

Coordinating Implementation Science for CAB for PrEP



AVAC/Biomedical Prevention Implementation Collaborative (BioPIC) and WHO

Thursday April 21st 2022 | Meeting Summary

Background/Rationale

Following the US Food and Drug Administration (FDA) approval of injectable Cabotegravir for Pre-Exposure Prophylaxis (CAB for PrEP), several donors and implementers have committed to funding and/or planning implementation studies across various countries and populations. Evidence from clinical trials demonstrated CAB was highly effective at reducing HIV acquisition and preliminary results of mathematical modelling studies highlighted the potential impact on curbing HIV epidemics and reducing AIDS related mortality. As CAB for PrEP moves from research to rollout there will be challenges in delivering it at scale.

As implementation studies for CAB for PrEP are being considered and as programs shift towards choice-based models for HIV prevention, this is the chance to correct for missed opportunities with oral PrEP roll-out, understand client preferences and patterns of use, and ensure more effective coordination across geographies, populations and projects.

To facilitate this coordination, AVAC/BioPIC and the WHO convened implementers, donors, and members of civil society organizations, along with ViiV Healthcare, the product developer and manufacturer of CAB for PrEP, to share plans for implementation studies. The meeting aimed to identify common threads, complementarities, duplication and remaining knowledge gaps across implementation studies to ensure that the evidence generated will answer [the critical questions](#) as CAB for PrEP transitions from clinical research to 'real world' settings. This meeting was the first in a series that will facilitate the exchange of lessons as implementation studies are designed and conducted, WHO and national guidelines revised, and CAB for PrEP integrated into HIV prevention programs.

Meeting Objectives:

1. Present ViiV's implementation science strategy.
2. Share and discuss two implementation studies planned in the United States with ViiV support.
3. Exchange plans for implementation and introduction studies across donors, geographies and demographics.
4. Identify remaining data and knowledge gaps that need to be addressed to scale and ensure equitable access to CAB for PrEP.
5. Agree on ways to strengthen coordination and share findings as they emerge across studies.

Key Highlights

- ViiV's "layer plus" implementation science strategy will involve integrating CAB for PrEP into existing PrEP programs while scaling up new PrEP programs to underserved populations. ViiV's two implementation studies will focus on two small projects for MSM and black women in the USA.
- AVAC has introduced two new tools, the [CAB for PrEP Implementation Study Tracker](#), which tracks all currently known BioPIC partner activities relating to landscaping, product introduction, introduction studies, and implementation research, and the [BioPIC CAB for PrEP Dashboard](#), which tracks progress against the CAB for PrEP strategy as well as clinical research and development. To ensure these tools remain up to date and can be used accurately for decision making, it is critical for partners to continually [share updates](#).

- There are currently 15 planned (but not all confirmed) implementation studies. Among these there are:
 - 6 in East and Southern Africa (Kenya, Lesotho, South Africa, Uganda, Zimbabwe)
 - 3 in Asia and the Pacific (Australia, Thailand, Vietnam)
 - 2 in North America (USA)
 - 2 in Latin America and the Caribbean (Brazil)
 - 1 in West Africa (Burkina Faso, Côte d'Ivoire, Mali, Togo)
 - 1 in Europe (France)
 - 0 in the Middle East and North Africa
- Most studies aim to include MSM, transgender women, cisgender women, and Adolescent Girls and Young Women (AGYW). However, there is less representation of sex workers (SWs), transgender men, gender non-conforming individuals, Pregnant and Breastfeeding People (PBFP), and People who Inject/Use Drugs (PWID/PWUD).
- Of the nine studies with identified sample sizes, over half include fewer than 500 participants. Sample sizes range from 220 to 7,455, with an average size of 1,796.
- Representatives from Wits RHI, Fiocruz, FHI360, PATH, IHRI, UCSF, Kirby Institute, and ANRS shared details on ten of these studies. Notably, many of the studies are focused on integration of CAB for PrEP into existing PrEP programs as well as assessing feasibility, acceptability and delivery of CAB for PrEP as a prevention option. A compendium of study overviews can be found [here](#).

ViiV's Implementation Science Strategy and Implementation Studies

Maggie Czarnogorski from ViiV Healthcare shared ViiV's "layer plus" approach to implementation research for CAB for PrEP, which refers to studying both the integration of CAB for PrEP into existing PrEP programs to expand choice ("layering") and expanded PrEP access for underserved and vulnerable populations and neglected geographies ("plus"). This approach is centered on supporting access through collaborations that answer critical implementation questions to inform CAB for PrEP policies, introduction, and scale-up.

Nanlesta Pilgrim from ViiV Healthcare presented on ViiV's two clustered, randomized implementation studies: PrEP Implementation Study for Cabotegravir LA for Men in the Real World (PILLAR) and Engaging Black Women on Cabotegravir LA for PrEP by Optimizing Novel Implementation Strategies (EBONI). The PILLAR study will focus on MSM, including transgender men, in the USA, and evaluate the process of integrating CAB for PrEP into the standard of care, comparing routine and dynamic implementation at existing PrEP sites from the perspective of staff and patients. The EBONI study was conceived following a landscaping exercise looking at PrEP knowledge, attitudes, and practices amongst providers and black women in the USA, which found PrEP uptake was low, even when knowledge and willingness was high. The study will focus on black cisgender and transgender women, and evaluate the process of integrating CAB for PrEP into clinical settings where black women who test HIV negative receive routine healthcare, including women's health clinics and general primary care.

Implementation Science Roundtable

Jessica Rodrigues from AVAC introduced AVAC's new [CAB for PrEP Implementation Study Tracker](#) and the [BioPIC CAB for PrEP Dashboard](#), followed by presentations from eight organizations with details on ten ongoing and planned implementation studies. Full details of all studies can be found in the [study tracker](#).

<p>Wits RHI (Saiqa Mullik)- Unitaid Project PrEP (South Africa)</p>	<p>Study objective: to improve the understanding of uptake and continuation of PrEP among AGYW and vulnerable groups in real world settings, and inform delivery models for service integration, by expanding PrEP choice through the introduction and integration of new biomedical prevention options (CAB for PrEP and PrEP ring) into comprehensive sexual and reproductive health services. To ensure engagement of AGYW in the design, Wits RHI has engaged two youth advisory groups, conducted a Human Centered Design (HCD) workshop with youth representatives, included young people on the project staff, and collaborated with several Community Based Organizations (CBOs).</p>
<p>Fiocruz (Beatriz Grinsztejn)- ImPrEP/CAB-Brasil (Brazil)</p>	<p>Study objective: to assess facilitators and barriers to integrating CAB for PrEP into existing public clinic health services and evaluate the effectiveness of CAB for PrEP at reducing risk of HIV acquisition in a study cohort of participants, including both adults and adolescents, in a context where they exercise choice in their HIV prevention method.</p>
<p>FHI360/MOSAIC (Elizabeth Irungu)- CATALYST (Kenya, Lesotho, South Africa, Uganda, Zimbabwe)</p>	<p>Study objective: to assess feasibility, acceptability, uptake and patterns of use with a service delivery package providing choice of oral PrEP, PrEP ring and CAB for PrEP among cisgender and transgender women, especially AGYW, at PEPFAR USAID delivery sites.</p>
<p>PATH (Kim Green)- STEPS (Vietnam)</p>	<p>Study objective: to assess acceptability and adoption of CAB for PrEP amongst key populations (KP), including those who have had lower uptake of oral PrEP, such as PWID, transgender men, and SWs.</p>
<p>IHRI (Nittaya Phanuphak)- Key Population Led Delivery of CAB-LA for PrEP in Thailand (Thailand)</p>	<p>Study objectives: to identify barriers and facilitators for the integration of CAB for PrEP in KP-led clinics, to design a KP-led CAB for PrEP service delivery model and multi-component implementation strategies based on identified barriers and facilitators, and to pilot the implementation of KP-led CAB for PrEP delivery in two KP-led clinics in Bangkok. It is hoped lay providers will be able to provide the injections.</p>
<p>UCSF (Cait Koss)- SEARCH Sapphire (Kenya, Uganda)</p>	<p>Study objectives: to determine if adding CAB for PrEP as a prevention choice using a patient-centered HIV prevention delivery model increases prevention coverage compared to standard of care and evaluate initial implementation of a patient-centered model for CAB for PrEP. It is still being discussed and agreed which out of clinic community settings are to be used in the study, but settings used in the initial SEARCH study included households, health facilities, beaches, trading centers, and other sites preferred by participants.</p>

Kirby Institute (Ben Bavinton)- Future PrEP and CAB for PrEP Implementation Trial (Australia)

Study objectives (Future PrEP): to assess issues for CAB for PrEP and future PrEP implementation, CAB for PrEP acceptability, and client preferences.

Study objectives (CAB for PrEP Implementation Trial): a planned implementation trial with final objectives to be confirmed.

ANRS (Jean-Michel Molina)- Prévenir (France) and CohMSM (Burkina Faso, Côte d'Ivoire, Mali, Togo)

Study objectives: to assess retention, acceptability, tolerability, safety, preferences, changes in sexual behavior, and Integrase Strand Transfer Inhibitor (INSTI) resistance in CAB for PrEP users.

Recommendations and Way Forward

- Although some of the planned studies are small, most are focusing on addressing critical implementation issues such as testing, which unless resolved will be impediments to implementation in lower- and middle-income countries. A plan for further larger, ambitious, real world studies, with clear pathways towards translation into national programs, should be developed for broader implementation once these initial issues have been answered.
- Sex workers are an important group to reach with HIV prevention options; currently, this population is only included in two studies. Future implementation studies should strongly consider including this group. There is also a need for additional studies featuring transgender men, gender non-conforming individuals, PBFP, and PWUD/PWID.
- There is currently a gap for studies located in West Africa, Europe, and the Middle East and North Africa; there are no studies planned for Eastern Europe or Central Asia.
- Choice will be a critical consideration as CAB for PrEP is scaled up. It will be important for implementers to track new PrEP users vs method switchers, and to monitor whether users are switching to CAB for PrEP because they are unhappy with their current method or because they are particularly interested in an injectable. This data will help strengthen the argument that more prevention options lead to higher uptake and may allay government concerns around the increased cost of existing oral PrEP users switching to CAB for PrEP.
- 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 explore ways to visually represent study tracker data to synthesize implementation study plans and highlight gaps (e.g. in geographies or populations).
- AVAC will schedule a follow-up call to facilitate sharing of additional implementation study plans.

Additional Resources:

- [Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women](#) – *NEJM*, August 2021
- [Characterization of Human Immunodeficiency Virus \(HIV\) Infection in Cisgender Men and Transgender Women Who Have Sex With Men Receiving Injectable Cabotegravir for HIV Prevention: HPTN 083](#) – *JID*, August 2021
- [Enhancing HIV Prevention with Injectable Preexposure Prophylaxis](#) – Quarraisha Abdool Karim *NEJM*
- [Editorial: HIV prevention injection should be fast-tracked like COVID-19 vaccines](#) – *Spotlight*, South Africa
- [Implementation Science Questions for CAB for PrEP](#) – BioPIC, April 2022 (revised)
- [Advocate Primer on Long-Acting Injectable Cabotegravir for PrEP Understanding the Initial Results of HPTN 083 & HPTN 084](#) – AVAC
- [CAB for PrEP Implementation Study Tracker](#)– AVAC
- [BioPIC CAB for PrEP Dashboard](#)– AVAC