdermal implant offers safe and effective long-lasting protection against HIV, where minimally-invasive transcutaneous refillability extends release potentially throughout the recipient's lifespan. Implant drug-agnosticity imparts flexibility for single- or multi-ARV delivery for PrEP or treatment, as well as combination with contraceptives, serving as a multi-prevention technology. Importantly, cost of good analysis estimates drug-loaded implant could be as low as USD 36/year, substantiating clinical viability for adoption in low resource countries.

OA1807LB

Intravenously delivered broadly neutralizing antibody VRC01 reaches the rectal lamina propria and provides partial protection in ex-vivo challenges with HIV-1 (HVTN116)

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Background: Effective concentrations of broadly neutralizing monoclonal antibodies are likely needed in the intestinal mucosa for HIV-1 immune-prophylaxis. Intravenous VRC01 at 10mg/Kg and 30mg/Kg was evaluated in two trials which demonstrated partial efficacy against neutralization-sensitive HIV-1 strains.

A parallel study, HVTN116, compared mucosal VRC01 levels, localization and functionality by doses, sex-assigned-at-birth, and geographic locations.

Methods: Thirty-one participants without HIV from Cape Town and Seattle received four VRC01 infusions (10mg/kg or 30mg/kg) given once every 2 months. Paired blood, rectal secretions and fecal matter were collected pre-infusion, and after the first and fourth infusions to examine bacterial diversity (16S sequencing) and VRC01 levels (Singulex). Rectal biopsies were collected pre-infusion and 1-28 weeks post-fourth infusion to assess VRC01 levels, localization (immunohistochemistry), and functionality (ex-vivo explant challenge).

Results: Within 2 weeks post-fourth infusion, VRC01 levels were ~2x higher in both sexes assigned at birth (SAAB) in serum (p=0.008), rectal biopsies (p=0.008), and rectal secretions (p=0.047) in the 30mg/kg vs. 10mg/kg group. There were no dose-related differences in mucosal half-life, accumulation (p=0.46), or penetration into rectal tissue (p=0.93) or secretions (p=0.67). Rectal biopsies from both doses showed significant ex-vivo protection against HIV-1_{Ba226} challenges 1-2 weeks post infusion, that waned

by 5-6 weeks (EC80=0.17µg/ml). Neither dose protected against HIV-1_{Ba226} (EC80>50µg/ml) or HIV-1₁₁₀₈₆ (EC80=2µg/ml) challenges, which require higher IC80.

There were no differences in VRC01 rectal levels (p=0.78), half-life (~22 days), or penetration into rectal lamina propria (p=0.11) by SAAB. The composition of Cape Town fecal microbiome differed from Seattle (p<0.001) but was not modified by VRC01 infusion. Cape Town participants also had shorter VRC01 half-life and lower levels at 5-6 weeks in serum (p=0.048) and rectal biopsies (p=0.048), even after adjustment for body weight and VRC01 dose.

Conclusions: Both VRC01 doses reached rectal compartments of participants regardless of SAAB with similar pharmacokinetics, although peak levels differed by dose and geographic region. Both doses mediated short-term, partial protection against HIV-1_{Ba226} in ex-vivo explant challenges; but were insufficient against strains with higher IC80s. Increased dose and repeated infusions did not improve penetration or rectal half-life. Longer-lived and more potent antibody cocktails may be needed for effective HIV-1 immuno-prophylaxis.

OA2007LB

HIV PEP-in-Pocket ("PIP") facilitates the de-medicalization of HIV prevention

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Background: Current HIV prevention programs tend to offer relatively static advice even though individual HIV risk is dynamic; for example, daily pre-exposure prophylaxis (PrEP) is routinely offered with limited re-evaluation of appropriateness. While this approach works for many, offering alternative approaches HIV prevention can broaden the reach to more individuals who may benefit from pharmacologic prevention tools and promote maintained engagement in care.

PIP is a novel approach to HIV prevention that mitigates gaps in care and significantly reduces the number of healthcare interactions associated with the provision of post-exposure prophylaxis (PEP). PIP involves proactively identifying clients who may have infrequent and occasionally unexpected HIV exposures and providing them with a full 28-day prescription for guideline-approved ARVs. Clients are instructed to self-initiate medications in the event of an exposure and follow-up for baseline screening within 14 days of initiation. Importantly, PIP clients have access to a full 28-day course of treatment without needing to visit urgent care or the emergency department.

Methods: PIP was integrated into two HIV prevention clinics as part of a "buffet approach" that prioritizes client autonomy and choice by offering a range of options and the flexibility to change as needed. Clinicians assess prevention strategies and HIV risk during every interaction and provide education on alternative approaches within



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the context of current life circumstances. Using a standardized form, we conducted a retrospective evaluation of PIP uptake, PIP use, and client-led modifications to HIV prevention strategies.

Results: PIP was prescribed to 126 individuals who were followed for 212 patient-years. There were 85 instances of PIP initiation by 36 individuals; though baseline screening was attended only 30.3% of the time, six-month follow up attendance following PIP initiation was 98.7%. Zero HIV seroconversions were detected. 31.7% of clients switched from PIP to PrEP, and 29.4% switched from PrEP to PIP.

Conclusions: The introduction of PIP has expanded available options for HIV prevention, which is of particular importance for those who have a lower frequency of HIV exposures. PIP promotes autonomy and reduces many burdens associated with emergency PEP access. PIP may be considered a cost-effective harm reduction approach to HIV prevention.

OA2407LB

Impact evaluation of a combination HIV prevention intervention for adolescent girls and young women in South Africa: a non-randomised controlled trial (the HERStory 3 study)

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Background: Adolescent girls and young women (AGYW) in South Africa are at high risk of HIV infection. A combination HIV prevention intervention for AGYW, the My Journey Programme, was implemented in South Africa from 2016 to the present, aiming to reduce HIV incidence, teenage pregnancy, and GBV, and to increase retention in school and access to economic opportunities.

The objective of this study is to determine the impact of the My Journey Programme on HIV prevalence (primary outcome), knowledge of HIV status, coverage of HIV prevention and care, pregnancy prevention, and school dropout.

Methods: We conducted a "post-intervention" survey in 12 intervention sub-districts, and 12 comparison sub-districts with equivalent demographics and HIV prevalences, across 8 provinces in South Africa. Two sites were purposefully selected within each intervention and comparison area, generating 48 sites. In each site, we conducted a representative household survey of 100 AGYW aged 15-24 years, (N=4,800).

The study was powered to detect a decrease in HIV prevalence from 12% to 6%. Dried blood spot specimens were collected and participants self-completed an electronic questionnaire. Frequencies and percentages for each

outcome were presented for intervention and comparison arms. Using a mixed effect model, accounting for clustering at four levels and potential confounders (age, maternal orphanhood, socio-economic status, and educational enrolment), the odds ratio of the study arms was determined.

Results: Across study arms, 37,714 households were visited, 22,263 were screened, 5,150 AGYW were invited and 5025 participated. HIV prevalence was 9.5% in the intervention and 10.4% in the comparison arm (OR: 0.88; 95% CI: 0.46 – 1.70). Knowledge of HIV status was 84.7% in the intervention and 80.5% in the comparison arm (OR: 1.46; 95% CI: 1.05 – 2.03). In the intervention arm, there were substantially fewer participants who did not know what PrEP was (28.2% vs 35.0%; p=0.03) and substantially more participants who had ever used PrEP (26.4% vs 13.0%; p=0.03). There was almost no intervention impact on condom or contraception use, but potential barriers to access were less prevalent in the intervention arm.

Conclusions: These findings demonstrate the potential and value of combination HIV prevention for AGYW.

OA2507LB

Crowdsourcing strategies to implement CAB-LA for sexual minority men in Chicago through a cutting-edge innovation tournament

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Background: Reducing HIV incidence requires the effective implementation of evidence-based prevention practices. In Chicago, HIV disproportionately impacts sexual minority men (SMM). Long-acting injectable cabotegravir (CAB-LA) offers a new form of HIV prevention. To maximize uptake of CAB-LA in Chicago, co-designing implementation strategies is critical. Through a partnership with key constituents, this research employed cutting-edge participatory methods to inform implementation of CAB-LA among SMM (≥ 13 years), particularly Black and Latino populations.

Methods: Innovation tournaments follow a three-step process: 1) participant submission of ideas, 2) participant voting on ideas, and 3) evaluation of ideas by a committee. A platform was developed to host the innovation tournament and allow participants to respond to the following prompt: "Describe your idea for how to get this new form of PrEP to gay, bisexual, and other men who

have sex with men (12 years and older) who want it in Chicago." Participants were recruited through social media, train advertisements, fliers, and in-person recruitment. Ideas were submitted in English and Spanish.

At the conclusion of the tournament, a committee of constituents with diverse expertise convened to evaluate the ideas for feasibility and acceptability and to select winning ideas.

Results: Forty-two participants completed 53 submissions comprised of 72 discrete ideas for implementation strategies. Advertisement on the public train yielded the most submissions (31%). Participants represented the key populations (31% Black, 19% Latino, 64% sexual minority population). Submissions described ideas to increase awareness (e.g., campaign on social media and dating apps, identification of LGBTQ champion), reduce cost (e.g., shot subsidization, transportation voucher), integrate care (e.g., STI services, pharmacies), and partner with community spaces (e.g., pop-up clinics, schools).

Conclusions: This research will contribute to the production of a menu of co-designed implementation strategies, which can guide plans for CAB-LA integration in Chicago and provide insights for other regions. As the first innovation tournament focused on HIV prevention, this research can provide a framework for participatory approaches across the care continuum. Given that the co-design of implementation strategies often does not involve the participation of individuals with lived experiences, this work will center the voices of those who will benefit most.

OA2607LB

Germline targeting SHIVs for the assessment of HIV vaccine immunogens

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Background: The induction of broadly neutralizing antibodies (bnAbs) against HIV Env remains a major goal of HIV vaccine development. Germline targeting, where immunogens are designed to engage bnAb unmutated common ancestor (UCA) precursor B cells, is a promising strategy for the development of priming immunogens. Here we explore the use of the SHIV model for the evaluation of HIV immunogens through the design of germline targeting SHIVs.

As proof of principle of this approach, we design and infect rhesus macaques (RMs) with a SHIV with enhanced affinity for the UCA of a RM V2-apex bnAb lineage V033-a.01 to re-elicite V033-like lineages.

Methods: V033 UCA affinity enhancing mutations were identified through mammalian display mutagenesis of a stabilized Env Q23.17-based trimer. These mutations were then introduced into the WT SHIV.Q23.17, resulting in the germline targeting SHIV Q23.V033GT. This germline

targeting SHIV demonstrated over 500-fold enhanced sensitivity to neutralization by the V033 UCA. Three RMs were inoculated with SHIV.Q23.V033GT. Neutralization assays, EMPEM, and single genome sequencing were used to characterize the antibody response and Env escape in these RMs.

Results: All RMs were productively infected with SHIV.Q23.V033GT. One RM developed a rapid progressor phenotype and failed to mount a detectable antibody response. In the two evaluable RMs, Env escape at the V2-apex C-strand and neutralization mapping with Env mutants confirmed the accelerated development of V2-apex C-strand targeted nAb responses as soon as week 12 post-infection. EMPEM suggested that these lineages had binding footprints similar to the V033 bnAb. Both RMs developed limited, C-strand targeted, heterologous tier-2 neutralization.

Conclusions: We find several advantages to the use of the SHIV model for immunogen evaluation:

- i. High antigenic loads during infection maximize the probability of engaging bnAb UCAs;
- ii. SHIVs coevolve with bnAb lineages resulting in the acquisition of neutralization breadth, verifying that primed B cells are genuine bnAb precursors; and;
- iii. Sequencing of Env escape serves as a sensitive indicator of nAb-targeted epitopes.

Overall, these data demonstrate a novel use of the SHIV model for the design and testing of HIV immunogens, and show the promise of Q23.V033GT as an immunogen to prime V2-apex bnAb lineages in RMs.



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TUPE001LB

MAdCAM-1 and IL-6 are key factors in the formation of gut Tissue Resident Memory T Cells

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Background: Persistent HIV reservoirs are established in the gut within the first weeks of infection, representing a barrier to an HIV cure. Tissue Resident Memory T cells (T_{RM} s) are a subset of terminally differentiated T cells constituting the first line of defense against pathogens. T_{RM} s are believed to contribute to the establishment of an HIV viral reservoir. Recently we identified the gut-homing ligand MAdCAM-1, in combination with retinoic acid (RA) and TGF- β , as drivers of the differentiation of CD4⁺ T cells into gut T_{RM} s (CD103-CD69⁻). These CD4⁺ T_{RM} s, which express $\alpha\beta$, and CCR5, are readily infectable, even in the presence of TGF- β .

We propose that this type of costimulation could help explain how gut tissues are rapidly and preferentially infected in the acute stage of HIV infection and might contribute to early gut tissue reservoirs.

Methods: Human CD4⁺ T cells were obtained from unidentified donor PBMCs using magnetic bead isolation. Cells were stimulated with anti CD3 plus immobilized MAdCAM-1. Treated cells were stained with fluorescent antibodies and analyzed using flow cytometry. We carried out gene expression profiling by RNAseq following MAdCAM-1 costimulation. We also measured cytokine production using multiplex cytokine assays.

Results: We noticed that donors PBMCs with greater amounts of naïve T cells produced more T_{RM} s. However, pure naïve T cells failed to effectively generate T_{RM} s. We conclude that MAdCAM-1 costimulation does not induce significant T_{RM} generation from naïve CD4⁺ T cells alone and that additional factors in the memory cell milieu are required. Supernatants from memory CD4⁺ T cells cultures were added to naïve CD4⁺ T cells culture, rescuing the generation of T_{RM} s. Using multiplex cytokine assay we identified several cytokines which were upregulated in the memory cell milieu. Employing cytokine blocking antibodies, we identified IL-6 as the major soluble factor necessary to generate T_{RM} s from naïve T cells costimulated with MAdCAM-1.

Conclusions: Identifying factors involved in gut T_{RM} generation may advance our understanding of the mechanism(s) involved in the formation and maintenance of

persistent viral reservoirs in gut tissues and point to potential new therapeutic approaches. We identified MAdCAM-1 and IL-6 as specific factors involved in the generation of gut T_{RM} s.

TUPE002LB

Neutralizing antibodies and viral rebound kinetics upon art interruption using HTI T-cell vaccines in early-treated HIV-1 infection

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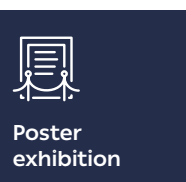
Background: Autologous neutralizing antibodies (anAbs) can emerge early in HIV-1 infection and expand during suppressive ART. How rebounding virus during a treatment interruption (ATI) further drives these antibody responses is not well understood.

Here, we aimed to evaluate the kinetics of the humoral responses and related immune parameters during ATI in early-treated participants from an HIV-1 therapeutic vaccine trial (AELIX-002 study, NCT03204617; Bailón, NatMed 2022).

Methods: Forty-one participants (26 active, 15 placebo) interrupted ART and were monitored weekly for a maximum of 24 weeks. ART was resumed if plasma viremia exceeded 100,000 copies/mL once or 10,000 copies/mL for 8 consecutive weeks.

Neutralization assays were performed using TZM-bl assays on plasma samples against six tier 1 and 2 HIV pseudoviruses (NL4.3, TRO.11, 25710, CE1176, 398F1, CNE8) and autologous virus isolated from cryopreserved PBMC stored at HIV-1 diagnosis pre/or within the first weeks of ART initiation (n=38/41). Samples from 4 timepoints, including ART initiation during acute/early HIV (pre-ART), at ATI viral recrudescence (>50 and <500 copies/mL, ATI-Rc), ATI peak viremia (ATI-Pk), and at ART resumption/end of ATI (ATI-End) were tested for T- and B-cell composition, activation, and exhaustion markers.

Results: At treatment initiation (pre-ART), only 1 (3%) participant had neutralization against autologous virus, and 3 (7.7%) against tier 1 NL4.3 pseudovirus. ART was discontinued after a median of 49 (34-80) months. At ATI-Rc (2 to 8 of weeks upon ART discontinuation), 2 additional participants neutralized their autologous virus. At ATI-End, 11 (28%) showed autologous neutralization, and 22 (54%) neutralized NL4.3.



No neutralization was detected against tier 2 pseudo-viruses pre-ART or any ATI timepoint. Higher NL4.3 neutralization correlated with lower levels of CD8+ T cells expressing activation and exhaustion markers and was also related to reduced ATI peak viremia, lower viremia at end of ATI, and longer time off ART.

Conclusions: In AELIX-002, one-third of early-treated PWH developed anAbs to their pre-ART virus after over 3 years on suppressive ART and a subsequent viral rebound during treatment interruption. Higher NL4.3 neutralization was associated with markers of improved viral control during the ATI. These results support the combination of T- and B-cell vaccination strategies within HIV cures strategies.

TUPE013LB

Effect of initiation of antiretroviral drugs for HIV prevention or treatment on the vaginal microbiome of pregnant women in Malawi

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Background: The vaginal microbiota is associated with spontaneous preterm birth (sPTB). The impact of antiretroviral (ARV) drugs for HIV treatment or prevention on the vaginal microbiome during pregnancy remains uncertain.

Methods: Using longitudinal data from the Tonse Pamodzi 2 study, we explored how HIV and ARV shape the vaginal microbiome among pregnant women in Lilongwe, Malawi. Pregnant women living with HIV (WLHIV) initiated three-agent antiretroviral therapy for HIV treatment (ART) while HIV-negative pregnant women initiated two-agent oral pre-exposure prophylaxis (PrEP) for HIV prevention. We explored associations between HIV serostatus, ARV initiation, the vaginal microbiome, and sPTB.

Results: In all, 255 pregnant participants provided vaginal swabs before initiating PrEP or ART: 191 from HIV-negative women and 64 from WLHIV. Of these, 181 participants pro-

vided additional swabs one month after starting PrEP or ART. At enrollment, Shannon diversity was higher among WLHIV, and WLHIV were more likely to have community state type (CST) IV-B than CST I (*L. crispatus*) or III (*L. iners*) (α OR: 4, 95% CI: 2, 10). Metagenomic subspecies of *Gardnerella*, *Sneathia amnii* and *Prevotella oris* were associated with WLHIV. After initiating ARV, α -diversity decreased among WLHIV and increased among HIV-negative women.

Exposure to PrEP resulted in 3-fold higher odds of transition to CST IV compared to ART exposure (α OR: 3.3, 95% CI: 1.1-10), and 6-fold higher odds of transition to CST IV compared to an external sub-cohort of pregnant, HIV-negative women unexposed to PrEP (α OR: 6.1, 95% CI: 1.3-30). HIV serostatus and transition to CST IV trended toward increasing the odds of sPTB.

Conclusions: Changes in the vaginal microbiome during pregnancy were unique to the initiation of ART or PrEP for HIV treatment or prevention. Larger, longer-term studies will be crucial to fully understand the impact of ARV exposure on pregnancy outcomes.

TUPE018LB

Cannabidiol prevents mucosal HIV-1 transmission by targeting Langerhans cells, macrophages and T-cells

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Background: Cannabidiol (CBD), a major cannabinoid (CB) in *Cannabis sativa*, has therapeutic potential and is used worldwide. CBD binds with low affinity its cognate CB1/CB2 receptors, and with high affinity the transient receptor potential vanilloid 1 (TRPV1) ion channel. TRPV1 activation in peripheral neurons not only mediates nociception, but also induces mucosal secretion of the neuropeptide calcitonin gene related peptide (CGRP).

We previously discovered an unexpected anti-viral role of CGRP, which strongly inhibits HIV-1 transfer from Langerhans cells (LCs) to CD4+ T-cells, i.e. a process initiating infection of mucosal tissues.

We recently showed that LCs express TRPV1, whose activation induces secretion of CGRP that inhibits LCs-mediated HIV-1 transfer. TRPV1 activation also inhibits direct HIV-1 infection of CD4+ T-cells, but independently of CGRP.

While CBs could limit chronic immune activation in HIV-1 infection due to their anti-inflammatory role, the anti-HIV-1 function of CBD remains elusive.

Methods: Using our models of *in-vitro* HIV-1 transfer and/or direct infection of human monocyte-derived LCs (MDLCs) / macrophages (MDMs) / primary T-cells, and *ex-vivo* transmission in mucosal tissues, the distinct roles of CB1, CB2, TRPV1 and/or CGRP receptors were determined using specific agonists and antagonists.



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Results: In MDLCs, CBD activated TRPV1 (not CB1/CB2) inducing CGRP secretion. In turn, CBD decreased CCR5 surface expression in CGRP-dependent manners, and CD4/langerin in CGRP-independent manners, inhibiting altogether the late phase of HIV-1 transfer. In MDMs, CBD inhibited direct HIV-1 infection via mechanisms dependent of both CB2 and TRPV1/CGRP. In primary blood CD4+ T-cells, CBD decreased CCR5/CD4 expression via TRPV1 activation (independently of CGRP and CB1/CB2) and impaired cellular activation, thereby limiting direct HIV-1 infection.

Finally, in inner foreskin tissue explants, CBD inhibited mucosal LC-T-cell conjugates formation, and ensuing HIV-1 transfer to and infection of CD4+ T-cells.

Conclusions: Our results show that CBD differentially activates TRPV1 and CB1/CB2 in several mucosal HIV-1 target cells, limiting their infection in both CGRP-dependent/independent mechanisms. We argue for repositioning of commercially available CBD-containing formulations as potential microbicides against mucosal HIV-1 transmission.

As an alternative to efficient Lenacapavir, which nevertheless induces escape mutations and remains expensive, our neuro-immune CBD-based approach represents a novel, cost-effective and accessible HIV-1 prevention strategy.

TUPE019LB

Accelerated development of cross-neutralizing VRC01-class antibodies by a three-step heterologous prime-boost immunization schedule

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Background: VRC01-class broadly neutralizing antibodies (bnAbs) have been isolated from several people living with HIV-1. They target the CD4-binding site of Env and are derived from the pairing of VH1-2*02 antibody heavy chains with light chains expressing specific 5-amino acid long CDRL3s. They prevent infection of humanized mice by HIV-1 and of non-human primates by S(H)IV.

Importantly, the first antibody isolated from this class of bnAbs (VRC01) prevented HIV-1 acquisition from susceptible viruses in two phase 3 clinical trials (HVTN 703/704). Hence, VRC01-class antibody elicitation is widely considered essential for an effective HIV-1 vaccine, however, such antibodies have so far not been elicited by vaccination.

Methods: Here, we report that a 'prime-boost' immunization regimen consisting of sequential administration of three different Env-derived immunogens, leads to the development of VRC01-class antibodies capable of neutralizing diverse heterologous, tier 2 HIV-1 viruses. The three immunogens in the order of their administration include the clade C germline-targeting 426c.Mod.Core

nanoparticle, the clade B HxB2.WT.Core nanoparticle, and the ConM SOSIP trimer. The immunizations were conducted in a transgenic mouse model (engineered by the Fred Alt group) that expresses the human VH1-2*02 gene allele and J domain, and the human k3-20 LC of germline VRC01 with CDRL3 of mVRC01. 8 weeks following the last immunization, Env+ B cells were isolated from spleens and lymph nodes and their VH/VL genes sequenced.

Results: The elicited antibodies showed accumulated somatic mutations present in human VRC01-class bnAbs. Selected VH/VL pairs were generated as IgGs, and their binding and neutralizing properties were determined.

Among the antibodies tested, we identified several that neutralized up to 33% of heterologous tier 2 viruses. Furthermore, purified serum IgG from immunized animals displayed cross-neutralizing properties.

Conclusions: Our study identifies an immunization strategy that rapidly guides the maturation of VRC01-class antibodies towards their cross-neutralizing forms and informs the development of phase 1 clinical trials, that are based on the 'germline-targeting' vaccination approach; and focuses on the elicitation of broadly neutralizing HIV-1 antibody responses.

TUPE033LB

Correlates of adherence to oral PrEP or a dual prevention pill in a crossover clinical trial in Harare, Zimbabwe and Johannesburg, South Africa

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Background: We conducted crossover studies in South Africa and Zimbabwe comparing preference, adherence and acceptability of an over-encapsulated dual prevention pill containing PrEP and an OC (DPP capsule) versus PrEP and OCs used separately for 3 months each.

While most participants had inconsistent adherence to both regimens per dried blood spots (DBS), 10% were consistently adherent. We aimed to identify baseline characteristics associated with adherence.

Methods: We defined "adherent" if tenofovir diphosphate (TFV-DP) levels in DBS were (≥ 500 fmol/punch, Month 1; ≥ 700 fmol/punch, thereafter), corresponding to taking ≥ 4 doses/week. We assessed potential correlates of adherence related to demographics and baseline responses to questions about partner/community support, education, income, food/housing security, intimate partner abuse/violence, transactional sex and condom use via computer-assisted self-interview (CASI). We tested associations between baseline characteristics and adherence per DBS

via mixed-effects logistic regression models with participant as a random effect to identify correlates of adherence in a multiple variable model.

Results: We analyzed data from 124 (29 Zimbabwe, 95 South Africa) participants who had at least one DBS result. TFV-DP levels averaged 294 fmol/punch (range 0-3274). Adherence did not differ by treatment regimen, period, or country. Women had 6-8-fold increased odds of adherence in the multiple variable model if they were living with their primary partner ($p = 0.002$), had a main sexual partner who supported their OC use ($p=0.012$) and responded "unlikely" that community would treat them like a social outcast for taking the DPP ($p=0.009$).

Table 1 summarizes responses by participants classified as always, sometimes, or never adherent with adjusted odds ratios from logistic regression modeling the probability of adherence at each visit.

	Adherent at all visits (n=12)	Adherent at some visits (n=27)	Never Adherent (n=85)	AOR (95% CI)	Multiple variable model p-value (Type 3 test of fixed effects)
Lives with Primary partner	6 (50%)	13 (48%)	17 (20%)	6.18 (1.95-19.6)	0.002
Main partner supportive of OC use	10 (83%)	24 (89%)	52 (61%)	6.83 (1.52-30.7)	0.012
Community supportive of DPP	5 (42%)	0 (0%)	8 (9%)	8.16 (1.49-44.6)*	0.009

*OR is for "unlikely" vs "very likely" that community would treat participant as a social outcast if it were known they were taking DPP

Table 1:

Conclusions: Engagement of male sexual partners and community will be important for supporting women to use contraception and HIV prevention products to protect their sexual and reproductive health.

TUPE034LB

Identifying preferred product attributes of long-acting implantable and injectable pre-exposure prophylaxis among men enrolled in the South African male user research on acceptability of implants and injections (SAMURAI) study

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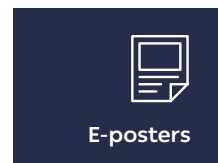
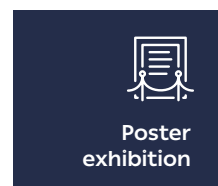
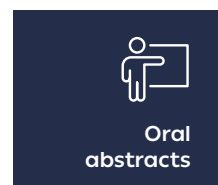
Background: The generalised South African HIV epidemic necessitates effective prevention options. Given the adherence challenges to daily oral pre-exposure prophylaxis (PrEP), exploring the preferences for long-acting alternatives to improve adherence and reduce HIV incidence is critical.

Methods: A discrete choice experiment (DCE) exploring preferences for future HIV prevention products was administered among a sample of gay, bisexual, and heterosexual men in two urban research clinics in Johannesburg and Cape Town, South Africa who completed a clinical study where a 6-month subdermal placebo implant and bimonthly intramuscular placebo injections were tried over a 1-year follow-up period.

The DCE presented four hypothetical HIV prevention modalities (two long-acting options vs. condoms vs. oral tablet PrEP) over 11 choice sets. Choice sets were characterized by four attributes with 2-3 levels each: product form; duration; side-effects; and access location. Hierarchical Bayes modeling estimated zero-centred preference weights across all 13 attribute levels and generated mean attribute relative importance scores (RIS).

Results: From July 2023 to June 2024, 158 HIV-negative cis-gender men (median age 22) completed the DCE. Overall, product form (RIS 56.5%) was the most influential product attribute, with preferred features being one or two injections. The condom and oral tablet PrEP options were the least preferred.

The protection duration (RIS 17.8%) and insertion/injection access location (RIS 17.4%) were the next two influential product attributes, with respondents preferring that protection duration last a year (vs. two or six months) and that the product be placed in the arm (vs. bum or stomach).





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Attributes and Levels	Total Sample (n=158)	RIS (%) [sum to 100%]
Product Form		
One Injection	61.10	56.5%
Two Injections	51.07	
Implant	5.95	
Condom	-34.03	
Oral Tablet PrEP	-84.08	
Duration		
Every year	22.40	17.8%
Every 6 months	10.55	
Every 2 months	-32.95	
Injection/Implant Access Location		
Arm	22.11	17.4%
Bum	8.26	
Stomach	-30.37	
Side-Effects		
Mild Side Effects	13.37	8.3%
Moderate Side Effects	-13.37	

Notes:

Zero-centered PW scores imply the positive or negative magnitude of the participant's preference for the level choice in relation to the other level options within the same attribute. RIS (%) reflect the magnitude of influence that each attribute has on the respondents' decision-making process.

Table 1. Preference weights (zero-centered values) and relative importance scores (RIS) of attributes and levels.

Conclusions: Assessing preferences of men with behavioural risk for HIV acquisition can inform a patient-centred approach to longer-acting PrEP product design. Among this population, prioritizing that longer-acting injectable PrEP is administered as one or two injections, along with a longer duration (1 year), and be placed in the arm, could facilitate optimal uptake and delivery of HIV prevention.

TUPE045LB

BG505 SOSIP.664 adjuvanted with 3M-052 tunes IgG Fc glycosylation towards a more functional state

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Background: Prior HIV-1 vaccine studies identified non-neutralizing Fc-mediated effector functions (FcMEF) as correlates of decreased likelihood of HIV acquisition. Conserved glycans on the IgG Fc are known to modify Fc-Fc receptor/C1q interactions that mediate cellular phagocytosis (ADCP) and complement deposition (ADCD). This study aimed to measure the impact of vaccine adju-

vants on glycosylation and FcMEF to understand potentially programmable antibody features for future vaccine designs.

Methods: HVTN 137 enrolled US adults without HIV (n=70) for a Phase 1 study evaluating an HIV-1 vaccine candidate featuring BG505 SOSIP.664gp140. Each group received a distinct adjuvant: CpG1018-Alum, 3M-052-AF-Alum, GLA-LSQ, or Alum.

In this exploratory analysis, serum collected two weeks after each of three vaccinations was evaluated for immunogen-specific IgG Fc glycosylation using technical replicates on a gel capillary electrophoresis platform, immunogen-specific IgG binding magnitudes using a binding antibody multiplex assay, and ADCP and ADCD using flow cytometry.

Results: Binding antibody titers were comparable within groups post-second and third- vaccinations, but highest in the 3M-052 group (e.g.3M-052: median AUC among positive responders 12,439.4&13,102.5; Alum: 1,521.7&898.4). Low-level ADCP and ADCD appeared only post-third vaccination and exclusively among the 3M-052-AF-Alum group (8/15,7/15, respectively). Bi-GlcNAc, di-sialylation, and total sialylation were negatively correlated with ADCP (Spearman's r=-0.63,-0.57,-0.52, respectively, p<0.05) while mono-galactosylation, total galactosylation, and fucosylation were positively correlated (r=0.75,0.56,0.61, respectively, p<0.05). IgG Fc glycosylation did not correlate strongly (no abs(r)>0.5) to ADCD.

Post-second and third vaccinations, median total galactosylation was higher among 3M-052-AF than Alum (3M-052: 90.7%&87.6% vs Alum: 84.3%&79.4%, p<0.05, Mann-Whitney U test), driven by increased mono-galactosylation (3M-052-AF: 28.9%&32.4% vs Alum: 14.4%&16.6%), but not significantly different from other groups. Total sialylation was lower among 3M-052-AF than all other groups (median 32.2%&26.3% vs 34.9-39.5%&29.7-35.2%, p<0.05), driven by decreased di-sialylation (6.3%&3.8% vs 12.5-15.7%&10.9-11.7%). Fucosylation was higher among 3M-052-AF than other groups at matching time points (92.8%&96.1% vs 71.5-82.3%&81.9-87.5%, p<0.05).

Conclusions: 3M-052-AF-Alum elicited the most functional antibody response evidenced by increased ADCP and ADCD post-vaccination three. Antibodies generated post-vaccination two lacking effector functions suggests qualitative tuning of the response.

Our data suggest increased Fc galactosylation and fucosylation and decreased sialylation could contribute to increased phagocytic function and can be tuned by adjuvant selection.

TUPE047LB

PedMAb1 clinical trial: Safety and dose escalation of CAP256V2LS and VRC07-523LS given to HIV-1 exposed uninfected neonates informed simultaneous administration of two bNAbs and dosing interval to prevent breastmilk HIV-transmission

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Background: PedMAb aims to ensure the development of a promising HIV-prevention strategy with broadly anti-HIV-1 neutralizing antibodies (bNAbs) to reduce HIV transmission postnatally via breast milk, which continues to contribute to residual paediatric HIV infections in high HIV-prevalence settings. Determining the optimal doses, ideal combinations and timing of subcutaneous (SC) bNAb's administration is crucial. We report on two bNAbs, CAP256V2LS administered to infants for the first time, and VRC07-523LS.

Methods: From September 2022 we enrolled eight eligible HIV-exposed infants born without HIV, in each study arm, assessing safety until 10th June 2024. They received 5, 10 or 20 mg/kg CAP256V2LS (arms 1-3) or 20 or 30 mg/kg VRC07-523LS (arms 4, 5) SC, within 96 hours of birth. Infants were observed for 4 hours post-dose, and seen at days 3, 14 and 28, then monthly until 6 months. Using ELISA we quantified the bNAb's concentration in dried blood spots (DBS) and serum samples. Pharmacokinetic (PK) population analysis and MonteCarlo simulations were done with a non-linear mixed effect modelling approach.

Safety data were reviewed bi-weekly internally and six-monthly by an external safety committee. The Division of AIDS Table, version 2.1. July 2017, was used to grade AEs.

Results: Reactogenicity grade 1 events observed at 4 hours or over the first 3 days post-dose were recorded in 3/8 and 2/8 infants in arms 2 and 3; and in 4/8 and 3/8 infants in arms 4 and 5, respectively. 117 Adverse Events (AEs) were reported in 24 infants receiving CAP256V2LS and 82

AEs in 16 infants receiving VRC07-523LS. AE's proportion according to sex was similar. All AEs were grade 1 or 2, except for one unrelated grade 3. AEs were mostly common childhood illnesses (except for low absolute neutrophils, a palatal cyst and an uncomplicated umbilical hernia). DBS and serum samples showed similar PK profiles, supporting a fixed-dose regimen of the simultaneous administration of CAP256V2LS and VRC07-523LS at birth and 12 weeks, which was applied for arms 6/6b.

Conclusions: CAP256V2LS and VRC07-523LS administered SC to infants are safe. Data on safety and PK of two bNAbs administered simultaneously at birth and 12-weeks is forthcoming.

TUPE064LB

Evaluation of the sexual practices and HIV prevention strategies used by male clients of brothel based female sex workers: an insight into the practices of a neglected key population

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Background: The male clients of female sex workers are a neglected group of high-risk individuals that play a great role in facilitating HIV transmission. Majority of HIV prevention programs are focused on female sex workers without considering their clients who are potential agents of transmission of the virus into the society. This study aims to assess the sexual practices, HIV prevention methods and identify factors that are associated with the use of a HIV prevention method among male clients of brothel based female sex workers within Lagos, Nigeria.

Methods: A cross-sectional study conducted in selected brothels in which participants were recruited via purposive sampling. Data was collected using an interviewer administered questionnaire by a 'brothel-based' assistant over a period of three months from March to May 2024. Multiple logistics regression model was used to identify factors that are associated with the use of a HIV prevention method.

Results: A total of 305 male clients were included in the analysis with a mean age of 34.21 ± 8.7 years of which majority have more than two sexual partners (58 %), had ever had an STI (61%), engaged in anal sex (43.3 %), have experienced a condom rupture (60 %), and are not aware of their HIV status (52.8 %). Although 78.4 % admitted to using an HIV prevention method only few assessed PrEP (0.7 %) or PEP (7.2%) while 70.5 % use condoms. In addition, 36.1 % will 'self-medicate' while 59.4 % will not seek medical care in the event of a condom rupture and 52.8 % will 'accept' if their partners decline condom use. Factors such as engaging in anal sex ([aOR] 3.069; 95% CI 1.625- 5.797) and the knowledge of their HIV status ([aOR] 2.202; 95% CI 1.263 - 3.841) has high odds of association with using a HIV prevention method.



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Conclusions: The male clients in this study engage in high-risk sexual practices and there is a very low uptake of PrEP and PEP among this group. This calls for urgent attention with strategic focus to reach out to this group of high-risk individuals in programmatic plans for HIV prevention.

TUPE074LB

Sustainable prison intervention towards comprehensive HIV & AIDS program

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Background: As per HSS Plus 2021- 1.93% HIV prevalence among inmates is higher than HIV prevalence among FSW (1.85%), Truckers (1%), Migrants (0.89%), and ANC (0.22%). Sexual Practices: Convicts (6.8%) and under-trial (4.6%) have reported sexual intercourse with other inmates. Injecting Drug Use: Inmates (2.3%) reported injecting drugs for pleasure [Convicts (1.7%) and under-trial (2.7%)]. As per PSI 2021, Majority of inmates (around 70%) are under-trial. This clearly shows inmates are at greater risk and exposers of HIV & AIDS.

Methods: A six-pronged strategy was adopted to deliver a comprehensive health care program with the aim to achieve the fast-track target of 95:95:95.

1. Mapping of Prisons & Other Closed Settings.
2. Coordination, Collaboration with Different Divisions and Ministry.
3. Sensitization of prison officials, health care providers (HCP), Stakeholders.
4. Identification and mentoring of Prison Peer Volunteers (PPV).
5. Organizing Camps to Provide Integrated screening services.
6. Linkages and follow up.

A close coordination was established with TB, Viral Hepatitis, NACP while planning the prison intervention and designing health camps in the prisons.

The main objective was to provide intergrade package of services at one go through these health camps. This has resulted in better participation on inmates in these health camps as other services were also offered and HIV was introduced along with other services which allowed time to the inmates to get mentally ready for the HIV test and possible future results.

Results: During the program period of around 20 months around .8 million HIV screenings were performed of which around .4% positivity was found. The inmates who were found HIV positive 83% were linked to ART. .14 million inmates tested for Syphilis and around .06 million for STI. .3 million inmates were given 4s screening to access their TB status.

Similarly, around .11 million inmates were offered hepatitis B and C testing services. These coverage numbers were achieved within a very short span due to the holistic pro-

gram stagey which was followed; PPVs and HCP provided enabling environment and ensured health services are available as per inmates need.

Conclusions: Integrated service delivery model is better than just focusing on HIV.

TUPE080LB

Introducing program policy shifts and adopting new demand creation strategies: their effect on voluntary medical male circumcision (VMMC) services uptake among men >15yrs in eight districts, Botswana, 2019-2024

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Background: While Voluntary Medical Male Circumcision (VMMC) is a proven efficacious prevention intervention, its uptake in Botswana is still relatively low. The 2021 Botswana AIDS Impact Survey showed coverage of 45% among men >15 years. To improve VMMC service uptake in the focus age range, new demand-creation approaches were introduced. A shift from school holiday-based campaigns to a door-to-door demand creation strategy was started in the 3rd quarter of fiscal year 2019 (FY 19Q3) and then continued. Then the human-centered design approach (HCD) started in FY 22Q1 to be used to address community barriers by integrating COVID 19 messaging with VMMC messages. Two policy shifts were also implemented. In FY 20Q2, men <15 years were de-prioritized for VMMC. From FY 20Q4-FY 22Q1, elective surgical procedures were suspended due to COVID-19 and lifted thereafter to date.

Methods: Data from the VMMC Program collected between FY19Q1 and FY 24Q1 through the Monitoring, Evaluation, and Reporting system from 8 PEPFAR priority districts among Botswana's 27 health districts were analyzed. Men >15 years who were circumcised were the measure of analysis.

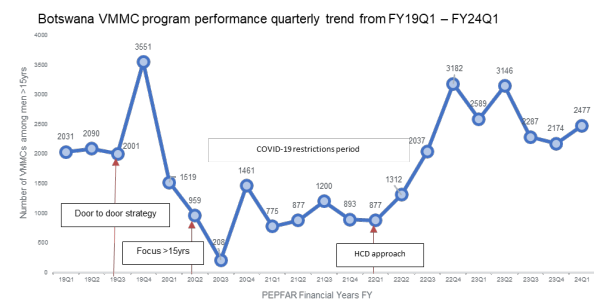


Figure 1: Circumcisions conducted between FY19Q1 - FY 24Q1.

Results: A total of 37,646 circumcisions were done during the study period, peaking in FY19Q4 at 3,551 procedures following the introduction of a door-to-door demand creation strategy. Circumcisions fell during COVID-19 restric-

tions and after the age policy shift, but with the adoption of HCD, procedures gradually increased to a high of 3,182 by FY22Q4.

Conclusions: Fluctuations in VMMC performance were aligned with policy shifts and changing demand creation strategies. Introduction of door-to-door demand creation aligned with increased service uptake among men >15 years.

Introduction of HCD solutions and resumed service availability are likely explanations for the mitigation of COVID-19 impacts leading to program recovery to levels before the start of the epidemic and an increased coverage.

TUPE099LB

Clients' related factors to the uptake level of Pre-Exposure Prophylaxis (PrEP) for HIV prevention among eligible Transgender women in Taraba

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Background: Transgender women face one of the highest HIV burdens worldwide. In Nigeria, 27% of Transgender women (TW) are living with HIV and in Taraba state, the prevalence is 23%, this is more than 18% higher than the adult general population in Nigeria. Pre-Exposure Prophylaxis (PrEP) is a highly effective HIV prevention strategy, however, the uptake of PrEP is less than 50% for all eligible Transgender women in Taraba state. This part of the study examined the clients' related factors to this level of uptake.

Methods: Between December, 2023 to March 2024, a community-based cross-sectional study was conducted to determine Transgender women's related factors to level of PrEP uptake. Transgender women eligible for the study were those who are negative, have been screened eligible for PrEP and have never being placed on Pre-Exposure Prophylaxis. Respondents were recruited from ICTHARAE's data base and during community HIV outreaches, and 158 Transgender women responded. SPSS V.27 was used for data analysis.

Results: Data revealed that the mean age of the respondents were 26±7.8, 158 Transgender women (100%) have been offered PrEP prior, 156 (98.7%) correctly knew what PrEP is and who should take it, their awareness about these PrEP varied from 156 (98.7%), 9 (5.7%), and 4 (2.5%) for daily oral PrEP, on-demand PrEP, and long-acting injectable PrEP (LAI-PrEP), respectively.

Clients' related factors for not utilizing PrEP services were Self Stigma 141 (89.2%), low risk perception 124 (78.5%), fear of disruption of daily routine 89 (56.3%), fear of side

effect 107 (67.7%), lack of transportation to closest facility center 55 (34.8%) and fear of adverse reaction from consuming PrEP while taking feminizing hormone therapy 53 (33.5%).

Conclusions: From this study, despite the high level of awareness about PrEP, obstacles arising from self is playing a hindrance factor against increasing PrEP uptake to 100% by all eligible transgender women. There is need to work hand in glove with Transgender community to educate and strengthen community system that will enhance PrEP uptake for all eligible transgender women in Taraba state.

TUPE126LB

Characterizing populations prioritized for PrEP in 19 African countries: a review of national guidance

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Background: Global institutions recommend offering pre-exposure prophylaxis (PrEP) to individuals with substantial HIV risk. Understanding which populations are prioritized is essential for determining the scope of PrEP distribution across Africa and identifying gaps in implementation.

Methods: To characterize populations prioritized for PrEP in Africa, we reviewed National HIV Treatment and Prevention Guidelines, National HIV Strategic Plans, and the United States President's Emergency Plan for AIDS Relief (PEPFAR) Country Operational Plans (COPs) for all African countries implementing PrEP programs supported by PEPFAR in 2022.

For each country, we summarized the populations prioritized for PrEP and the circumstances under which each group was eligible for PrEP.

Results: Of the 19 African countries implementing PrEP programs supported by PEPFAR in 2022, 18 contributed National Guidelines, 18 contributed National Strategic Plans, and 19 contributed COPs to this review. Twenty-nine population groups were prioritized for PrEP in these documents (Figure 1).



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WEPE014LB

Machine learning to unveil therapeutic targets for bacterial vaginosis in a cohort of HIV positive Tanzanian women

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Background: Bacterial vaginosis is a driver of the HIV epidemic and women of African descent are disproportionately affected. BV increases risk of HIV transmission from sexual partners and vertical transmission of HIV from mother to child. Current BV treatment strategies lack the specificity to prevent recurrence, especially given the diversity of the microbial communities in women of African descent. The use of high-throughput sequencing data and Machine Learning (ML) allows for the delineation of microbe-informed therapeutic strategies towards personalized medicine. Here, we evaluate ML performance in a unique cohort of Tanzanian women living with HIV using 16S rRNA sequencing data.

Methods: This study analyzed 272 samples from 118 Tanzanian women between 18 and 45 years old (Hummelen et al). Data output were operational taxonomic unit (OTU), number of reads, Amsel's criteria, and Nugent score. We predicted BV status using bacterial variables (OTU) and four machine learning classifiers: Random Forest, Logistic Regression, Support Vector Machine, and Multi-layer Perceptron. We compared the predictive performance of the models for diagnosing BV in this HIV cohort to two non-HIV cohorts. BV was diagnosed based on Nugent score. Each classifier was evaluated using area under the receiver's operating curve (AUROC), balanced accuracy, precision, recall, false positive rate (FPR), and false negative rate (FNR). Feature selection was performed to identify bacterial features important for accurate prediction. t-SNE plots were used to visualize how the vaginal microbiome composition varied by HIV status.

Results: Model performance for prediction of BV in this cohort of HIV positive women from Tanzania was significantly lower than both symptomatic and asymptomatic cohorts of women from the United States (Balanced Accuracy: 78%, 90%, 91% respectively). The Multi-Level Perceptron was the best performing for the HIV positive cohort (AUROC: 89%, Balanced Accuracy: 78%, Precision: 76%, Recall: 75%). *L. iners* was the most significant predictive feature. t-SNE plots revealed more overlap in clustering of bacteria in intermediate and positive samples for the Tanzanian dataset, showing the impact of HIV status on vaginal microbiome composition.

Conclusions: These findings highlight the difference in vaginal microbial communities in women living with HIV that must be considered when investigating novel patient-informed therapies.

WEPE017LB

Oral Islatravir in macaques decreases total lymphocytes and monocytes and is associated with immune dysregulation

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Background: Treatment with oral Islatravir (ISL) in humans has been associated with decreases in total lymphocytes and CD4+ T-cells in a dose-dependent manner. We modeled in macaques the effects of oral ISL on lymphocytes, monocytes, granulocytes, and gene expression in PBMCs.

Methods: Female pigtailed macaques (n=5) received oral ISL (30 mg/kg) once weekly for 12 weeks. The ISL dose was adjusted by allometric scaling to mimic the monthly 60mg PrEP dose in humans. Total lymphocytes, monocytes, and granulocytes (n=78, 60, and 25 total observations, respectively) were monitored weekly prior to treatment, during ISL treatment, and after treatment cessation using a hematology analyzer. Changes in cell counts overtime were evaluated using a repeated measures model. All outcome variables were log₁₀ transformed and fit to a linear mixed effects model.

Pairwise comparisons were then performed. RNAseq analysis was done from PBMCs collected before, during, and after ISL treatment. Gene Set Enrichment Analysis (GSEA) was done using the fGSEA R Package and pathway definitions from gene set collections.

Results: ISL treatment resulted in median (range) C_{max} and C_{trough} ISL-triphosphate values in PBMCs of 20.4 (12.8-25.5) and 1.4 (0.6-2.2) pmols/10⁶ cells, respectively. ISL treatment was associated with a significant decline in total lymphocytes (11.9%, p=0.0015) and monocytes (22.4%, p=0.0003) but not granulocytes (0.3%, p=0.9781) compared to pre-treatment values.

Total lymphocytes and monocytes returned to pre-treatment levels after treatment cessation (p=0.82244 and p=0.4620, respectively). GSEA analysis showed negative enrichment of gene sets associated with IFN signaling (Normalized Enrichment Score (NES)=-1.9; p_{adj}=0.0001), IL signaling (NES=-1.5, p_{adj}=0.0076), B cell receptor signaling (NES=-1.9; p_{adj}=0.0019), TLR cascades (NES=-2.0; p_{adj}<0.0001), TNF_α signaling (p_{adj}<0.0001), inflammatory responses (NES=-1.7; p_{adj}=0.0024), diseases of the immune system (NES=-1.9; p_{adj}=0.0059), and primary immunodeficiency (NES=-1.8; p_{adj}=0.046).

Conclusions: ISL treatment in macaques resulted in significant reductions in lymphocytes and monocytes reproducing clinical toxicity. This effect reverted after treatment cessation as observed in humans.

Our findings documenting alterations of key gene expression pathways associated with immune regulation and inflammation provide the first insights on the mecha-





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nisms of ISL-induced lymphopenia. These results highlight the value of the macaque model to study immune alterations at the preclinical stage.

WEPE029LB

Preference of home delivery of oral PrEP versus clinic pick-up among postpartum South African women

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Background: Expanding the modalities of PrEP service delivery to include home based options may help improve PrEP adherence for postpartum women in South Africa. We observed the PrEP delivery preferences of postpartum women and examined the association between baseline delivery selection and self-reported PrEP adherence.

Methods: SCOPE-PP is a two-stepped RCT. Starting April'23, Step 2 enrolled postpartum women living without HIV who had PrEP exposure with poor adherence in Step 1. Step 2 is ongoing and aims to enroll to 250 participants. This analysis studies a cohort, n=81, participants that were observed for up to 9 months. Participants had a choice of PrEP differentiated service delivery (DSD) at baseline (home delivery or clinic pick-up) as well as a choice of HIV-testing method (self-test or clinic rapid test). Choices were dynamic and changeable every 3 months. We used descriptive statistics to summarize participant choice patterns and compared demographic characteristics by baseline DSD choice. Logistic regression adjusted for *a priori* confounders (maternal age, education) was used to model the association between baseline DSD and self-reported adherence after 3 months.

Results: Among N=81 postpartum women, median age (IQR) was 25 years (21,23) and 59% were unmarried. As of July 2024, 169 total choices were made at enrolment and follow-up visits; home delivery: 101 (60%) and clinic pick up: 68 (40%). At enrolment, 47 selections (58%) were for home delivery, and 34 (42%) were clinic pick-up. Of 88 choices at follow-up visits, 62 were re-selections of their previous preference (n=42 home delivery, n=20 clinic pick-up), and 26 were changes (n=16 switches to clinic pick-up, n=10 switches to home delivery). Choices regarding HIV test type; n=169, self-tests:101 (60%) and 68 (40%) rapid clinic tests. The adjusted odds of reporting PrEP adherence after 3-months were significantly higher among those who selected home delivery at baseline compared to those who selected clinic pick-up (aOR=3.6, 95%CI=1.1, 14.3).

Conclusions: Early results demonstrate home delivery of PrEP was often selected among postpartum women. These preferences, along with positive associations between home delivery and reported PrEP adherence suggest it may be a viable option for differentiated PrEP service delivery among this key population.

WEPE031LB

Acceptability of intravenous (IV) and subcutaneous (SC) infusion administration of monoclonal antibody (mAb) combinations: VRC07-523LS with PGT121, PGDM1400, PGT121.414.LS and PGDM1400LS in phase 1 anti-HIV mAb trials

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Background: While the number of HIV prevention tools has recently increased, they face limitations including uptake, adherence and accessibility. More options are needed to address these challenges and individual preferences. Combinations of monoclonal antibodies (mAbs) are promising for HIV prevention. Understanding acceptability and addressing challenges for large scale use are crucial for development of a successful HIV prevention modality.

Methods: This retrospective cross-protocol analysis assessed 3 phase 1 randomized, open label studies [HVTN 130/HPTN 089 (n=6), HVTN 136/HPTN 092 (n=15), and HVTN 140/HPTN 101 (n=71)] conducted in United States, South Af-

rica, Kenya and Zimbabwe in participants without HIV. We included participants (n=92) who received a combination of 2 or 3 mAbs by IV (n=55) or SC infusions (n=37) and completed all infusion visits (2 or 3 total). MABs were administered at doses of 5, 20 or 40 mg/kg or 1.4 grams per mAb every 4 months. Procedure acceptability questionnaires were completed within 2 hours after completion of combination infusions.

Results: Most participants would be very willing to use the route of administration they received (IV or SC infusion) to protect themselves from HIV (n=81/92 after first and n=80/92 after last infusions). Of the 55 participants who received IV infusions, 19 would choose IV; 21 would choose intramuscular (IM). Of the 37 participants who received SC infusions, 15 would choose SC; 12 would choose IM. The remainder chose either SC injection, pills or condoms, or did not know.

Overall, participants considered the time for infusion visits to be acceptable (n=77/92 after first and 76/92 after last infusions) and would recommend an IV or SC infusion to a friend vulnerable to HIV (n=84/92 after first and n=85/92 after last infusions).

Conclusions: Participants consistently chose the route of administration that was used during study participation (IV or SC) or IM injection as their method of HIV prevention. Additionally, opinions of infusion visit time and recommendation of their route of administration was not different after the first and last administrations.

These data support consideration for multiple routes of mAb administration appropriate for the volumes and doses needed for HIV prevention.

WEPE036LB

Geographical analysis of gang violence and HIV epidemic in Haiti: a case study of the impact of violence on HIV treatment patterns in the North district

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Background: With an HIV prevalence rate of 1.7%, Haiti has the highest HIV rate in the Caribbean. Since 1986, Haiti has had ongoing political turmoil, specifically in the form of gang violence. The intensification of gang violence in the country within the last two years has raised much concern. In addition to presenting new challenges in diagnosing new cases, the crisis also affects the ability to provide effective treatment for people already living with HIV. This study is a geographical analysis of gang violence and HIV burden in Haiti.

Methods: Spatial analyses involved descriptive cartographic analysis and spatial autocorrelation analysis which were performed in Arc Map, a Geographic Informa-

tion System (GIS) Software. Visual comparisons between the maps of gang activity, HIV prevalence, and HIV treatment centers and testing sites were performed. A comparative analysis of treatment data in the North district was performed on data from 2022 and 2024 to determine the extent to which the treatment patterns changed during this timeframe.

Results: As of 2022, there are believed to be more than 200 gangs in Haiti. The West and the Artibonite departments have the highest gang activities. Throughout the West Department, several clusters of gangs with influence cover most of that region. Fewer gangs are operating in the south. HIV prevalence is lower in the south than the north. Despite having a high prevalence rate, the Centre and Nord-Est have fewer treatment centers. The West has the lowest prevalence of HIV, the highest number of treatment sites, and the highest gang activity.

Comparing the data for 2022 with the first 6 months of 2024, the North district recorded a 3-fold (206%) increase in the number of people who were tested for HIV, a 2.82 (182%) increase in positive diagnosis, and a 2.93 (193%) increase in the number of people who sought treatment.

Conclusions: The crisis in Haiti has led to an imbalance in HIV treatment. People may have migrated from the West Department to the rural areas in the north because of the intensity of gang activity in this area. This pattern calls for the expansion of treatment sites in the North East.

WEPE040LB

Isolation and characterization of heterologous tier 2 HIV-1 neutralizing antibodies from SHIV-infected neonate macaques

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Background: We recently demonstrated that a pathogenic simian-HIV (SHIV) infection of neonatal rhesus macaques (RMs) mimicked pediatric human HIV-1 infection. A subset of these animals generated polyclonal plasma heterologous tier 2 or difficult-to-neutralize HIV-1 NABs. Here, we interrogated the B cell repertoire of representative SHIV-infected neonate RMs that had the best plasma HIV-1 NAB responses.

Methods: We studied 13 therapy-naïve neonate RMs infected with a SHIV bearing Env designed to elicit precursors or mature bNABs, and isolated antigen-specific B cells from peripheral blood in two RMs via Barcode Enabled Antigen Mapping (BEAM)-Ab assay (10X Genomics). Recombinant monoclonal (m) Abs derived from the anti-



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gen-specific B cells were characterized for binding specificities, neutralization, and Env-interaction via structural analyses.

Results: Plasma Abs from RMs V093 and V055 had maximal HIV-1 neutralization potency and breadth by 24 months post-infection. We isolated antigen-specific B cells from peripheral blood of V093 and V055, at months 14 and 20, respectively. We found 3 mAbs that neutralized ~90% of viral particles in 2-4 of nine tier 2 global reference HIV-1 strains. Two of three mAbs were clonally related, DH1518.1 and DH1518.2, and used IGHV4-NL-22*01 with 17 amino acids long HCDR3 paired with VK2-x. DH1518 mAbs demonstrated ~13% neutralization breadth against a panel of 119 tier 2 HIV-1 strains with geometric mean IC50 titer of ~8-11µg/ml. Heterologous HIV-1 neutralization titers of DH1518 mAbs were enhanced 3-10 fold by mutations that disrupted V2-apex, V3-glycan, and CD4-binding site bNAb epitopes, including removal of glycans at the V2-apex and V3-glycan bNAb epitopes. Negative stain electron microscopy of DH1518 mAbs in complex with stabilized HIV-1 SOSIP trimers suggested that they targeted multiple bNAb epitopes partially occluded by glycans. Ongoing high resolution cryo-EM studies will fully define the neutralizing epitopes for DH1518 mAbs.

Conclusions: SHIV-infected neonate RMs developed heterologous tier 2 HIV-1 NAbs with characteristics of bNAbs, including DH1518 NAbs. Our data implied that DH1518 mAbs matured to accommodate glycans in bNAb epitopes. Understanding the maturation pathway of heterologous HIV-1 NAbs, including DH1518, from these SHIV-infected neonate RMs may inform future pediatric HIV-1 vaccine strategies to elicit NAbs that can mature to bNAb status prior to sexual debut.

WEPE050LB

Persistence of Env-specific antibody responses elicited by polyvalent DNA prime - protein boost HIV vaccine (PDPHV) in phase I clinical studies

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Background: An effective HIV vaccine will need to exhibit potent immunogenicity with broad cross-subtype coverage which can be long lasting. The polyvalent DNA-protein HIV vaccine (PDPHV) regimen with matching envelope (Env) immunogens has been tested so far in three phase 1 clinical trials: DP6-001, HVTN 124, and WHV138.

DP6-001 evaluated an early generation of the PDPHV regimen and the published results demonstrated high titer, cross-subtype, functional antibody responses, and more significantly, durable antibody titers and a long-term Env-specific B cell memory. HVTN 124 (phase 1a) and WHV138 (phase 1b) used the 2nd generation of PDPHV with optimized Env immunogens and GLA-SE adjuvant that has a good safety profile.

Recently published results from HVTN 124 showed a wide range of potent and broad immune responses with improved safety in healthy adult volunteers compared to the DP6-001 study. WHV138 (N=42) tested the same PDPHV formulation as in HVTN 124 (N=60) but with varied immunization schedules.

In the current report, we evaluated the development and dynamics of Env-specific antibody responses in HVTN 124 and WHV138 participants.

Methods: Serum samples were collected from participants two weeks after each vaccination, 6 months post last vaccination in HVTN 124, and both 6 months and 12 months after the last vaccination in WHV138. Enzyme-linked immunosorbent assay (ELISA) was conducted to measure the gp120-specific IgG responses.

Results: Similar to DP6-001, HVTN 124 showed durable antibody responses over the 6-month period after the last vaccination with less than one-log drop of the antibody titer.

Furthermore, antibody responses in WHV138 were durable over a 12-month period with also less than one-log drop after last vaccination. Serum IgG from volunteers in both HVTN 124 and WHV138 were cross-reactive to Env antigens from subtypes A, B, C and AE.

Conclusions: These data indicate that PDPHV is effective at inducing durable, cross-clade gp120-specific antibody responses for at least 12-months after the last immunization. A Phase 2 study with a larger size of study group is warranted to confirm the findings from HVTN124 and WHV138 including more in-depth questions regarding to the immunogenicity of PDPHV.

WEPE058LB

Engagement and training of barbers to deliver an HIV prevention intervention to their clients – HPTN 111

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Background: HIV-prevention, engagement, and care for heterosexual men in high HIV-prevalence settings remains limited. HPTN 111 assesses feasibility and acceptability of a barbershop-based HIV prevention intervention to improve heterosexual men's engagement in HIV services.

Methods: In a cluster randomized trial, 18 barbershops in Kalangala district, Uganda were randomly assigned (2:1) to provide the intervention or standard-of-care. All participating barbers recruit their clients, with barbershops assigned to intervention (N=12) delivering the intervention to participants, including status-neutral HIV education, HIV self-test kits, and barber-led group discussions. To deliver the intervention, barbers required training for skills and competency.

Between November 2023 and March 2024, consultative and participatory approaches were used to engage, assess commitment, and train barbers on general HIV education, communication skills, recruitment requirements, and study overview through didactic presentations, illustrations, group discussions, and role plays. Barbers from barbershops assigned to the intervention arm received an additional two days of training on implementation of the intervention. Pre- and post-training assessments evaluated changes in barber knowledge about HIV and the intervention.

Results: 19 barbers from 18 barbershops were trained; all participating barbers are male, a median age of 29 years, with median 10 years of education, median 5 years of barber experience, and the majority (72%; N=13) own their own shop. Before training, barbers generally scored low on HIV and study comprehension, with a median score of 57%. Following the first training, all barbers showed an increase in knowledge, with a median score of 86% (Figure 1).

Intervention group barbers (N=12) further increased their knowledge following the implementation training, with a median post-assessment score of 100%.

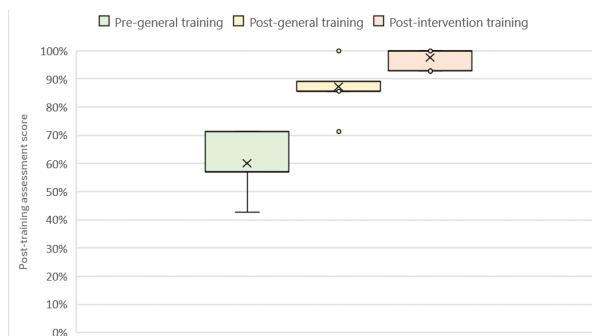


Figure 1. Pre- and post-training assessment scores of barbers attending training.

Conclusions: Through training, barbers can successfully acquire knowledge about HIV and delivery of an HIV prevention intervention.

WEPE059LB

Digital solutions ecosystem to enhance HIV/AIDS response measures in Moldova

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Background: This initiative aims to enhance the efficiency and speed of data collection, storage, and analysis, improve coordination between service providers, and reduce dependency on physical interactions, operating times, and geographical constraints of state and community-based service providers for accessing HIV prevention, care, and support goods and services.

Methods: Moldova has implemented a comprehensive electronic system and mobile app to enhance its HIV/AIDS response. This digital setup supports service registration, client management, case handling, and distribution of HIV prevention products and medications. By May 2024, the system facilitated 1.9 million services and distributed over 40.9 million items to approximately 53,000 clients through 16 providers, including civil society and state health services. The network also features 25 vending machines providing 24/7 access to HIV prevention goods and self-testing kits, used by 3,701 individuals. Integrated health measurement devices in this network feed vital data directly into a secure database, supporting personalized care for 1,738 people.

Furthermore, electronic screening tools within the platform have helped identify human rights violations for 6,637 individuals, while advanced analytics enhance service quality insights and operational efficiency. Launched in March 2024, the mobile app improves access to HIV services, supports digital consultations, and enables interactive decision-making and reporting of rights violations, with gamification features that promote positive health behaviors.

Results: Moldova's digital ecosystem significantly enhanced HIV/AIDS service delivery, managing 1.9 million services and distributing 40.9 million products to over 53,000 clients.

Conclusions: Automated vending machines offering 24/7 access to preventive goods and HIV self-tests have reduced barriers to accessing services by eliminating direct human interaction, thus addressing stigma, limited hours, and geographical constraints, while reaching a broader audience. The introduction of digital tracking enhances transparency and accountability in the distribution of prevention products, fostering trust and reliability. This system also saves significant time in data registration and reporting, freeing healthcare professionals to focus on complex care tasks. Real-time data management improves inventory coordination, prevents waste, and allows for targeted interventions through geolocation services. Moreover, gamification in mobile apps increases user engagement and health behavior adherence, while the integration of business intelligence tools enables informed decision-making and resource allocation.



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WEPE098LB

Exploring HIV prevention care continua outcomes and destigmatizing, wellness-based counseling intervention approaches for YSGM of color

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Background: While much is known about the barriers to positive HIV prevention care continua outcomes experienced by young/sexual gender minorities of color (YSGM), more research is needed to document care needs and intervention priorities which may reduce stigma.

We partnered with a large HIV prevention service provider to explore:

- Gaps in HIV prevention care continuum outcomes among YSGM of color clients ages 18 to 29; and,
- Perceived acceptability of HIV prevention counseling utilizing sexual pleasure-based, rather than risk-based approaches as a possible stigma-reducing intervention approach.

Methods: Using EHR data, demographics and PrEP initiations, prescriptions, fills, and appointments were extracted to conduct longitudinal analyses of continuum outcomes. For aim 2, we conducted formative surveys with clients recruited at the site to explore how well pleasure-based counseling approaches could address gaps in care like those illuminated by our secondary analyses of client data.

Our counseling intervention is based on the *Pleasuremeter*, a motivational interviewing tool that utilizes domains of wellness like safety and pleasure to engage in holistic conversations with clients about sexual wellbeing.

Results: Among our pooled sample of 6,038, 39.75% were people of color, and 34.90% were Hispanic or Latino. Compared to White populations, YSGM of color had greater drop-off in receipt of second PrEP refill prescriptions (50% versus 57%, respectively). In formative surveys, 71% of the participants expressed a greater likelihood of seeking a health professional who assesses sexual health by exploring various aspects of relationships, as outlined in the *Pleasuremeter* tool, compared to those employing a traditional risk-based approach (N=45). Nearly two-thirds stated that the domains covered in the *Pleasuremeter* tool were very important (64.4%).

Conclusions: Our healthcare center data found that YSGM of color continue to experience less benefit from PrEP than other populations. Our formative research, so far, suggests that the *Pleasuremeter* was found to be highly acceptable by SGM youth of color and has potential to destigmatize HIV and PrEP care by normalizing ho-

listic, judgement-free, and sex-positive discussions about sexual health and use of HIV prevention methods. Additional findings from our analyses and formative research will be shared if this work is accepted.

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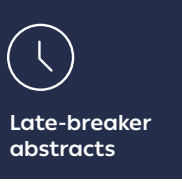
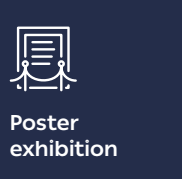
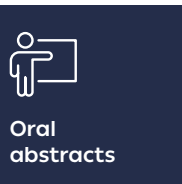
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