

Coordinating Implementation Science for CAB for PrEP: Inclusion of Key Populations

AVAC/BioPIC and WHO

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Introduction

New HIV infections in key populations (KP), including trans and gender diverse people, gay and bisexual men who have sex with men (GBMSM), sex workers, and people who use and inject drugs (PWU/ID), [are not declining globally](#), preventing the global HIV response from reaching 2030 targets. While each of these populations faces unique barriers to accessing HIV prevention services, there are many commonalities, including [stigma, discrimination, and criminalisation](#). The introduction of new HIV prevention methods, including cabotegravir (CAB) for PrEP, provides an opportunity to increase usage of biomedical HIV prevention within these populations; however, for these products to achieve their full potential, these barriers need to be addressed. Implementation Science (IS) research will allow implementers to test out different approaches to addressing barriers to access, ensuring that CAB for PrEP services are safe, effective, and acceptable to all users. To further explore how this could best be achieved, this meeting, part of an ongoing series of BioPIC Think Tanks, focused on strategies to include trans and gender diverse people, GBMSM, sex workers, and PWU/ID in implementation science projects as well as the rollout and scale-up of CAB for PrEP.

Meeting Objectives:

1. Share and discuss key barriers to and opportunities for reaching trans and gender diverse people, GBMSM, sex workers, and PWU/ID with HIV prevention services
2. Identify critical knowledge gaps and barriers that need to be addressed via IS research in order to ensure a successful scale-up of CAB for PrEP services

Cross Cutting Issues and Opportunities

Key Barriers to Access

- Though the introduction of new PrEP products may increase usage of PrEP by KPs, many barriers to access are structural, systemic, and human rights-based, and cannot be solved by new products alone; these include discrimination, criminalisation, and inability to pay for services.
- In addition to addressing the evidence gaps for KPs and CAB for PrEP, implementation studies should seek to answer questions on optimised strategies for addressing structural issues that impact PrEP access; this can be done by looking at data around the profile of those who enrol in the study, costs of delivery, and the synergistic benefits of combining PrEP with other services.

Community Engagement

- Engaging communities continuously and from the start is an essential component of designing PrEP research and programming, so that barriers to access can be well understood and addressed.

- Working closely with communities to help them understand their risk and the benefits of PrEP, even in contexts where generalised epidemic control has nearly been achieved, can help them to prioritise HIV prevention and promote PrEP uptake.

Demand Generation

- Lack of information on how PrEP could benefit them or where to access it is a barrier for many KPs.
- Both general and targeted approaches to promotion of HIV prevention methods are necessary, so that communities with higher HIV incidence are prioritised without being stigmatised, and those who are not from KP communities but want to access HIV prevention are not discouraged from doing so.
- To have significant impact, promotion of CAB for PrEP should be prioritized among those who are not using a method of HIV prevention or those who struggle to use their current method, rather than encouraging switching by users who are satisfied with their method, in an effort to expand the overall prevention and PrEP market.
- Strategies that may have worked to promote HIV treatment don't necessarily work for prevention; the introduction of CAB for PrEP provides an opportunity to help reimagine HIV prevention and PrEP provision in this context by expanding choice of PrEP options.

Service Delivery

- Providers have an important role to play in combatting stigma and need to be supported to offer non-judgemental, inclusive services.
- Task-shifting can facilitate community-based and community-led service delivery which some KPs may find more acceptable and preferable.

Further Guidance

- The Global KP Advisory Group, run by [Global Black Gay Men Connect](#) and AVAC, provides strategic guidance and recommendations on HIV prevention initiatives, policies, and programs to high level stakeholders to inform the development and implementation of evidence-based HIV prevention strategies for key populations globally, and can provide guidance on priority issues for implementation studies to address.

Key Populations and PrEP: Insights and Outstanding Questions

Trans and Gender Diverse Populations

- Awareness of oral PrEP in trans communities is increasing but uptake is still low.
- Barriers to trans people using PrEP include unaffordability, concern about side effects, low risk perception, HIV stigma, dislike of taking a daily pill, dislike of pill size, and need for minors to obtain parental consent; CAB for PrEP may help address some of these issues, including pill burden, side effects, and stigma.
- Facilitators to accessing PrEP include trans-inclusive and gender affirming sexual health services, trans-competent providers, active provider engagement on PrEP, peer navigation, and information, education, and communication materials that reflect trans identities.

CAB for PrEP Evidence and Gaps

- [HPTN 083](#) found CAB for PrEP is safe and effective for trans women, and that feminising gender affirming hormone therapy (GAHT) does not impact CAB concentrations.
- More data is needed on safety, efficacy, and acceptability on use of CAB for PrEP by trans men and non binary individuals, and how to best deliver acceptable services, including in contexts where LGBTQ+ identities are criminalised.
- More data is needed on impact of CAB for PrEP on feminising GAHT, interactions between CAB for PrEP and masculinising GAHT, and best practices for integrating CAB for PrEP with gender affirming care.
- A [survey of trans men in the USA in 2017](#) noted a preference for injectable PrEP over oral PrEP.
- A [survey of trans women in the USA in 2019](#) noted interest in injectables but concerns around scarring, GAHT interactions, and number of provider visits.
- There are currently 11 known implementation studies including trans women- five in Eastern and Southern Africa, and two each in East Asia, Latin America, and North America.
- There are currently six known implementation studies including trans men- three in Eastern and Southern Africa, one in East Asia, one in Latin America, and one in North America.
- There are currently two known implementation studies including non-binary individuals – one in Eastern and Southern Africa, and one in Latin America.
- Fiocruz’s IMPrEP study will assess the facilitators and barriers to integrating CAB for PrEP delivery into public health services in Brazil, giving users a choice between CAB for PrEP and oral PrEP, and includes trans men, trans women, and non-binary individuals.

Gay and Bisexual Men who Have Sex with Men

- PrEP is less likely to be used by GBMSM who are migrants, people of colour, experiencing housing challenges, experiencing poverty, or under 25.
- Barriers to GBMSM using PrEP include lack of knowledge, lack of awareness they could benefit from PrEP, HIV stigma, lack of control over ability to access PrEP, lack of acceptable service delivery channels, inaccessibility, providers not offering PrEP, and lack of knowledge on how to take PrEP optimally or restart after stopping; unaffordability is also a barrier in contexts where PrEP is not free at the point of service.
- Some GBMSM may prefer oral PrEP to an injection as it’s user-controlled and doesn’t require as many visits to a health provider, so is more discreet; the introduction of self-administered injectable PrEP or availability in non-clinical settings may impact user preference.

CAB for PrEP Evidence and Gaps

- [HPTN 083](#) found CAB for PrEP is safe and effective for GBMSM.
- More data is needed on how to best deliver acceptable services, including in contexts where LGBTQ+ identities are criminalised.
- There are currently 16 known implementation studies including GBMSM- five in Eastern and Southern Africa, three in Europe, two in East Asia, two in Latin America, two in North America, one in Oceania, and one in West Africa.

- Fiocruz's IMPrEP study will assess the facilitators and barriers to integrating CAB for PrEP delivery into public health services in Brazil, giving users a choice between CAB for PrEP and oral PrEP, and includes GBMSM.

Sex Workers

- Barriers to sex workers using PrEP include lack of access to health facilities, judgemental attitude of healthcare providers, lack of knowledge of HIV prevention methods, concerns about arrest or prosecution in contexts where sex work is criminalised, privacy concerns, structural inequalities such as poverty, limited representation, and stigma.
- Decriminalisation is a form of HIV prevention, as it can improve sex workers' access to healthcare services and ability to engage with PrEP- therefore structural reform advocacy must accompany implementation projects.
- Data generated from PrEP studies can provide insights into supporting sex workers' health and wellbeing, which can be turned into advocacy priorities.
- Addressing barriers to PrEP use requires a multi-faceted approach that involves legal reform, advocacy, education, community engagement, and collaboration with sex worker-led organisations.
- Sex workers may not prioritise HIV prevention due to feeling a lack of control over their lives and a sense of resignation about acquiring HIV; interventions that empower sex workers to take control of their health can help address this.

CAB for PrEP Evidence and Gaps

- [HPTN 084](#) included participants who reported recent transactional sex and self identified as sex workers; these participants noted they liked the discretion provided by CAB for PrEP.
- More data is needed on effectiveness of different communication and outreach strategies, willingness to pay for PrEP, how to deliver acceptable services- including in the context of criminalisation, optimal strategies to address provider stigma, strategies for community involvement, and integration with other healthcare services.
- Research that includes sex workers should recognise that sex workers are not a homogenous group, and take account of their intersecting identities.
- There are currently seven known implementation studies that include sex workers- six in Eastern and Southern Africa and one in East Asia.
- CeSHHAR's AMETHIST trial evaluated the impact of a peer support intervention, including the promotion of oral PrEP use, on risk of HIV acquisition and transmission amongst sex workers, and found impact on reduced transmission but not acquisition. Another study, TOPAZ, operated within the same programme, will include pharmacy-based distribution of both oral PrEP and CAB for PrEP to evaluate if this delivery model improves PrEP continuation.

People who Use and Inject Drugs

- Barriers to PWU/ID using PrEP include lack of access to healthcare services, unaffordability, lack of awareness, concerns around ethics and human rights, structural issues, reluctance to take daily pills, reluctance to regularly visit a doctor due to time commitment and potential travel involved, stigma, drug and alcohol use leading to difficulties taking medication regularly and travelling for healthcare services, and lack of access to mobile phones making it difficult to receive motivational counselling and health promotion messages.
- Some PWU/ID find the side effects of oral PrEP intolerable- other options, such as CAB for PrEP, may have more tolerable side effects leading to increased usage.
- Context and setting matter for targeting PrEP promotion, as some regions have much higher HIV prevalence amongst PWU/ID than others.
- In Ukraine, the war has made it difficult for many PWU/ID to access PrEP.
- Most PrEP users in Europe are GBMSM; expanding PrEP programmes, including CAB for PrEP, to PWU/ID and other key populations could have a significant impact on HIV incidence in the region.
- Considering the needs of women who use/inject drugs is also critical, and they could benefit from other long-acting methods like the dapivirine vaginal ring.
- Clinical trials for HIV prevention products have historically not included PWU/ID, resulting in a lack of evidence for use by PWU/ID.

CAB for PrEP Evidence and Gaps

- Neither HPTN 083 nor 084 included individuals who injected drugs in 90 days prior to enrolment (though on-study injection behaviour did not lead to discontinuation); this has resulted in a lack of information on safety, efficacy, and acceptability of CAB for PrEP by PWU/ID.
- More data is also needed on drug-drug interactions with illicit drugs, potential side effects, cost, optimised service delivery, how to address stigma, and strategies for community involvement.
- A harm reduction study integrating CAB for PrEP could provide useful data on integrated services for PWU/ID.
- There is currently one known implementation study including PWU/ID, PATH's Vietnam CAB-PrEP Choice Study, which will integrate CAB for PrEP into existing PrEP clinics to measure the extent to which CAB for PrEP addresses unmet demand for PrEP and demonstrates scalability.

Actions:

- To keep the [Integrated Study Tracker](#) up to date, so evidence generated regarding delivery of CAB for PrEP to KPs can be tracked and monitored, all updates and changes to studies should be shared with [Catherine Verde Hashim](#) as soon as possible.

Additional Resources:

- [Shaping and Coordinating the Implementation Science Agenda for Injectable Cabotegravir for PrEP: The role of the Biomedical Prevention Implementation Collaborative \(BioPIC\)](#), JIAS, 2023
- [Dangerous Inequalities](#), UNAIDS, December 2022
- [HIV and Stigma and Discrimination Factsheet](#), UNAIDS, 2021
- [Optimizing HIV Prevention and Care for Transgender Adults](#), AIDS, 2019
- [LGBT Rights](#), Human Rights Watch 2023
- [HPTN 083](#)
- [HPTN 084](#)
- [The role of sex work laws and stigmas in increasing HIV risks among sex workers](#), Nature Communications, 2020
- [HIV prevalence among men who have sex with men, transgender women and cisgender male sex workers in sub-Saharan Africa: a systematic review and meta-analysis](#), JIAS, 2022
- [The Epidemiology of HIV Among Sex Workers Around the World: Implications for Research, Programmes, and Policy](#), Sex Work, Health, and Human Rights: Global Inequities, Challenges, and Opportunities for Action, 2021
- [An Advocates' Primer on Injectable Cabotegravir for PrEP: Trials, Approvals, Rollout and More](#), AVAC, February 2022
- [WHO Guidelines on Long-Acting Injectable Cabotegravir for HIV Prevention](#), July 2022
- [Accelerating access and introduction of injectable CAB for PrEP](#), June 2022
- [CAB for PrEP Implementation Study Tracker](#), July 2022