

AVAC/BioPIC and WHO

Thursday June 23rd 2022 | Meeting Summary

Background/Rationale

The first BioPIC Implementation Science meeting, held in April 2022, focused on sharing plans for cabotegravir (CAB) for PrEP implementation studies. Based on the information exchanged, there are currently 17 planned implementation studies. Among these, East and Southern Africa is the most represented region, with eight studies. Two studies each include locations in East Asia/Pacific, North America, and Latin America/Caribbean. There are gaps in West Africa, South-East Asia, and Europe with one study location each and no studies planned in the Middle East and North Africa.

Of the 13 studies with known sample sizes, nearly half include fewer than 500 participants, with four studies of over 5,000 participants. As several of the studies will offer a range of PrEP options, not all participants will be taking up CAB for PrEP. Men who have sex with men (MSM), trans women, cis women, and adolescent girls and young women (AGYW), are well represented. However, there is less representation of female sex workers (FSWs), trans men, gender diverse individuals, and pregnant and breastfeeding people (PBFP), and no representation of people who inject/use drugs (PWID/PWUD). The majority of studies are of 2-3 years duration. Five have funding confirmed, with the remainder still in the early planning stages.

One of the lessons learned from oral PrEP roll-out is the importance of ensuring PrEP is available to diverse populations and through different delivery models that are convenient and easy to access.

This second meeting of the BioPIC implementation science series focused on how CAB for PrEP can be integrated into existing community, pharmacy and facility-based delivery for HIV prevention.

Meeting Objectives:

1. Share and discuss delivery approaches for six planned implementation studies
2. Discuss key considerations and questions across different delivery models: community, pharmacy and facility-based.
3. Identify remaining knowledge gaps that need to be addressed to scale and ensure equitable access to CAB for PrEP.

Key Highlights

- Representatives from CeSHHAR, Desmond Tutu Health Foundation, the Blantyre Prevention Strategy, University of Washington, Africa Health Research Institute, and Ezintsha shared details on six planned and ongoing implementation studies. Many of the studies focus on differentiated service delivery channels for PrEP, including pharmacy and community-based delivery, and are designed to reach young people. A compendium of study overviews can be found [here](#).
- Ideal PrEP service delivery should offer choice, be safe, and be as simple as possible, while taking the opportunity, where appropriate, to be integrated with other relevant services to increase impact. Services should be user-friendly and acceptable to clients; future implementation studies should continue to explore how use of differentiated service delivery (DSD) models can achieve this.

- The need to consider Ministry of Health (MoH) priorities when planning for implementation research was emphasized. Representatives from MoH of South Africa, Zimbabwe, and Kenya shared their priorities for CAB for PrEP implementation studies, which include generating evidence to help with target setting, optimising service delivery strategies, and getting buy-in from providers.
- Data from the Open Label Extensions of the HIV Prevention Trial Network studies 083 and 084 have shown that the majority of participants taking CAB for PrEP choose to stay on CAB, while many of those taking oral PrEP choose to switch to CAB. This early data points to a preference for CAB for PrEP. Further information from the planned projects will enable greater undersating of choice, continuation on and possible switching between products. This emerging evidence does highlight interest in CAB for PrEP and the critical role of implementation studies to plan for much wider use of CAB for PrEP when people are offered PrEP choices.

Implementation Science Study Briefs

Representatives from six organisations shared plans for their ongoing and planned implementation studies.

CeSHHAR (Frances Cowan) - AMETHIST (Zimbabwe)

Study objective: to refine and operationalize pharmacy-based PrEP distribution for FSW, including an escalating incentive to motivate PrEP continuation; determine whether the addition of pharmacy-based PrEP distribution increases PrEP persistence; and understand the PrEP pharmacy program’s potential to scale and translate lessons learned into a future effectiveness study.

Desmond Tutu Health Foundation (Linda-Gail Bekker) - FASTPREP (South Africa)

Study objective: to understand the preferences of AGYW (including PBFP), young MSM, and their partners for PrEP delivery and products; PrEP will be delivered using a hub and spoke model, with the mobile phone as the hub and a mixture of local clinics, community-based facilities/spaces (including youth clubs), and homes (via a courier service) as the spokes. A subset of study participants will be offered a choice of oral PrEP, CAB for PrEP, or the dapivirine vaginal ring (DVR), with the option to switch. A third party has been engaged to monitor time and cost of testing to help understand the trade-offs between oral PrEP, DVR, and CAB for PrEP. To help participants understand risk, the study will include a decision-making tool which will be implemented by peer navigators.

Blantyre Prevention Strategy (BPS) (Charles Holmes) (Malawi)

BPS is a five-year programme led by the government of Malawi with the support of Georgetown University and other partners, with the goal of developing the essential functions of HIV prevention and embedding them into district structures to accelerate the uptake of new and existing products and interventions. A study proposal is currently in development with the government of Malawi to leverage the BPS platform to scale up CAB for PrEP, building on Malawi’s experience with scale up of antiretrovirals (ARVs). More information will be shared with the BioPIC platform as the proposal is finalised.

University of Washington (Katrina Ortblad) - Pharmacy-delivered Long Acting HIV PrEP in Kenya (Kenya)

Study objective: to collaboratively design, pilot, and evaluate an acceptable care pathway for pharmacy-delivered PrEP, including oral PrEP, CAB for PrEP, and DVR, and identify strategies for sustainability. The investigators are working with the National AIDS and STI Control Programme (NASCOP) to develop a training curriculum for pharmacists.

Africa Health Research Institute (Maryam Shahmanesh) - Theta Nami Ngithethe Nawe (“Let’s Talk”) (South Africa)

Study objectives: to evaluate the implementation of CAB for PrEP within community-based nurse-led sexual and reproductive health (SRH) facilities for youth on uptake and retention of effective HIV prevention amongst adolescents and youth in rural KwaZulu-Natal; in addition to measuring HIV infection as a primary outcome, sexually transmitted infection (STI) and unintended pregnancy will be measured as secondary outcomes to evaluate the impact of integrated services. Peer navigators will support participants with linkages to other supportive services.

Ezintsha (Francois Venter) - Axis (South Africa)

Study objectives: to understand user preferences for oral PrEP (tenofovir/lamivudine) versus CAB for PrEP, as well as switching behaviour, user persistence, willingness to pay, provider perspectives, and cost-effectiveness in two to three high volume PrEP pharmacies. Pharmacists must pass a rigorous two-week training course to participate in the study. It is possible the DVR could be added as an option. If successful, it is hoped that pharmacy delivery of PrEP could be scaled up in government programmes.

Ministry of Health Priorities for CAB for PrEP Implementation Research

South Africa (Hasina Subedar)

- Understanding how CAB for PrEP fits in with the overall PrEP method mix so targets can be set.
- Incorporating choice into existing tools for HIV prevention, particularly with young people, MSM, and FSW.
- Developing cost effective methods of delivering new HIV prevention products, especially CAB for PrEP.

Zimbabwe (Gertrude Ncube)

- Embracing simple and user-friendly service delivery strategies.
- Setting targets to enable accurate quantification and forecasting.
- Understanding the key issues around testing and how testing can be integrated into different service delivery models.
- Gaining buy-in from healthcare workers.

Kenya (Ruth Kamau and Mary Mugambi)

- Improving programme efficiency and understanding the client flow pathway.
- Characterising potential users and understanding user preferences, acceptability, risk profile, and switching behaviour.
- Understanding and implementing different testing protocols.
- Developing models for task-shifting.
- Understanding provider knowledge, attitudes, and practices.
- Determining the short and long term safety profiles of different HIV prevention methods.
- Developing new dispensing models, including via telemedicine and pharmacies.

Recommendations

- Ideal PrEP service delivery should be differentiated, simple, user-friendly, and acceptable to clients.
- Effective delivery models should assist users with understanding their risk; this can be done through use of peer navigators and decision-making tools.
- Implementers need to consider user preferences for delivery channels as well as method choice, both of which may change over time.
- Training for providers, including cadres like pharmacists, is a key component of implementation science studies. This may also include addressing national Ministry of Health issues regarding by whom and where CAB for PrEP can be delivered.
- Implementers using DSD models should ensure proper monitoring and reporting systems are in place for their delivery channel.
- Implementers need to track which populations are reached by the pharmacy model compared to other channels; early evidence from Kenya shows that pharmacy models reach individuals with different characteristics than public clinic models. In this study, for example, older men preferred pharmacy delivery options.

- Evidence from Viet Nam shows that involvement of organisations representing key populations in the design of service delivery models can lead to more successful outcomes.
- Linkages to supportive services are an important part of service delivery and can be managed through peer navigators or formal and informal referral systems. Loss to follow-up for services can be minimised by having multiple services available in the same location (integrated service delivery models) or in a nearby location.

Gaps Requiring Attention

- The trade-offs between different PrEP products (oral PrEP, DVR, and CAB) with regards to their respective testing requirements, and how it impacts cost and user experience.
- Ways to combat stigma which may prevent potential users from seeking services.
- Ways to monitor coverage of exposure without using biomarkers (note this is much less of an issue for CAB for PrEP where a health worker will directly administer the product than for oral PrEP or DVR which rely on client use).
- Ways to monitor switching across delivery systems as well as products.
- Scalability and financing of community- and pharmacy-based models.
- Integration with SRH services and management of misalignment of CAB and DMPA dosing schedules (or overcoming this if pharmacokinetics in women suggests that 12 week dosing is effective).

Way Forward

- To ensure the [CAB for PrEP Implementation Study Tracker](#) remains up to date, AVAC encourages implementers to continue [to share](#) study plans and data.
- AVAC will continue holding Implementation Science coordination meetings every two months. Dates for the meetings will be communicated.

Additional Resources:

- [Accelerating access and introduction of injectable CAB for PrEP](#), June 2022
- [CAB for PrEP Implementation Study Tracker](#), July 2022
- [BioPIC CAB for PrEP Dashboard](#), May 2022
- [BioPIC Implementation Science Meeting Report](#), April 2022
- [BioPIC Implementation Science Questions](#), April 2022