Accelerating Access to Long-Acting PrEP

Oral PrEP Progress and Planning for the Future

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Executive Director, AVAC

Making PrEP Accessible: Updates on Long-acting Injectable Options
30 March 2023
Key Updates

- Zimbabwe, South Africa & Malawi approvals – with quite permissive labels in terms of age, oral lead-in, use in pregnancy and testing
- Eight implementation science projects approved
- PEPFAR procurement plans and COP agreements in 6 countries
- Global Fund and CIFF partnership in 6 countries
- Limited supplies available from ViiV thru 2023, pending additional mill approval from FDA to expand
- Three generic sub-licenses from MPP announced today
- Coalition to Accelerate Access to Long-Acting PrEP working with wide range of stakeholders
Parallel Universes/Journeys

**Providers & Health Systems**

- Who is at risk?
- Where do I find them?
- When I can test them?
- What do I tell them?
- Where can I provide px info and products to them?
- What px options can I provide them?
- Oral, ring, injectable, condoms, DPP?

**Users**

- What do I want?
- Who do I want to talk with about sex and relationships?
- Do I want an HIV test?
- Where do I want to get an HIV test?
- Do I need and want HIV prevention?
- What kind of HIV px do I want?
- Oral, ring, injectable, condoms, DPP?
- Where and from whom do I want it?
Global PrEP Uptake – 10+ years in

Approx. total PrEP initiations: 3.8 million with strong increases in 2022 – BUT significantly missed UN target of 3 million users by 2020
Learning from and Building on Oral PrEP

Oral PrEP Implementation Studies

- **Post-approval studies and projects**
  - 131 Distinct post-approval oral PrEP implementation projects and studies; most were small-scale

- **Countries**
  - 68 Different countries conducted projects including multiple in the same country (e.g. 25 in one country)

- **Stakeholders**
  - 54 Different organizations involved in oral PrEP implementation research

Key Takeaways from early Oral PrEP rollout

- Post-approval studies were not all designed to address decision-maker questions
- Data from research was not well timed to inform decision making at global or country level
- Complex, fragmented stakeholder landscape

Lessons From Oral PrEP Programs & Implications for Next Generation Prevention
The Way Forward

Requirements of Collaboratively Planning for Successful Introduction:

- Mapping decision-maker questions against studies
- Planning in parallel with clinical trials
- Shared strategy developed by diverse stakeholders

Ideal Scenario for Future Px Products:

- Post-approval studies are well designed to address decision-maker questions
- Data from research is well timed to inform decision-making at global and country level
- Coordinated stakeholder landscape with roles agreed upon in advance

BioPIC CAB-LA initial Introduction Strategy
Translating Scientific Advance into Public Health Impact: A Plan for Accelerating Access and Introduction of Injectable CAB for PrEP

Product
- ViV to license injectable CAB to the Medicines Patent Pool (MPP).
- The MPP and ViV to work with generic manufacturers and donors, including Africa-based manufacturers, to expedite technology transfer and ensure sustainable supplies of the product.
- Generic manufactures, with MPP, to identify capital expenditure needs and timeframe to be able to develop capacity.
- Innovative donor(s) to fund capital investments needed for generic manufacturing to reach scale.
- ViV to confirm publicly, maximum quantity and minimum price for 2022-2025.
- Donors to negotiate this price/volume guarantee to ensure sustainable supply for initial introduction period, given the timeline for generic licensing agreements and manufacturing upgrades (likely 4-5 years).

Regulatory Approval & Normative Guidance
- Eight regulators currently reviewing injectable CAB for PrEP to ensure priority review.
- ViV to pursue widespread registration of CAB in high-burden countries.
- ViV to register with WHO Pre-Qualification (PQ) to allow expedited registration in countries participating in WHO’s Collaborative Procedure for Accelerated Registration process.

Planning & Budgeting
- Governments and donors to set targets for supply and programs at scale – what is needed and possible in 2022-2023 in implementation science projects, and what is needed from 2024 to begin programs at scale.

Delivery / Supply Chain
- Large, resourced and coordinated implementation studies to begin immediately to answer critical questions about how CAB performs outside the clinic setting and across populations.
- Provider training materials and tools updated to incorporate CAB administration and implementation studies that assess the feasibility of task-shifting to expand the cadre of providers that are authorized and trained to administer injections and that offer choice (explaining efficacy, clinic visits, side effects, etc. of all methods available) and assist in shared decision-making.
- Innovative demand creation strategies (for injectable PrEP and for “choice” among options) developed with process to test and iterate, and share across projects.

Individual Uptake & Continued Use
- Testing requirements should not become a barrier to CAB introduction. Testing strategies should be both robust and feasible and work with locally available tests and assays to maximize the benefits of access to CAB while minimizing the risk of undetected cases.

Research
- Data to be collected on the benefit of injectable CAB as PrEP for populations that were not part of efficacy trials, especially adolescents, pregnant and breast-feeding people, and transmasculine and gender non-conforming individuals.
- Study alternate injection sites and frequency of injections, recognizing that the impact of injectable CAB holds the potential to expand, if the injection schedule could align with injectable contraception.

Stakeholder Engagement
- Integrate and engage civil society in all decision-making relevant to planning and preparation for access to CAB, including designing, conducting and monitoring implementation studies and delivery programs.
Coalition to Accelerate Access to Long-Acting PrEP

- Build on lessons learned from oral PrEP and coordinate stakeholders activities
- Jointly develop strategies to identify and overcome access challenges for new PrEP options in near- to medium-term (ViiV’s injectable CAB, including generics, and dapivirine vaginal ring) and medium- to long-term (future PrEP products)
- Ensure new, longer-acting PrEP options reaching the market will be available and equitably accessible to all who need them more quickly than ever before
## PrEParing for New Products

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<td>10,214</td>
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<td>28,603</td>
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<td>170,551</td>
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<td>Catalyst; MOSAIC; SEARCH</td>
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**Note:** AVAC Global Advocacy for HIV Prevention.
PrEParing for New Products – Geographically

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Implementation science studies are planned in 19 countries with cabotegravir (CAB) for PrEP and/or dapivirine vaginal ring (up):

Some studies are happening in more than one country, with a total of 25 studies in 32 countries.

BioPIC Implementation Study Tracker
BUT, significant questions remain about timing:

- National regulatory approvals of product
- ViiV internal approvals of protocols
- Product supply – manufacturing capacity, timing, shipping
- Actual product delivery to participants
- Answers to critical questions to inform models, policies, program design, procurement, investment
PrEParing for New Products – By Population

**Study Populations**

- Cis Men: 12
- Cis women: 10
- Gay and Bisexual MSM: 10
- Not Specified: 6
- Trans Women: 6
- Adolescents: 5
- Pregnant and Lactating People: 4
- Adolescent Girls and Young Women: 4
- Sex Workers: 3
- Trans Men: 3
- Gender Non Conforming People: 2
- People who Use Drugs: 1

**Sample Sizes (where known)**

- <1,000
- 1,000-5,000
- 5,000+

- Not all studies have established sample sizes
- Only four studies with over 5,000 participants: CATALYST (MOSAIC), Project PrEP (Wits RHI), FASTPrEP (DTHF), and Theta Nami Ngithethe Nawe (“Let’s Talk”) (AHRI)
- Most studies plan to run 2023-2025, dependent on approvals and CAB supply

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**BioPIC Implementation Study Tracker**
Now What?

- Translate biomedical options into viable choices for users, providers and health systems
  - Intro new options as part of marketing and programming for choice
  - Identify (and differentiate) service delivery models that work for users
  - Ask and answer critical implementation science questions for each product, while building prevention platforms for the future
- Understand testing and initiation needs for PrEP
- Ensure robust civil society engagement in intro/implementations research and planning
- Procurement/commodity funding – for launch and ongoing
- Provider training – both clinical guidelines AND appropriate counseling, support, empathy
- Realistic targets for interventions, especially intro – and not just coverage targets
- Identify what products can “solve for” – and what they can’t
- Ensure we do better, more equitable intro with ring and injectable than with oral PrEP and COVID-19 vaccines
Resources

- **Podcast:** *New Products are Needed & a New Paradigm is Essential: A new era in prevention?*
- **Summary slide decks:**
  - *Advocates Guide to CAB for PrEP*
  - *Advocates' Guide to Product Introduction*
  - *Advocates' Guide to HIV Testing and PrEP*
- **AVAC’s Plan for Accelerating Access and Introduction of Injectable CAB for PrEP & summary document**
- **Advocates’ Primer on Injectable Cabotegravir for PrEP: Trials, Approvals, Rollout and More**
- **Implementation Science Questions for CAB for PrEP**
- **Implementation Study Tracker**
- **Cost of Goods Sold (COGS) Analyses: FAQ Brief** – AVAC & CHAI
- **A New Shot Guards Against HIV, but Access for Africans Is Uncertain** – New York Times
- **Global PrEP Tracker** (that includes DVR and CAB in addition to long-standing oral PrEP info)
- **Lessons Lessons From Oral PrEP Programs & Implications for Next Generation Prevention**
- **BioPIC CAB-LA Initial Introduction Strategy**
- **BioPIC Adaptable Framework for Product Introduction**
- **Dual Prevention Pill Market Preparation and Introduction Strategy**
Acknowledgements

- Carolyn Amole
- Rachel Baggaley
- Linda-Gail Bekker
- Susan Buchbinder
- Connie Celum
- Sinead Delany-Moretlwe
- Kim Green
- Beatriz Grinsztejn
- Sharon Hillier
- Brian Kanyemba
- Grace Kumwenda
- Raphy Landovitz
- Kenneth Mwehonge
- Definate Nhamo
- Nittaya Phanuphak
- Yvette Raphael
- Helen Rees
- Zeda Rosenberg
- Kenly Sikwese
- Kristine Torjesen
- Jacque Wambui

Coalition to Accelerate and Support Prevention Research (CASPR)

Cooperative Agreement No. AID-OAA-A-16-00031
HIV Vaccine and Biomedical Prevention Research Project—Objective 3

BioPIC > Biomedical Prevention Implementation Collaborative

HIV Prevention Market Manager
Acclerating Product Introduction
Informing Product Development
Reducing Time to Impact

Supported by the Bill & Melinda Gates Foundation

Biomedical Prevention Implementation Collaborative