

Product Introduction/Implementation Project Planning for Next-Generation PrEP

September 22-23, 2021

Meeting Summary

Early data from clinical trials indicating that long-acting injectable cabotegravir (CAB-LA) is safe and effective in reducing the risk of HIV acquisition in multiple populations has led to those trials transitioning from blinded to open-label studies in which all trial participants are offered the choice between CAB-LA and oral TDF/FTC. With an accelerated timeline for planning and preparing to introduce CAB-LA, and progress of other long-acting HIV prevention products through the pipeline, AVAC and WHO jointly convened a think tank to strategize about demonstration projects and other planning for product introduction. Over two days of virtual sessions, some 55 participants across geographies and perspectives worked together to:

- Share initial results and recommendations across various CAB-LA landscaping analyses to get a shared understanding of what is already planned.
- Identify common questions, hypotheses and knowledge gaps which need to be answered by CAB-LA introduction projects across contexts and partners.
- Outline a cohesive approach for designing implementation projects and defining the implementation science agenda for CAB-LA and other next-generation PrEP options.
- Identify mechanism(s) for future coordination, information sharing and engaging other stakeholders.

Lessons from oral PrEP programs and infrastructure to inform new product introduction

Drawing on a wealth of experience in the meeting, as well as a [recent analysis from the HIV Prevention Market Manager project](#), participants highlighted critical lessons from oral PrEP of particular relevance to potential introduction programs for CAB-LA and other next generation PrEP options.

Demand	<ul style="list-style-type: none">• Invest in and partner with community and users throughout - from research to demonstration to delivery.• Ensure implementation research and programs are inclusive of diverse populations across user groups and geographies, especially the underreached such as transgender people and people who inject drugs (PWID).• Address providers as a key driver of demand.• Utilize a two-tiered communications approach: general media to inform the public about the new product and normalize its use, along with specific actionable information to generate interest and uptake among users and potential users.• Messaging and services tailored to specific users and user groups can create stigma for those clients and the product.• Avoid “risk” based campaigns and messages, and instead use positive benefit-/gain-framed messaging.
Delivery	<ul style="list-style-type: none">• De-medicalizing products increases access to those who most need and will benefit from them.• Simplify delivery of biomedical HIV prevention methods, and experiment with multiple approaches early.• Services need to anticipate and support switching, stopping and restarting product use.• Introduce new products in many delivery systems from the beginning, with careful monitoring to ensure ongoing learning, adaptation and expansion.

Data	<ul style="list-style-type: none"> Monitoring and evaluation approaches do not reflect real service or user experiences, including cycling on and off PrEP, switching, and daily vs. event driven use. Information on cost and cost-effectiveness is critical for government decision-making. Limited coordination among PrEP demonstration projects led to challenges in comparing or aggregating data, some duplication and overlap, and key gaps.
------	---

Insights from landscape analyses and ViiV’s plans

Landscape analyses conducted in Kenya, Malawi and Zimbabwe explored key topics for introducing HIV prevention products including CAB-LA: health system readiness, preferred platforms for service delivery, understanding and reaching specific geographies and populations, structural barriers, supply chain and logistics, and a range of other factors. These and other country-specific analyses are an important resource to highlight critical questions and guide project design for implementation research and demonstration projects in these countries.

ViiV, the manufacturer of CAB-LA, outlined how it is working toward product introduction, including:

- Its strategy focuses on women of reproductive age while being supportive of access for other key populations.
- A rolling regulatory submission to the US FDA is in process for expedited review in January 2022. Filings in countries that participated in the HPTN 083 and 084 clinical trials have been initiated but not completed.
- ViiV has a dedicated implementation science team that can review and collaborate on proposed implementation research efforts. Its initial strategy will focus on providing CAB-LA in existing HIV prevention programs.
- ViiV is committed to a non-profit price for low-income countries with specifics in negotiation.
- It is working to strengthen and extend relationships with a variety of stakeholders, including partnerships with HIV prevention advocates and civil society.

Demonstration Project Planning

In small group discussions participants applied lessons from oral PrEP and a wide range of expertise and experience to insights for robust, strategic, and informative demonstration and introduction projects.

Population	<ul style="list-style-type: none"> Generate information for implementation among diverse populations and geographies, looking especially beyond AGYW in SSA, the focus of many PrEP programs to date. Explore concerns, questions, service preferences and other issues through demonstration projects when feasible or other research and community-based approaches. Ensure that all regions and “missing populations” such as people who inject drugs and sex workers are included in some aspect of this research. Balance messaging and services tailored to specific users and user groups with normalizing use and avoiding stigma. Define potential users and user groups by behaviors rather than risk. Reframe CAB-LA – and other products – affirmatively by stressing their benefits rather than “risk reduction” or the product’s limitations. Ensure that messages and delivery systems for pregnant and breastfeeding women are clear early on, even if the product is not available.
Demand	<ul style="list-style-type: none"> Invest in robust partnerships with community and users early and continuously, using multiple approaches – advisory groups, meetings, media, materials, online.

	<p>Involve civil society from the beginning as experts in designing services, communications strategies and materials, and outreach.</p> <ul style="list-style-type: none"> • Explore messages and strategies for a two-prong communication approach with general media to create awareness and normalize use, and specific information aimed at potential users and prioritized populations. • Invest in “demand generation” among a range of actors: donors, government policymakers, providers, and influencers in addition to potential clients. • Acknowledge potential for confusion and ensure that messaging clarifies differences between vaccines and “injectable PrEP”, especially given emerging challenges of misinformation and confidence in the current COVID-19 environment. • Ensure that messaging emphasizes HIV prevention choice and does not play one PrEP product against another.
Delivery	<ul style="list-style-type: none"> • Design demonstration projects to explore and anticipate a range of models and approaches such as integration with other services, community providers, peer counseling and pharmacies. Experiment with models for delivering CAB-LA more simply from the outset as it can be challenging to de-medicalize delivery once the norm of a medical framework is established. This de-medicalization will look different for different products, and demonstration projects should explore what elements of care can be provided in less medical settings. • Locate projects within existing services for HIV prevention, family planning, primary health care and others to explore how people choose and potentially switch among different options like oral PrEP, CAB-LA, ring, and condoms. • Draw on lessons and examples from a range of health services and systems beyond PrEP. For example, contraceptive programs have long experience with offering clients a choice of methods and in managing switching and “discontinuation”, and injectable contraception has clear parallels with CAB-LA. • Plan demonstration projects that more closely mirror service delivery rather than clinical research to better inform program planning, implementation and scale up. • Explore and determine a specific, feasible, affordable protocol for testing for initiation and continuation, including the implications for service delivery options.
Data	<ul style="list-style-type: none"> • Include specific outcome measures that explore how people choose among different prevention options, as well as patterns of starting/stopping and switching, and their reasons for doing so. Anticipate how these can inform agile M&E systems and indicators that can accurately monitor use patterns in programs. • Support effective drug resistance monitoring systems for PrEP. • Develop an evidence base and clear strategy to actively cultivate interest and address questions from governments that may have limited capacity for and interest in investing in new products, including cost and cost-effectiveness. • Coordinate and share information among demonstration projects to ensure they are strategic, efficient, and complementary, and that select agreed indicators can be compared and aggregated across projects.

Follow up/Next Steps

Implementation research/demonstration projects

- Design and fund specific implementation research/demonstration projects in diverse geographics and populations.

- Develop high-level research and implementation questions for CAB-LA as a reference in the design, funding and gap-filling of implementation projects.
- Establish an ongoing forum for exchange among those designing and conducting implementation studies to share information, trouble shoot and adapt in real-time.
- Develop generic protocol and/or guideline from WHO on demonstration projects.

Information sharing

- Clearinghouse of information on trials, studies, implementation research, demonstration projects and other efforts to track all relevant work (by questions, populations, geographies and other key factors) with protocols, tools and other resources integrated into PrEP Watch, expanded to include resources for CAB-LA and other HIV prevention technologies.
 - Include funding sources for projects and overview of who is funding what where.
- Updated BioPIC dashboard to track CAB-LA trials and studies.
 - AVAC [launched a survey to generate](#) comprehensive and up to date information (see attached).
- Develop and disseminate an overview guide to the HPTN 083 and 084 open label extension studies that outlines questions they will answer and remaining gaps.
- Continue exchange among implementers across and within regions to ensure that evolving understanding and adaptation draws on all relevant innovations and insights in addition to lessons from oral PrEP that focus on SSA. More investment is needed so that program implementers and innovators from Southeast Asia and Latin America/Caribbean can fully participate in and inform the global discourse on HIV prevention.

Expert meetings/think tanks/consultations to further refine thinking and questions on specific topics

- Maintain momentum among think tank participants for ongoing, quarterly updates.
- Testing for PrEP initiation and continuation.
- Marketing prevention:
 - Develop an overarching messaging framework for positioning and marketing prevention overall and specific products within the context of choice that can be used across implementation research and demonstration projects.
 - Evolving terms and concepts (e.g., risk, target population, engagement vs. partnership, pleasure as backdrop for prevention).
- Insights from family planning, especially DMPA-SC introduction, to apply to CAB-LA introduction in the context of comprehensive HIV prevention, especially related to choice and method switching.

Community Partnerships

- Develop global community/advocate advisory mechanism as an ongoing reference group for introduction activities.
- Link global group to support national and regional advisory boards and connect civil society and advocates in systematic, ongoing efforts.
- Identify civil society partners and community organizations as experts to link with national implementation projects and campaigns to generate insights and perspectives from different user groups and geographies.
- Consider formal roles for community partners in implementation projects, especially around social and behavioral aspects and de-medicalization efforts.