Improving PrEP rollout, uptake and retention

PEPFAR Watch Webinar
20th January 2023

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The PrEP Pipeline

Currently available:
- HIV treatment for people living with HIV
- Male & female condoms
- Voluntary medical male circumcision
- Syringe exchange programs

Pending/in regulatory review:
- Dapivirine vaginal ring
- Long-acting injectable: Every 6 months

In development: Efficacy trials under way:
- Long-acting injectable: Every 2 months
- Preventive vaccines

In development: Preclinical and clinical:
- Long-acting implants
- Preventive vaccines
- Multipurpose vaginal ring
- Broadly neutralizing antibodies
- Inserts
- Patches
- Long-acting vaginal ring
- Enema

And in implementation science projects:
www.prepwatch.org/resources/implementation-study-tracker/
Advocacy Context for 2023

• Primary prevention often cut when budgets drop, so important to review planning letters.

• Renewed PrEP targets commitment in the HIV prevention roadmap (80% FSW - 50% MSM - 15% PWID - 50% TRANS - 15% - Prisoners and closed settings enrolled on PrEP)

• New HIV infections are still on the rise especially among Key populations and AGYW; yet efforts to reduce new HIV infections are fettered by inequalities

• The HIV prevention tool box is slowly bulging; but how do we ensure that HIV prevention programs are pro-choice?

• COP planning happening in concurrent with Global Fund NMF4 process; a great opportunity to leverage on both funding streams
Global PrEP landscape – 10 years in

PrEP Initiations by Country, October 2022

Approx. total PrEP initiations: 3,315,726
Global trends in oral PrEP uptake

- Global cumulative PrEP initiations have increased substantially in approximately 6 years – **from 102,446 in Q3 2016 to 3,315,726 in Q3 2022.**

- **Over 1.3 million initiations** in 2022 alone, comprising 40% of total initiations over the past 6 years.

- About **76%** of cumulative global PrEP initiations, or **2,536,329**, were in sub-Saharan Africa (SSA) as of Q3 2022 – a stark increase compared to earlier years.
Country trends in oral PrEP uptake

- Eight countries in SSA have surpassed 100,000 PrEP initiations, accounting for 86% initiations in the region
- **South Africa** and **Kenya** were two of the earliest adopters with national programs scaling up over time
- **Zambia, Uganda** and **Nigeria** have seen steep growth from 2020-2021; nearly 100% of initiations in these countries were PEPFAR-driven
CAB for PrEP Regulatory Approval Statuses

**Injectable PrEP**

- **Approved**
  - Australia
  - South Africa
  - USA
  - Zimbabwe

- **Submission Under Review**
  - Botswana
  - Brazil
  - China
  - European Medicines Agency
  - Kenya
  - Malawi
  - Malaysia
  - Myanmar
  - Philippines
  - Thailand
  - Uganda
  - Vietnam
PrEP Ring Regulatory Approval Statuses

- **Approved**
  - Kenya
  - Lesotho
  - South Africa
  - Uganda
  - Zambia
  - Zimbabwe

- **Submission Under Review**
  - Botswana
  - Malawi
  - Mozambique
  - Namibia
  - Rwanda
  - Tanzania
Drivers of PrEP uptake at country level

What do countries with high uptake tend to have in common?

• Ambitious targets + adequate funding
• Early adoption
• National commitment to scale-up with sub-national buy-in
• Coordinated partner landscape
• Broad access (e.g., to the general population)
• Community awareness/engagement
• Programs tailored to different populations offering:
  – Community-led, accessible, non-discriminatory services
  – Linkages to social support

Lessons learned for PrEP implementation

Demand Generation
- Engage users early in product design and development
- Socialize PrEP for general population with tailored outreach & messaging
- Invest early in communities to support PrEP use
- Empowerment messaging that resonate with people’s lives and goals

Delivery
- Differentiated, de-medicalized, simplified, integrated models; combination of facility and community-based settings
- Training and task shifting to broader range of providers
- Adapt quality assurance standards and mechanisms

Data and Decision-making
- Invest in implementation research at scale with community engagement
- Understand individual patterns of use while measuring PrEP impact
- Greater transparency in pricing and commodity costs
Apply lessons to new product introduction: CAB for PrEP

• Injectable cabotegravir (CAB for PrEP) is an injection every two months; found to be safe and effective across pops in clinical trials and recommended by WHO

• As it is longer acting than oral PrEP, it may help improve adherence for some users who face barriers to taking daily pills (e.g. stigma, side effects, pill size)

• However, also has limitations- requires seeing a healthcare provider in person, can’t discontinue an injection- so ensuring choice is critical

• Approved in Australia, South Africa, the USA, and Zimbabwe; and submitted in: Botswana, Brazil, China, Kenya, Malawi, Malaysia, Myanmar, Philippines, Thailand, Uganda, Vietnam, and to the European Medicines Agency
Apply lessons to new product introduction: CAB for PrEP

- **Coalition to Accelerate Access to Long-Acting PrEP** - new initiative started in July 2022 to make longer-acting PrEP options, including CAB for PrEP, accessible as quickly as possible- convened by Unitaid, WHO, UNAIDS, Global Fund, and PEPFAR with AVAC as secretariat

- Manufacturer ViiV has signed a **voluntary license agreement** with the Medicines Patent Pool to allow for manufacture of **generics**, helping to enable wider access – licenses to 3 generics to be announced by March

- **Advocacy Priorities:**
  - Ensure affordable pricing: leverage PEPFAR and Global Fund to lead on this
  - Apply learnings from oral PrEP, e.g. differentiated service delivery
  - Ensure choice: through provider training and a strong supply chain
  - Leave no one behind: undertake research to ensure CAB for PrEP can be used by diverse populations
# CAB and PrEP Ring Implementation Studies (1/2)

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Product</th>
<th>Countries</th>
<th>Populations</th>
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<tbody>
<tr>
<td>MOSAIC- CATALYST</td>
<td>CAB, Ring</td>
<td>Kenya, Lesotho, South Africa, Uganda, Zimbabwe</td>
<td>AGYW, sex workers, PLP, trans women and non binary individuals</td>
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<tr>
<td>Project PrEP</td>
<td>CAB, Ring</td>
<td>South Africa</td>
<td>AGYW</td>
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<tr>
<td>ImPrEP/CAB-Brasil</td>
<td>CAB</td>
<td>Brazil</td>
<td>GBMSM, Trans women, trans men, non binary individuals</td>
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<tr>
<td>PrEP1519</td>
<td>CAB</td>
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<td>Young GBMSM, young trans women</td>
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<tr>
<td>FASTPREP/PrEPared to Choose</td>
<td>CAB, Ring</td>
<td>South Africa</td>
<td>AGYW, young GBMSM, PLP</td>
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<tr>
<td>Axis</td>
<td>CAB</td>
<td>South Africa</td>
<td>Adult women and men</td>
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<tr>
<td>Thetha Nami ngithethe nawe (“Let’s talk”)</td>
<td>CAB</td>
<td>South Africa</td>
<td>Men and women aged 15-30</td>
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<tr>
<td>Key Population Led Delivery of CAB-LA for PrEP in Thailand</td>
<td>CAB</td>
<td>Thailand</td>
<td>GBMSM, trans women</td>
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<tr>
<td>SEARCH</td>
<td>CAB</td>
<td>Kenya, Uganda</td>
<td>All</td>
</tr>
<tr>
<td>STEPS</td>
<td>CAB</td>
<td>Vietnam</td>
<td>All KP</td>
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<tr>
<td>CohMSM</td>
<td>CAB</td>
<td>Burkina Faso, Cote d'Ivoire, Mali, Togo</td>
<td>GBMSM</td>
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# CAB and PrEP Ring Implementation Studies (2/2)

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<td>Pharmacy-delivered LA HIV PrEP in Kenya</td>
<td>CAB, Ring</td>
<td>Kenya</td>
<td>All</td>
</tr>
<tr>
<td>AMETHIST- Pharmacy-based PrEP</td>
<td>CAB, Ring</td>
<td>Zimbabwe</td>
<td>Female sex workers</td>
</tr>
<tr>
<td>Mozambique CAB study- name TBC</td>
<td>CAB</td>
<td>Mozambique</td>
<td>GBMSM, trans women, sex workers</td>
</tr>
<tr>
<td>Blantyre Prevention Strategy CAB study- name TBC</td>
<td>CAB</td>
<td>Malawi</td>
<td>TBD</td>
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<tr>
<td>PICASSO</td>
<td>CAB</td>
<td>South Africa</td>
<td>TBD</td>
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<tr>
<td>CAB LA in Private Pharmacies</td>
<td>CAB, Ring</td>
<td>South Africa</td>
<td>TBD</td>
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<tr>
<td>PrEP-PP</td>
<td>CAB</td>
<td>South Africa</td>
<td>PLP</td>
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<tr>
<td>MOBILE MEN</td>
<td>CAB</td>
<td>Uganda, South Africa</td>
<td>Cisgender men</td>
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<tr>
<td>Zimbabwe Dapivirine Ring Study</td>
<td>Ring</td>
<td>Zimbabwe</td>
<td>Cisgender women</td>
</tr>
<tr>
<td>Increasing PrEP options for women in Eswatini</td>
<td>Ring</td>
<td>Eswatini</td>
<td>AGYW, sex workers, PLP, trans men</td>
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Key Resources

- **Report**: Lessons from Oral PrEP Programs and their Implications for Next Generation Prevention

- **Issue briefs** featuring key PrEP learnings:
  - Simplifying and improving delivery
  - Reframing risk
  - Generating demand
  - Monitoring and evaluation for next-generation PrEP

- **Resource hub**: PrEP Watch

- **Data hub**: Global PrEP Tracker

- **Implementation Research**: Implementation Study Tracker
New Biomedical prevention strategies – coming SOON
Dapivirine Ring

Current status

- Female initiated HIV option to reduce the risk of HIV infection: monthly vaginal ring using ARV dapivirine
- Received positive scientific opinion from the European Medicines Agency (EMA) in July 2020
- Recommended by WHO an additional HIV prevention option as part of the prevention package; added to the WHO’s list of prequalified medicines; in March 2021, the WHO released updated clinical recommendations on HIV prevention which included detailed guidance for the DVR as an additional prevention choice for women at substantial risk of HIV infection
- Kenya, Lesotho, South Africa, Uganda, Zambia & Zimbabwe have already approved DVR; Licensure applications also submitted to Botswana, Malawi, Mozambique, Namibia, Rwanda & Tanzania.
- More submissions to be made and approvals expected in 2023.
- Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC), a new $85 million program funded by PEPFAR
Why the Ring?

• Provide additional HIV prevention option to CHOOSE from
• Not all are able to take a daily pill, nor will all cis-women prefer injectable PrEP
• Discreet; does not require negotiation with partner
• A combination prevention strategy is needed to achieve epidemic control; DVR ring could have a meaningful impact as part of that approach
• As we have learnt from the contraceptive experience, the ring would increase the number of women using an HIV prevention method
• Requires routine (quarterly) HIV testing to confirm negative status, as required for all biomedical HIV prevention products
• *Note: Future versions of the ring would be longer acting and include a contraceptive as well.*
Why the Ring?

Women in studies reported…

I like that the ring stays inside you and nobody can see it…. you don’t have to disclose ring use to others if you want. My family doesn’t know that I am using the ring. … And the partner can’t feel it as well. ¹

It wasn’t difficult, I got enough education before using it because I was really scared when I first saw it… But during education I learned that the ring was soft, I thought the ring was hard and painful. They showed that to insert the ring you need to twist it like 8 and when I tried it, it was easy and doable.”¹

I don’t feel the ring when it is inside me, I only feel it during insertion. I don’t feel it though when I’m seated or walking. The ring has never fallen; it’s not painful… the ring is not felt when you are walking or sleeping; it doesn’t even move²

Credit: IPM
Key Resources

IPM Ring backgrounder

IPM ring program

IPM Video describing the ring

Ring Introduction Planning

AVAC resources on the ring
COP23 guidance for new PrEP tools

- “In COP23, PEPFAR will continue to focus on prevention with an equity lens- especially for AGYW, KP and pregnant and breastfeeding mothers. It will thus plan to expand access to PrEP for diverse populations at risk of acquiring HIV”

- “COP23 plans to scale up PrEP and sees it as part of flexible prevention programming for the populations at risk. PrEP is also recommended as an evidence based prevention method”

- “PEPFAR will also work with the global community to advance the availability of generic versions of CAB-LA for over 90 low and middle income countries. It intends to hasten adoption of PrEP through market shaping a critical tool across diagnostics, therapeutics and prevention”

- Partner countries will also be assisted to include PrEP in their national guidelines.
What to ask for:

Investments in policy and guidelines for new PrEP options

- Civil society coalitions in countries where CAB for PrEP and DVR licensure has not yet happened could ask for fast tracking of the approval process.

- In countries where licensure has already happened, CSO should ask for a specific line item investment for policy and guideline development – you can ask that this be benchmarked off of the budget for and approach to oral PrEP introduction – and/or AVAC can help supply specific language.

- For Countries without the Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC) project should demand for a similar programme i.e. Tanzania and Malawi should demand for this.

- Push for integration with other existing services i.e oral PrEP, family planning and other SRH services and that those guidelines reflect that (e.g. guidelines on training of HCWs, training materials, program change considerations etc.).
What to ask for:

Investments in policy and guidelines for new PrEP options

• Push for civil society and community involvement in policy and guideline development processes (in TWGs, task forces)

• Given that Viiv Healthcare is still the sole supplier of CAB-LA, the cost of CAB-LA is still uncertain, we can demand for pooled procurement from PEPFAR and GF as a way of reducing cost as we continue to push for generic manufacturing.

• Ensure new PrEP options are being considered in tandem rather than guidelines and programs developed in silos
What to ask for:

Investments in policy and guidelines for new PrEP options

• Guidelines that support ring promotion and distribution within a comprehensive sexual and reproductive health and rights framework.
• Expand eligibility criteria by removing age and other policy restrictions to ensure more women have access to the ring and CAB LA.
• Ensure that community members and end-users are engaged in developing the national ring introduction plan, including implementation studies, demand creation strategies, and training materials.
• Support for implementation projects to introduce DVR and CAB-LA.
What to watch for…

- Statements that pit tools against each other: the new injectable or ring will be “easier” for people to take than daily oral PrEP, that cisgender women “prefer” injectable contraceptives so will prefer injectable PrEP.
- Statements that the DVR efficacy is not good enough; comparing DVR efficacy with that of CAB-LA

You can respond with …

- Communities have noted over and over again the importance of "choice" in the toolkit as different options work for different people at different times of their lives
- Some users want HIV prevention options that are discreet, long-acting, and can be used without partner cooperation - the ring and CAB-LA provide that
- Available HIV prevention products have not stopped the epidemic among these populations- no single product will
- Evidence from the contraceptive field shows choices increase uptake of all options. People at risk of HIV, not providers should decide what’s easiest.
- Expanding oral PrEP programs + investing in policy and guideline development + partnering with civil society = success for future PrEP
Checklist/Menu for PrEP Advocacy

What to ask for - who to ask

- **PEPFAR:**
  - At minimum, maintain PrEP budget from previous year AND/OR set target that is proportionally equivalent to highest recent increase
  - Ask for specific line item investment for DVR and CAB for PrEP policy and guideline development

- **Government/policy makers:**
  - Start guidelines and policy development review process for DVR and CAB for PrEP – if budget need, share with CSOs and with PEPFAR
  - Adopt or formalize differentiated PrEP delivery approaches – multi-month dispensing, peer-supported, community-based distribution

- **Global Fund:**
  - Procurement of commodities (Oral PrEP, DVR, )
  - Training of health care workers
  - M&E and data management
Questions, comments, reflections!!!
Thank you!