



PrEP Ring Early Market Access Vehicle Launch

30th October 2024

Agenda

| S/no | Agenda Item | Time | Speaker/ moderator |
|------|------------------------------------|---------|---|
| 1. | Introductions and Housekeeping | 8 mins | Manju Chatani-Gada (AVAC) and Yvette Raphael (APHA) |
| 2. | Why the ring is important | 10 mins | Seema Sayyed and Sinenhlanhla Gogela (Advocates) |
| 3. | Brief overview of ring information | 5 mins | Heather Ingold (WHO) |
| 4. | Product pipeline for ring | 7 mins | Brid Devlin (Population Council) |
| 5. | Overview of the EMAV | 10 mins | Amina Ja'afar (The Global Fund) |
| 6. | Walking through EMAV Request Form | 10 mins | Chris Obermeyer (The Global Fund) |
| 7. | Available resources and TA | 15 mins | Philip Imohi (MOSAIC - FHI 360) |
| 8. | Q&A | 25 mins | Chris Obermeyer (The Global Fund) |

Housekeeping

- **Recording** – This webinar will be recorded and shared with all attendees afterwards.
- **Questions** - Please ask questions via the *Q&A button* at the bottom of the screen (click the three dots if you do not see it) or raise your hand when prompted for questions. We don't want questions being lost in the chat.
- **Timing** - We want to ensure there's time for everyone to present, so we will be trying to stick closely to agenda timing and moving us along to the next presenter if needed.

Why the ring is important

Advocates

Dapivirine vaginal ring for HIV Prevention

Heather Ingold, WHO Geneva

WHO recommendation: Dapivirine vaginal ring

The dapivirine vaginal ring may be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches.

(conditional recommendation; moderate-certainty of evidence)

DVR should be offered with other PrEP products to enable women to make a



Efficacy

A systematic review commissioned for the WHO recommendation found that the **ring is effective in reducing the risk of acquiring HIV infection.** (*Fonner V et al*)

-Two RCTs reported that the DVR was approximately **30% effective in reducing HIV infection** in intention-to-treat analysis.

-Two OLEs found **increased efficacy, increased adherence and increased retention** relative to the randomized controlled trials

-The results from one of the OLEs indicated a **62% reduction in HIV transmission**, comparing study results to a simulated control

Greater dapivirine release from the dapivirine vaginal ring is correlated with lower risk of HIV-1 acquisition: a secondary analysis from a randomized, placebo-controlled trial

Elizabeth R Brown^{1,2,5} , Craig W Hendrix³ , Ariane van der Straten⁴ , Flavia M Kiweewa⁵ , Nyaradzo M Mgodi⁶, Thesla Palanee-Philips⁷, Mark A Marzinke³, Linda-Gail Bekker⁸ , Lydia Soto-Torres⁹, Sharon L Hillier¹⁰, Jared M Baeten¹¹  and the MTN-020/ASPIRE Study Team

- Dapivirine levels, as an objective measure of adherence, were correlated with HIV-1 protection in a secondary analysis of a randomized trial.

- Found that the **degree of HIV-1 protection** with greater adherence **exceeds 50% and may be as high as 75%.**

Safety – Pregnancy and breastfeeding

Safety studies of DVR use during pregnancy have shown a favorable safety profile among pregnant women and their infants; there is no evidence of negative impact on pregnancy or infant outcomes.

DVR safety data during pre-conception and early pregnancy

- While MTN-020/ASPIRE did not enroll pregnant individuals, almost 90 incident pregnancies occurred among participants using the DVR, offering insight on pre-conception and early pregnancy exposure safety data.
- Among participants, there was no impact on fertility rates and no association with preterm birth, pregnancy loss, congenital anomalies, or poor infant growth.

DVR safety data during pregnancy

- MTN-042/DELIVER was the first major study among pregnant individuals in three gestational age cohorts. Participants were randomized to use the DVR or oral PrEP through delivery.
- Data showed the DVR had no association with preterm birth or stillbirth or maternal or infant SAEs. There were also no HIV seroconversions and pregnancy complications were uncommon, similar to the background rates observed in study communities.

DVR safety data during breastfeeding

- MTN-043/B-PROTECTED enrolled approx. 200 exclusive breastfeeding mother-infant pairs. Participants were randomized to use DVR or oral PrEP with product used for 12 weeks.
- Key findings showed a good safety profile in both mothers and infants, with no SAEs related to the DVR in either group and very little dapivirine present in milk, with even less passed to infants.

Implementation considerations / Research gaps

Address the provision of the DVR as part of **comprehensive HIV and SRH services**;

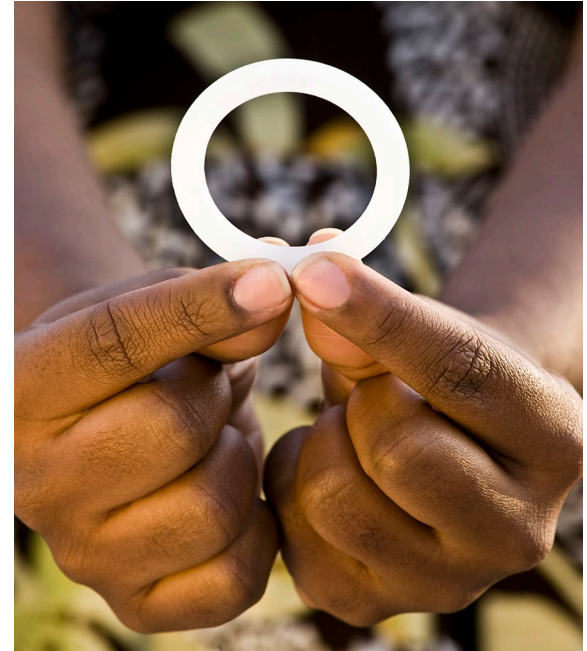
Ensure women are offered full information in order to make an **informed choice** about the benefits and potential risks when considering to use the ring (together with other available PrEP products);

HIV self-testing can be used to initiate, re-initiate the DVR and for monitoring during continuous use;

Adolescent girls and young women may need more support during initiation and for continuation;

Training and support for providers to understand and be able to offer this new product;

Further information on **cost-effectiveness** (*for all new PrEP products*).



Thank you



I thank my colleague at WHO Michelle Rodolph. I also thank all colleagues who contributed to the information included in this presentation as well as the community and MOH member who shared their voices

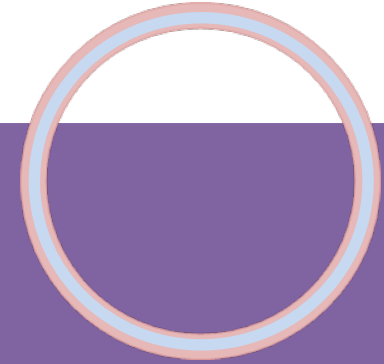
<https://www.who.int/groups/global-prep-network>
<https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/overview>

Please contact me for questions or further information: ingoldh@who.int

DAPIVIRINE RING PIPELINE

EMAV Launch
October 2024




The Dapivirine Ring Portfolio



Monthly DVR (DapiRing®)

Three-Month DVR

Contraceptive-DVR

| | Monthly DVR (DapiRing®) | Three-Month DVR | Contraceptive-DVR |
|------------|--|--|--|
| INDICATION | HIV prevention | HIV prevention | HIV and pregnancy prevention |
| REGIMEN | 1-month continuous use | 3-month continuous use | 3-month continuous use |
| DESIGN | Silicone Matrix | Silicone Matrix | EVA core-sheath design |
| PHASE | Marketed  | Preparing for Regulatory  | Clinical  |

Expanding DVR access: Additional Populations



[https://doi.org/10.1016/S2352-3018\(23\)00227-8](https://doi.org/10.1016/S2352-3018(23)00227-8)

Adolescent Girls: findings show promising results toward consistent HIV prevention product use in AGYW:

- **Choice:** 67% of participants chose to use DVR and 31% oral PrEP
- **Safety:** No safety concerns were noted for either product
- **Acceptability:** 88.5% for the DVR and 64% for Oral PrEP
- **Adherence:** 97% of participants used DVR or oral PrEP some or all of the time
- **Data submitted to the EMA in Q4 2024 to expand the label to include AGYW**



Pregnant Women: The DELIVER study has reported interim findings:

- Three cohorts have completed the study and no safety concerns
- Infant follow-up is ongoing (final cohort)
- **Data planned for EMA submission in 2025 to expand label to include pregnant women**



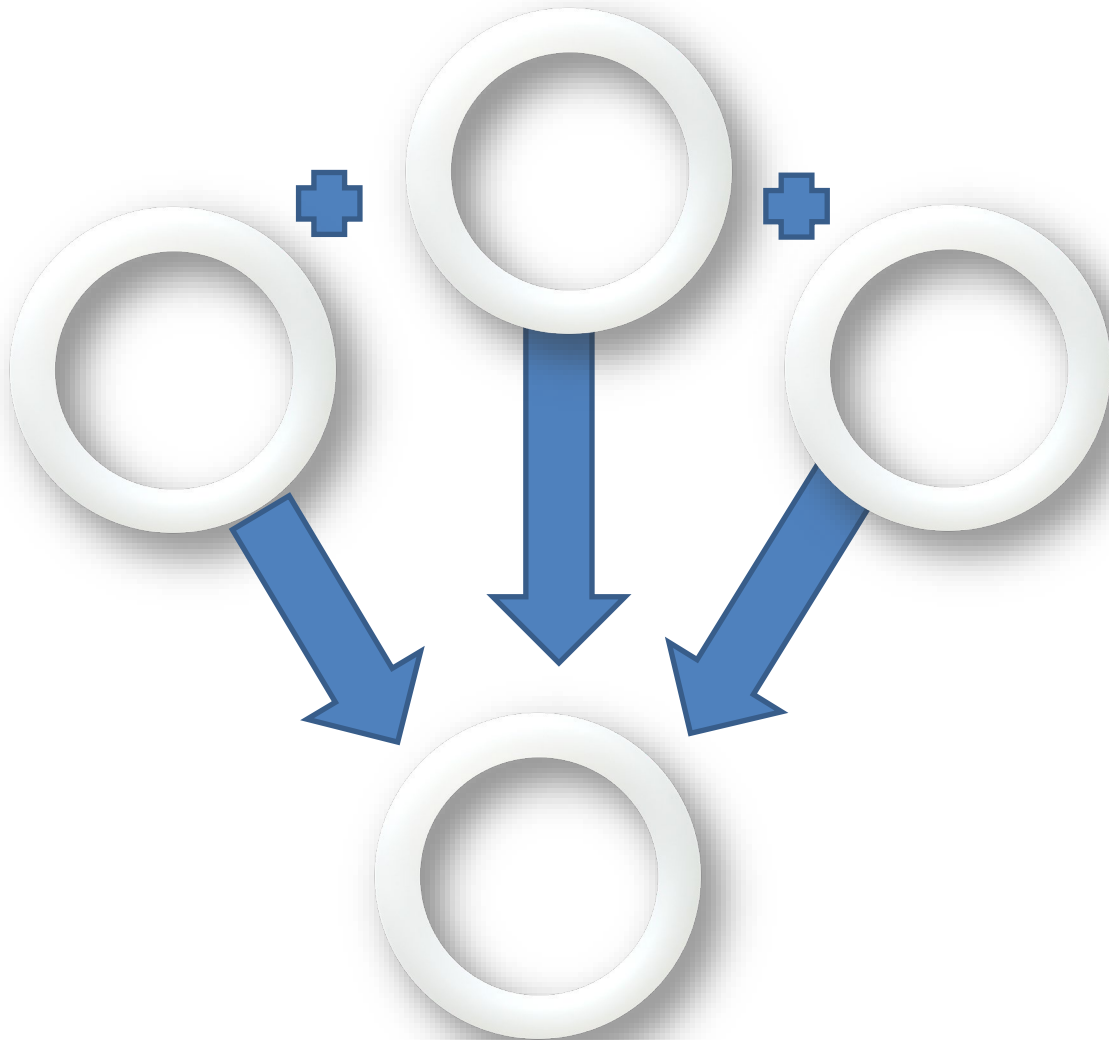
Breastfeeding Women: The B-Protected study has reported findings:

- Favorable safety profile and previous data showing low drug transfer to breastmilk supports updates of WHO to include breastfeeding women
- **EMA has approved expansion of the product label for the breastfeeding population**



Three-month DVR

Why a 3-month DVR?



3-month extended-release formulation provides several advantages over 1-month DVR:

- Only four rings required per year versus 12
- Reduced Cost: Estimated cost US \leq \$16 per ring excluding distribution \rightarrow ~60% reduction/year compared to 1-month ring
- Reduced waste and environmental impact
- Increased convenience for the User
- Potential for increased adherence

Key Studies Completed to Date

Phase I trial in US Completed.

Compared PK and safety of two extended-use dapivirine rings (100mg and 200mg) with monthly dapivirine ring (25mg) when used for 13 continuous weeks

Results found no safety concerns, supported further development

100mg Ring selected for further clinical development

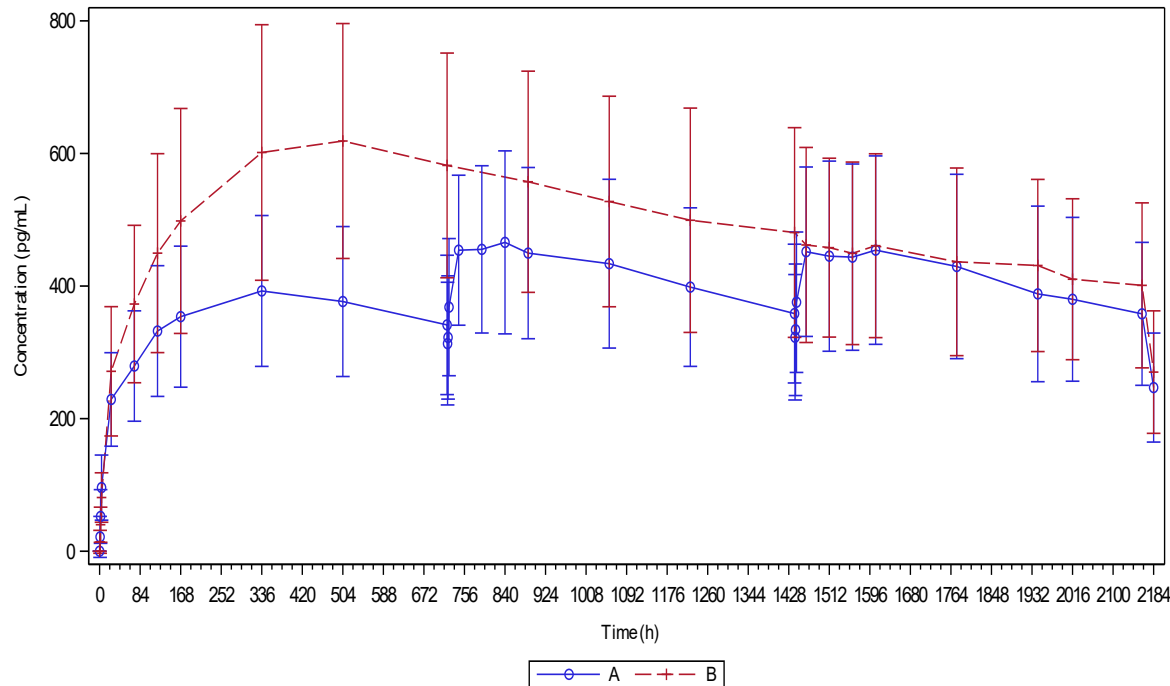
Manufacturing Process Validation at clinical scale complete

Commercial scale ongoing

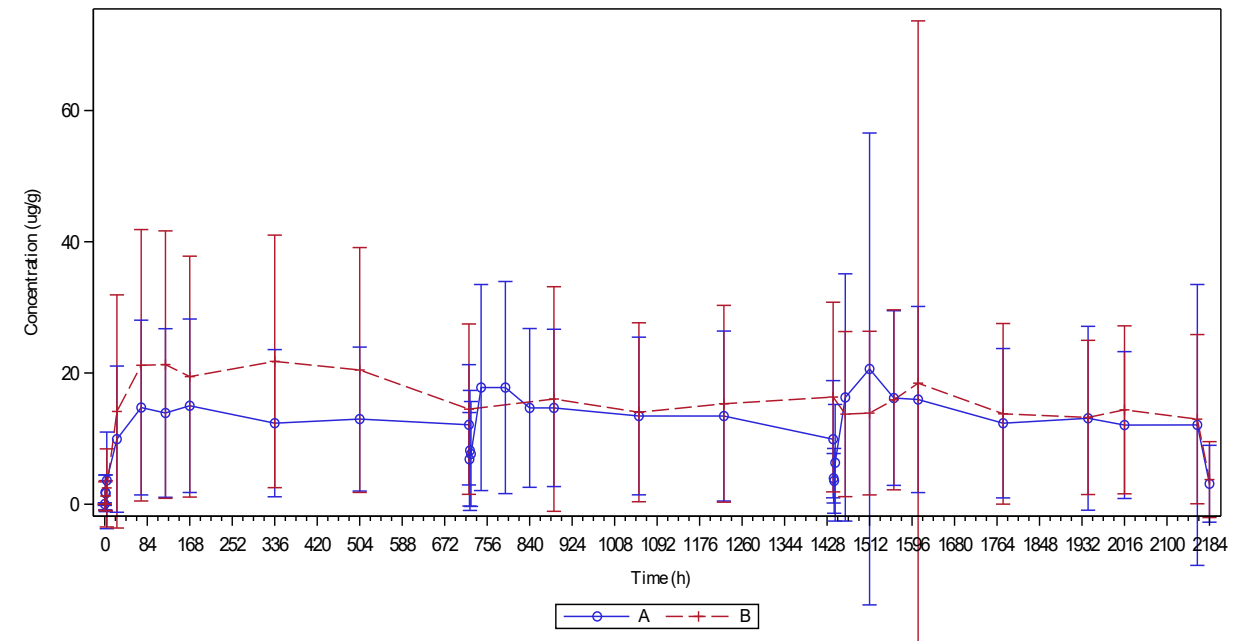
Pivotal Bioavailability Trial Implemented 2022-2024

Three-Month DVR Bridging Trial: Results

Mean (\pm SD) Plasma Dapivirine Concentrations



Mean (\pm SD) Vaginal Fluid Dapivirine Concentrations






Conclusions

100 mg ring non-inferior to 25 mg ring
100 mg ring superior to 25 mg ring

Three-Month DVR Bridging Trial: Results

To understand women's perceptions of the overall acceptability of the 1- vs. 3-month rings, a subset of participants who completed IPM 054 were invited to participate in an in-depth interview
31 women participated

-  The majority of participants interviewed preferred the 3-month ring, driven by greater convenience
-  Most participants would consider using the dapivirine vaginal ring in the future
-  If only the 3-month ring were available, most women would be willing to switch

Three-Month DVR: Next steps

Next Steps

Bridging Trial Reporting

- Study reports complete Q4 2024

Optimize Manufacturing at 5X scale and Tech Transfer to Kiara Health

- Optimization targeted for Q4 2025
- Tech transfer targeted Q4 2027

Prepare and submit regulatory dossiers

- Submission to the EMA as a line-extension (early 2025)
- Initial market entry 2026 (current manufacturer)

Advocacy and Access Activities

- Conduct community engagement and other market access activities to prepare for market introduction



Contraceptive DVR



- **Women face dual risks.** Women in areas with high rates of HIV often have the greatest unmet need for modern contraception.

Women in multiple studies have shown strong interest in and willingness to use multipurpose products versus HIV/STI prevention products alone.



Lack of access to contraception is a major contributor to maternal and newborn deaths in LMICs, largely due to complications during pregnancy and childbirth.

Integrated sexual and reproductive health care may offer:

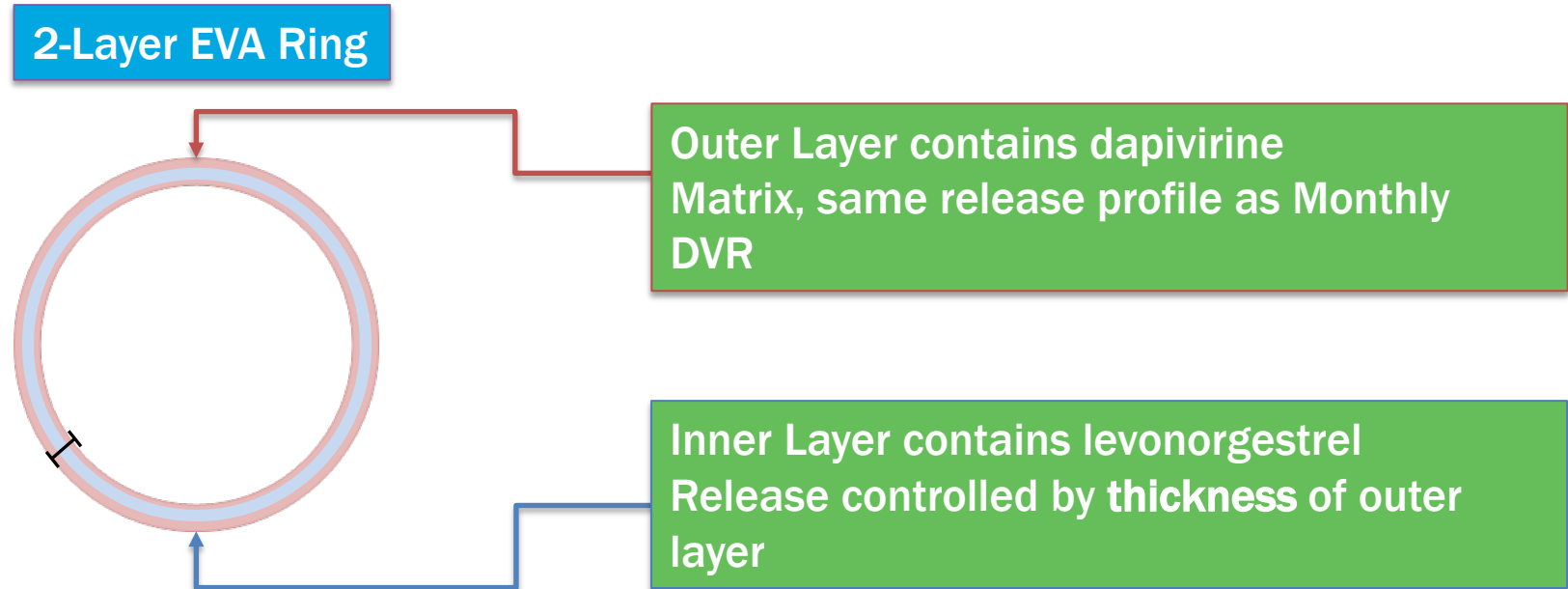
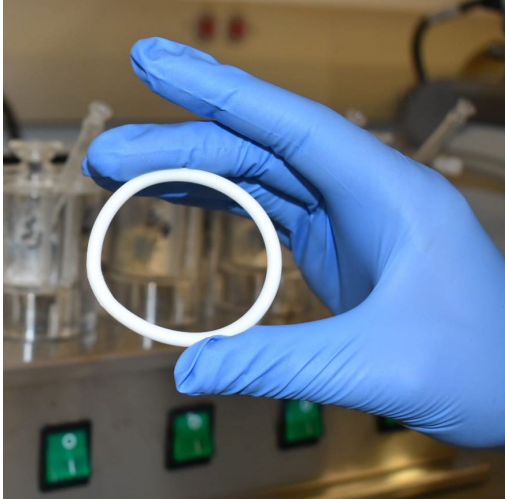


Expanded method mix for HIV prevention and contraception

Fewer clinic visits and greater efficiency by addressing multiple needs together

Reduced stigma associated with seeking HIV care

Three-Month Contraceptive DVR: Dapivirine + Levonorgestrel



Two Phase I clinical trials previously performed in silicone matrix

No major safety signals for dapivirine or levonorgestrel

Phase Ib study initiated in 2022 at two strengths **in EVA material**

Results expected in Q4 2024

Contraceptive-DVR: Next Steps

Next Steps

Regulatory strategy for an MPT to prevent HIV and unintended pregnancy

- Expected mid-2025 following consultation with regulators

HIV-efficacy bridging and Phase III contraceptive clinical trials

- Planning to initiate after regulatory feedback received

Manufacturing Optimization

- Expected to complete mid-2026

Community engagement and access plan

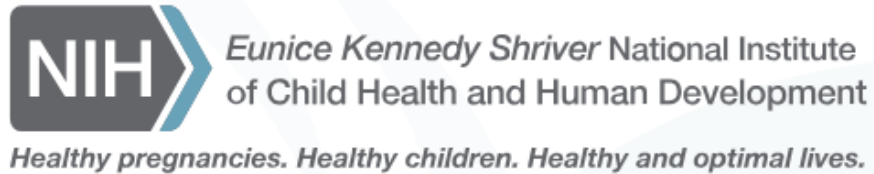
- Ongoing in parallel to the activities above

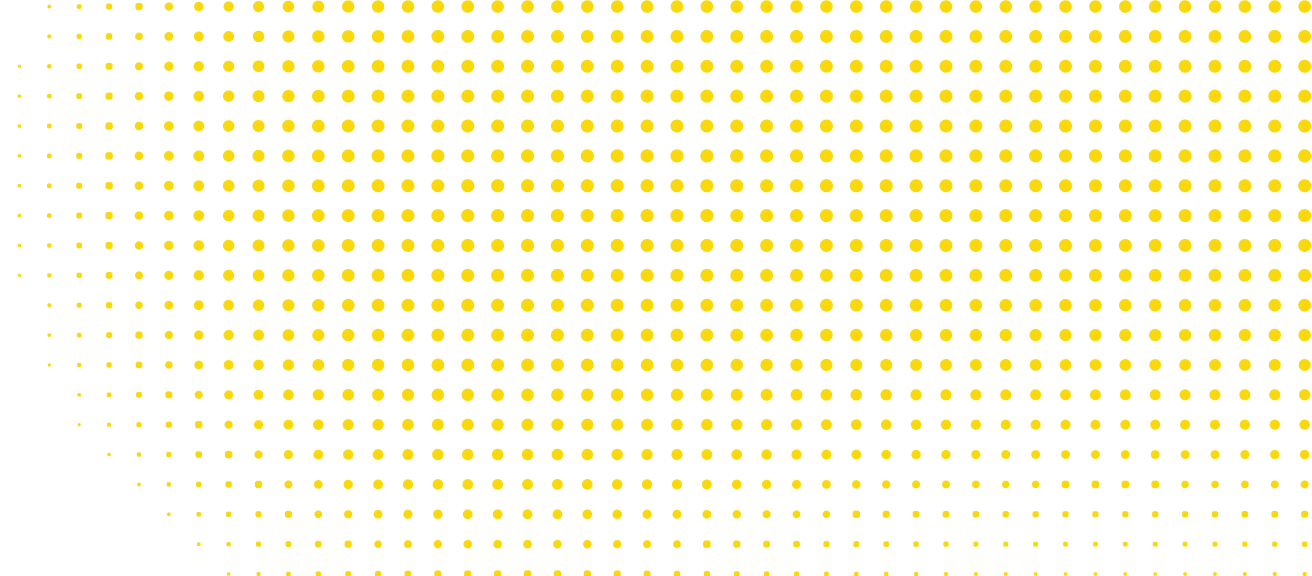
Acknowledgement and Thank you

Champions, Stakeholders, Trial Participants, and Donors



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PrEP Ring Early Market Access Vehicle

30 October 2024



VOLUNTARY MEDICAL MALE
CIRCUMCISION (VMMC)



PRE-EXPOSURE PROPHYLAXIS (PREP)



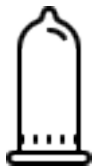
PRE-EXPOSURE PROPHYLAXIS +
ORAL CONTRACEPTIVE (DUAL PREVENTION PILL)



HIV SELF-TEST (HIVST)



STERILE INJECTION
EQUIPMENT



CONDOMS AND
LUBRICANTS



OPIOID SUBSTITUTION THERAPY



POST-EXPOSURE
PROPHYLAXIS (PEP)

Considerations for People Needing HIV Prevention

PERCEIVED BENEFITS

PERCEIVED LIMITATIONS

| | Condoms | Oral PrEP (TDF/FTC or TDF/3TC) | Dapivirine vaginal ring (PrEP ring) | Cabotegravir long-acting injectable (CAB-LA) |
|-----------------------|--|--|---|---|
| PERCEIVED BENEFITS | <ul style="list-style-type: none"> • Triple prevention - HIV, other STIs, unintended pregnancy • User controlled (insertive partner) • Familiar • Easy to use (esp. with lubricants) • Available beyond clinics in pharmacies/shops/kiosks • Strong efficacy if used consistently • Effective for both vaginal and anal sex; inexpensive • No side effects. | <ul style="list-style-type: none"> • Familiar for most potential users • Ease of use • User-controlled • Easy to cycle on and off • Available now • Can be used to prevent HIV during all modes of exposure • Strong efficacy with effective use • Opportunities to align visits with quarterly visits for family planning | <ul style="list-style-type: none"> • Familiar for some potential users • User-controlled • User action required only once per month • Easy to cycle on and off • Can be discreet for some users • Can be used to prevent HIV during receptive vaginal sex • Opportunities to align visits with quarterly visits for family planning | <ul style="list-style-type: none"> • Familiar for some potential users • Injection once every two months • Can be discreet for some users • Familiar modality for many who use injectable contraception or have received other injections • Can be used to prevent HIV during vaginal or anal sex • Strong efficacy with effective use |
| PERCEIVED LIMITATIONS | <ul style="list-style-type: none"> • Effects on sexual pleasure/performance • Limited control/agency for receptive partners • Requires negotiation/use each time • Requires lubricants for maximum effectiveness/pleasure • Can be used as evidence of illegal and/or stigmatized behaviors- sex with more than one partner, sex work, sex between men or trans and gender diverse people | <ul style="list-style-type: none"> • Pill burden • Pill size • Requires daily use for many potential users • Stigma; pill bottles and regular use are not discreet enough for all users • Side effect profile • Pre- and post-sex dosing needed for highest effectiveness • Quarterly healthcare visits are standard | <ul style="list-style-type: none"> • Low familiarity or discomfort with vaginally inserted products • Side effect profile • Must be used before, during, and after sex for highest effectiveness • Cannot be used to prevent HIV during anal sex or injection related exposures • Concerns with efficacy • Quarterly healthcare visits or dispensation is likely to be standard | <ul style="list-style-type: none"> • Delays in HIV detection with available tests • Long PK “tail”; potential for resistance • Not reversible • Gluteal injection requires privacy • Side effect profile • Not known to prevent HIV during injection related exposures • Healthcare visits every two months in a clinic are likely to be standard • Few opportunities to align visits with quarterly visits for family planning |

Note: Not exhaustive of all HIV prevention options

Adapted from MOSAIC, 2022, Overview of PrEP Product Pipeline

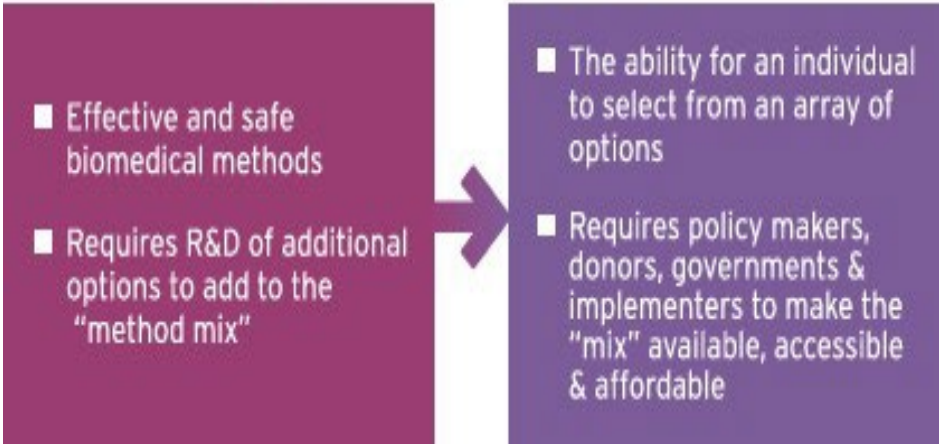
Choice Manifesto for Women and Girls in Africa

Call to Action:

Choice Is Key

1. Ensure available HIV prevention options are in the hands of women and girls.
2. Ensure massive scale-up and increased access to all safe and effective HIV prevention methods. A choice-centered approach for programming and procurement of new biomedical strategies must be adopted. No strategy should be presented as “preferred” or “better”.
3. Ensure women and girls have control over their health and their bodies and access to the full range of safe and effective options so that they can choose what works best for them at different times of their lives.

Options vs. Choice



PrEP ring regulatory approvals and access are expanding

| Reg. Status/Region | Countries |
|------------------------------|---|
| Submitted (Pending Approval) | Ethiopia, Ghana, Mozambique, Nigeria (Pending), and Tanzania, |
| Approved | Botswana, Eswatini*, Kenya*, Lesotho*, Malawi, Namibia, Rwanda, South Africa*, Uganda*, Zambia, and Zimbabwe* |
| Planned Implementation | Burundi, Cambodia, Indonesia, Tunisia, and Sierra Leone |

Population Council is willing to consider additional regulatory submissions and support import waivers

*Countries with current implementation

Countries which have already placed orders with GF support

Countries with planned orders 2024-2026 with GF support

The cost of the PrEP ring is expected to plummet in the years ahead

| Ring Type | Cost/month | Availability | Manufacturing Location |
|--------------|---------------|-------------------|------------------------|
| 1-month ring | \$12.78/month | Currently in use | Sweden |
| 3-month ring | <\$5.33/month | Within ~1.5 years | Sweden |
| 3-month ring | ~\$?/month | Within ~2-3 years | South Africa* |

Pricing of the 1-month and 3-month rings manufactured in Sweden may be further reduced by other mid- and long-term options supporting cost reductions for rings eventually manufactured in South Africa.

PrEP Ring Access Initiative

The Global Fund, CIFF, and Unitaid

Key Points

1. Expanding ring access is a responsibility of the global community required by the Choice Manifesto for Women and Girls in Africa. With limited quantities of CAB-LA in the near future, the ring is the only other long-acting option that could be available to users immediately – if we do nothing, near-term PrEP choice will be highly limited
2. Current pricing is a barrier to widescale uptake, hampering development of an attractive market for future products – **if we do nothing, current product will not be accessed at-scale, and future products may not come to market**

The Way Forward: As the largest funder of the PrEP ring, the Global Fund alongside Children Investment Fund Foundation (CIFF) are implementing the PrEP Early Market Access Vehicle (EMAV) aimed at achieving sustained impact faster and creating a bridge to lower cost products.

PrEP Ring EMAV announcement at AIDS 2024

CIFF To Propel PrEP Revolution with up to US\$2 Million for Immediate Access to PrEP Rings

21 July 2024

MUNICH – The Children’s Investment Fund Foundation (CIFF), in partnership with the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), announced on 21 July at the 25th International AIDS Conference an initiative of up to US\$2 million over the 2024-2025 period for the purchase of approximately 150,000 dapivirine vaginal rings in countries that implement Global Fund grants to fight HIV and AIDS. The PrEP ring is a long-acting HIV pre-exposure prophylaxis (PrEP) option for women.

Bis zu 2 Millionen US-Dollar der CIFF für sofortigen Zugang zu PrEP-Ringen revolutionieren Präexpositionsprophylaxe

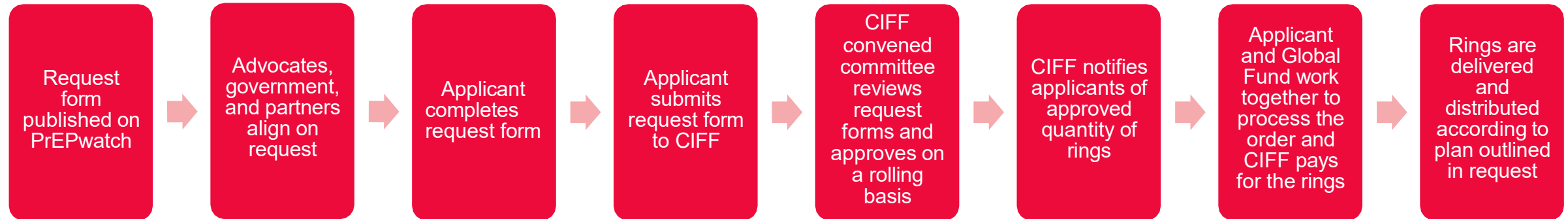
[download in [Deutsch](#)]



PrEP Ring EMAV Summary

Objective: Facilitate immediate access to one-month ring to accelerate availability for users, expand PrEP choice, and catalyze impact while less expensive rings come to market with an approximate 60% drop in price/month

Mechanism Summary:



Eligible Applicants: Country entities with HIV product procurement and supply chain responsibilities who may or may not be GF PRs or SRs in countries which received an HIV allocation for GC7. Endorsement by National Ministry of Health or other government agency responsible for the HIV response is required. Product registration is not required if import waiver can be obtained.

Available Volumes: 2,400 (min.) and 24,000 (max.) one-month rings, per country, for use across 2025 and 2026. Available rings will be allocated on a first-come first-served basis to requests which meet the criteria below. CIFF will fund up to 150k rings in total. The AVAC website will be updated as volumes are allocated.

Deadline: Requests are accepted at emav@ciff.org on a rolling basis after launch in October

M&E: Quarterly reporting to CIFF and leveraging reporting of GF and PEPFAR, when applicable.

Evaluation Criteria

| Criteria | Response |
|--|----------|
| 1 Does the request have endorsement from the National Ministry of Health or other government agency responsible for the HIV response? (Section 3) | Yes/No |
| 3 Does the request outline a strategy to have national guidelines or operational procedures that are aligned with WHO guidance in place before rings are delivered? (Section 5) | Yes/No |
| 4 Does the request outline a plan to provide rings to populations and geographies where they have high potential for impact? (Sections 6 & 7) | Yes/No |
| 5 Does the request thoroughly describe how and who will be responsible for product customs clearance, storage, distribution to sites, pharmacovigilance, provider training, client awareness, and engagement of focus populations? (Section 8) | Yes/No |
| 6 Does the request describe how all results will be reported and if not leveraging reporting mechanisms for Global Fund and PEPFAR, commit to reporting quarterly results directly to CIFF? (Section 9) | Yes/No |
| 7 Does the request outline an intended plan to ensure ongoing access to rings for those who want them after the EMAV has ended? (Section 10) | Yes/No |

Ring EMAV Request Form

Dapivirine Vaginal Ring (DVR Ring) Early Market Access Vehicle (EMAV) Request Form

Instructions: Complete the portions of the form which are green. Do not make changes to any other part of the request form.

Section 1. By submitting this request, the applicant acknowledges they have read and understood the parameters outlined above.

Section 2. Which organizations were involved in the development of the Request Form? *Add rows as needed to show full breadth of organizations included in developing the request, including that from community organizations.*



| | Organization Name | Primary point of contact name | Primary point of contact email |
|-------------------|-------------------|-------------------------------|--------------------------------|
| Lead organization | | | |
| | | | |

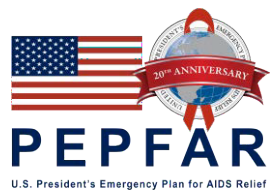
Section 3. Which organizations are supportive of this request? Attach documentation of support (email, letter, etc.) with submission of the Request Form. *Add rows as needed to show full breadth of support, including that from community organizations.*

| Organization* | Yes/No/Unsure | Is documentation of support provided? |
|---------------|---------------|---------------------------------------|
| | | |

Supporting PrEP Ring Introduction

TECHNICAL ASSISTANCE & AVAILABLE RESOURCES

Phil Imohi, MD, MPH, PhD©, FBDFM





MOSAIC PROJECT OVERVIEW

- MOSAIC is a 7-year global project funded by PEPFAR through USAID (2021-2028)
- Focuses on introduction and access for new biomedical prevention products to prevent HIV for women in Africa
- Works across multiple countries – Botswana, Eswatini, Lesotho, Kenya, Namibia, Nigeria, South Africa, Uganda, Zambia, and Zimbabwe
- Supports a multi-product market with informed choice for HIV prevention
- Collaborates closely with ministries of health, missions, implementing partners, civil society, end users, providers, other local and global stakeholders, and product developers

OUR VALUES

COUNTRY-LED

WOMEN-
FOCUSED WITH
EMPHASIS ON
AGYW

INFORMED
CHOICE

EQUITABLE CO-
LEADERSHIP

INTENTIONALITY

1

MOSAIC TECHNICAL ASSISTANCE

MOSAIC SUPPORTS NATIONAL PROGRAMMING

We work alongside ministries of health, implementing partners and civil society to strengthen the HIV prevention platform

We support ministries of health and interagency partners to:

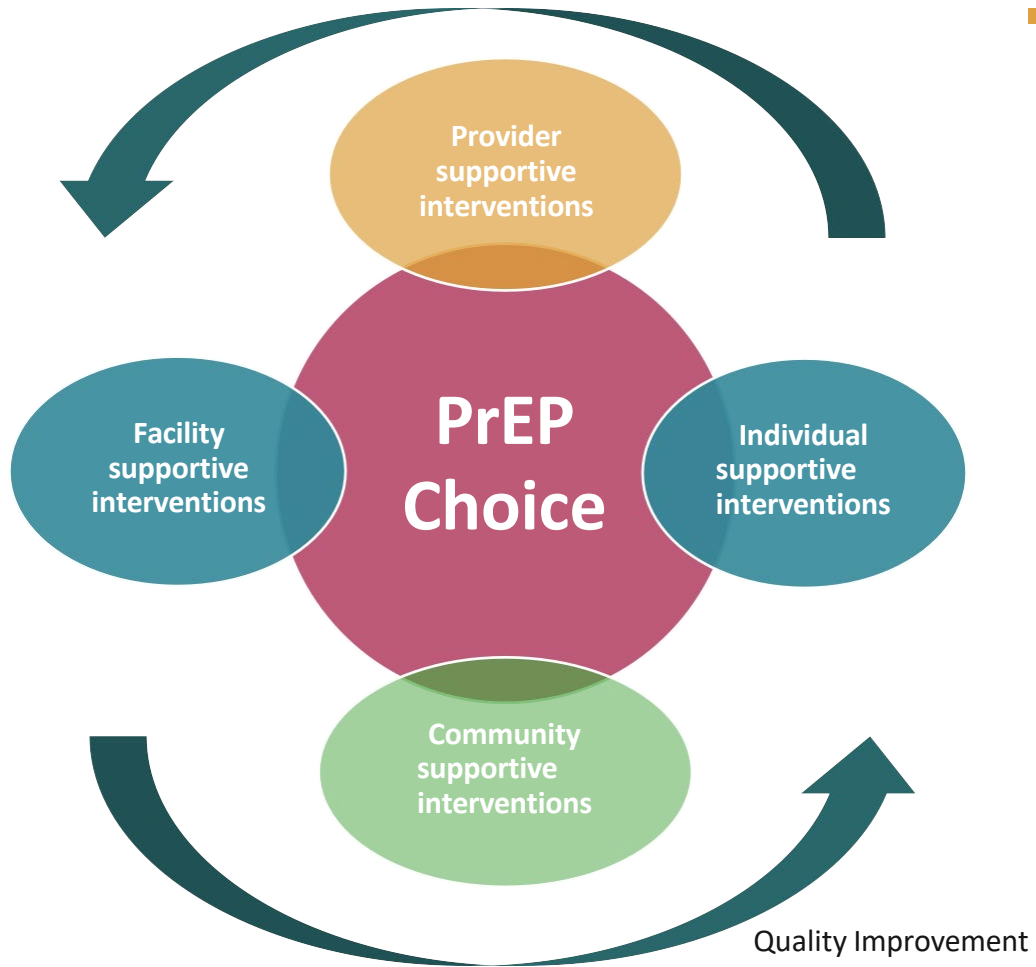
- Conduct analyses for PrEP **target setting, demand forecasting, costing and budgeting**
- Integrate new products into national **policies and guidelines**
- Integrate new products into the **supply chain system**
- Integrate new products into **M&E and surveillance systems**, including **laboratory strengthening** for HIV drug resistance
- Integrate new products into **differentiated service delivery** models
- Build **awareness, support and demand** for new products
- Expand and strengthen **provider training** and **effective use** of new products among end-users



Snapshot of MOSAIC's PrEP work along the introduction pathway

| Policy, Plans & Costing | Supply Chain & Market Development | Service Delivery | Uptake & Effective Use | Monitoring & Evaluation | Cross-Cutting Activities |
|--|---|---|--|--|---|
| <p>Global guidance & national guidelines Contributing updates to WHO PrEP Implementation Tool, developed template guidelines for CAB PrEP, supporting adoption of national guidelines for CAB PrEP, integration with PMTCT and FP guidelines</p> <p>Implementation plans & national strategies Developing implementation plans and integrating CAB PrEP into national strategies, including support for target setting and forecasting (PrEP-it)</p> <p>Costing Conducting costing studies and analyses to inform implementation planning and budgeting</p> | <p>Market shaping Contributing to market shaping efforts to address supply-side barriers and global demand</p> <p>Demand forecasting Conducting analyses for demand forecasting</p> <p>Supply chain Assessing supply chain readiness</p> | <p>Implementation research Conducting studies to assess implementation, acceptability, choice, uptake, patterns of use, prevention effective use, and cost; strengthening integrated and client-centered service delivery through quality improvement collaborative</p> <p>Provider training/ job aids/ counseling materials Developing and integrating CAB PrEP into national PrEP curricula, job aids and counseling materials</p> <p>Research and program collaborations Collaborating to identify common study indicators, pregnancy registry study; rapid data sharing to inform program scale-up</p> | <p>End-user engagement Implementing strategy to meaningfully engage potential end-users</p> <p>Positioning Strategy Expanding PrEP positioning strategy to include providers and key influencers</p> <p>Demand generation strategies & tools Providing technical guidance on integration of CAB PrEP into demand creation national strategies and integrating CAB PrEP into demand creation tools, including the HIV Prevention Ambassador Training</p> | <p>Resistance surveillance Supporting inclusion of CAB PrEP in HIV drug resistance surveillance platforms</p> <p>Routine M&E Assessing feasibility and acceptability of novel PrEP indicators for multi-product M&E, supporting system improvements/integration</p> <p>Laboratory strengthening Increasing capacity for HIVDR testing</p> | <p>Civil society engagement Developing and strengthening civil society partnerships, engagement, and advocacy</p> <p>Global collaborations Building and strengthening global collaborations with programs, networks, product developers, and funders</p> <p>Situation analyses Conducting value chain situation analyses to build on lessons learned from oral PrEP to inform rollout of CAB PrEP</p> <p>Capacity strengthening Strengthening local partner capacity to design and implement biomedical prevention product introduction activities and research</p> <p>Evidence & Resources Synthesizing and sharing CAB PrEP evidence and resources</p> |

Implementation Research TA



- Our flagship study, **Catalyzing access to new prevention products to stop HIV** (CATALYST) launched in May 2023. This study introduces the PrEP ring and CAB PrEP in 5 countries. The enhanced service delivery package will:
 - **Support choice** among the PrEP products that have regulatory approval in each country.
 - Include components at the **individual, provider, facility and community levels**
 - Use **quality improvement** methods to refine components and identify a core service delivery package for PrEP choice.

All [implementation materials](#) are **publicly available on PrEPWatch** and MOSAIC can provide TA in protocol development and/or implementation as needed/requested

2

AVAILABLE RESOURCES

PrEP Template Guidelines

Who is it for

- Policymakers and program staff supporting policy development at the ministry level

What it does

- The intent of [this document](#) is to provide adaptable guidelines to support the development and adoption of national guidelines that align with WHO PrEP recommendations and guidance, including those for oral PrEP, PrEP ring, and CAB PrEP.

How to use it

- The document includes prompts for national-level consideration during the guideline adaptation process.
- Available in English and French

Template Guidelines for Oral Pre-Exposure Prophylaxis, PrEP Ring, and CAB PrEP

Updated on December 12, 2022

The intent of this document is to provide adaptable guidelines to support the development and adoption of national guidelines that align with World Health Organization (WHO) pre-exposure prophylaxis (PrEP) recommendations and guidance, including those for tenofovir disoproxil fumarate (TDF)-based daily and event-driven oral PrEP, the monthly dapivirine vaginal ring ("PrEP ring" or "the ring"), and injectable cabotegravir (CAB PrEP). The document includes prompts for national-level consideration during the guideline adaptation process. Areas specifically requiring national updates are indicated in **red font**; sections for additional consideration by policymakers, shown in green boxes, are informed by regulatory bodies, available product information, and country-level insights. Once a decision has been made about the considerations in green boxes, text can be added, and the green boxes can be removed.

The content of this document was sourced largely from:

- Australian Product Information for [Apretude](#) (August 2022, pending public sharing)
- [Updated Differentiated and Simplified Pre-exposure Prophylaxis for HIV Prevention](#) from WHO (July 2022)
- [Guidelines on Long-Acting Injectable Cabotegravir for HIV Prevention](#) from WHO (July 2022)
- [Consolidated Guidelines on HIV Viral Hepatitis and STI Prevention, Diagnosis, Treatment, and Care for Key Populations](#) from WHO (July 2022)
- [United States Food and Drug Administration Apretude Label](#) (December 2021)
- [Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring: Recommendations for a Public Health Approach](#) from WHO (July 2021)
- [Summary of Product Characteristics for PrEP Ring](#) from the European Medicines Agency (April 2021)
- [Updated Recommendations on HIV Prevention, Infant Diagnosis, Antiretroviral Initiation and Monitoring Guidelines](#) from WHO (March 2021)

MOSAIC TA: Ensures the template is up to date with latest WHO guidance; supports in application during national policy/guideline updates

PrEP Implementation Plan Template

Who is it for

- It is an adaptable template can be utilized by national governments, their ministries, and relevant stakeholders involved in rolling out new PrEP products

What it does

- The intent of [this document](#) is to provide a template that countries can adapt to outline their approach in rolling out new PrEP products.

How to use it

- This template is designed to be **adaptable**, enabling the incorporation of pertinent contents that align with country-specific requirements.

New PrEP product implementation plan template

INTRODUCTION TO THE TEMPLATE:

The intent of this document is to provide an adaptable template that can be utilized by national governments, their ministries, and relevant stakeholders involved in rolling out new pre-exposure prophylaxis (PrEP) products as they come into market through a programmatic approach. This implementation plan template contains vital components of the value chain and outlines considerations for countries wishing to layer on these new PrEP products in existing PrEP programs. Please note that countries wishing to introduce new PrEP products through pilot or demonstration studies will require a different approach, including development of a research protocol. An example of an introduction study with associated materials, including the research protocol, can be found [here](#).

This template is designed to be adaptable, enabling the incorporation of pertinent content that aligns with country-specific requirements. The document incorporates prompts that guide national-level consideration during the adaptation of the template. Suggestions on what to include in specific sections are provided within brackets in each section, and blue boxes provide considerations or information that countries may choose to incorporate. Once relevant text has been included in the respective subcategories, the text within the brackets and blue boxes can be removed.

This document was developed by MOSAIC (Maximizing Options to Advance Informed Choice for HIV Prevention) in close collaboration with the U.S. Agency for International Development (USAID). It is made possible by the generous support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and USAID. The contents are the responsibility of the MOSAIC project and do not necessarily reflect the views of PEPFAR, USAID, or the U.S. Government. MOSAIC is a global cooperative agreement (Cooperative Agreement 7200AA21CA00011) led by FHI 360, with core partners LVCT Health, Pangaea Zimbabwe AIDS Trust, Wits Reproductive Health and HIV Institute, Jhpiego, and AVAC.

Background

Situation Analysis

Implementation Framework

Budgeting and financing

Appendices
Implementation Plan Guidelines/Gantt

MOSAIC TA: Ensures the template is up to date with latest WHO guidance; supports in application during national policy/guideline updates

PrEP-it

Supply Chain

Who is it for

- Tool can be applied at the national, sub-national, donor, implementer or site level and can be applied to multiple PrEP methods simultaneously

What it does

- [PrEP-it](#) is a web-based tool that helps users set targets, estimate costs and impact associated with targets, identify priority areas for PrEP for adolescent girls and young women, and forecast needed commodities.

How to use it

- Through a guided step-by-step approach to country-specific [configurations](#). [See video on introduction to PrEP-it and slide-deck with step-by-step guidance on how to complete the PrEP-it modules](#)



MOSAIC TA: In-person or virtual support for tool use. Several countries have participated in a number of in-country PrEP-it workshops to date.

Provider Training Materials

- PrEP ring [Clinical Training](#) for providers (developed for CATALYST)
- PrEP ring [training manual](#) (from Population Council)
- [Global AHI Job Aid](#): for ruling out acute HIV infection by offering guidance for new or returning adherent or non-adherent clients using PrEP ring and other methods
- [PrEP Ring 101](#)
- [Oral PrEP or PrEP Ring for PBFP Training Package](#)
- [Job aids and materials from CATALYST](#)

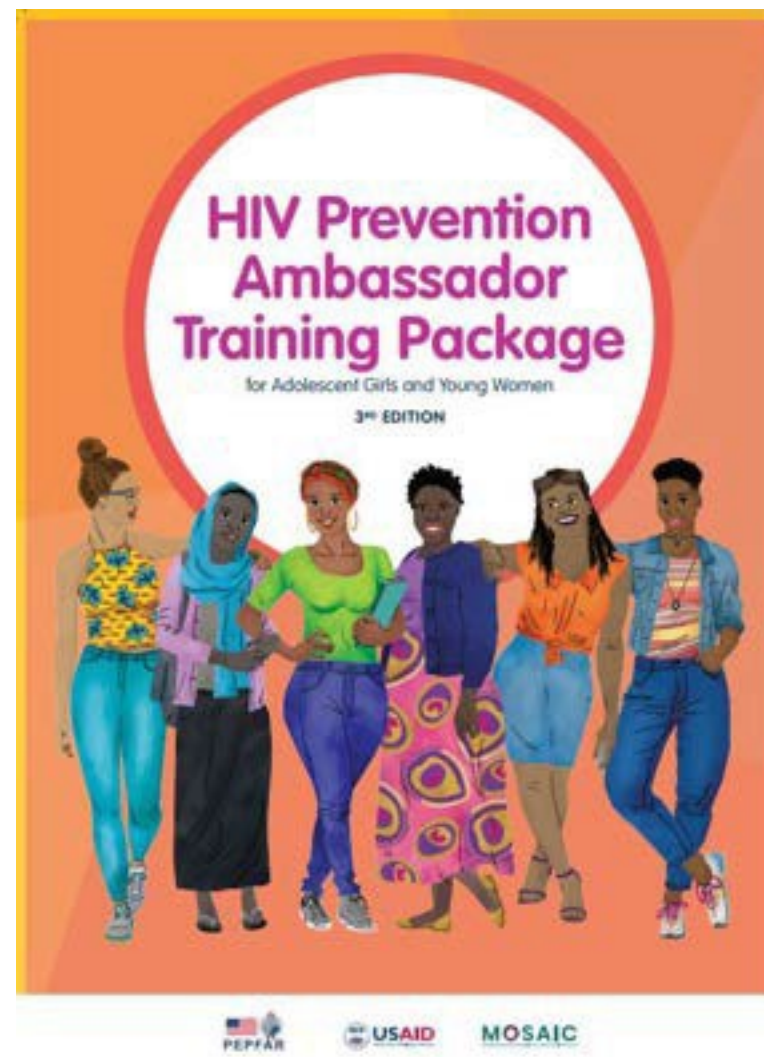


MOSAIC TA: Support in the adaptation/development of national training curricula to align with Toolkits developed in consultation with WHO, ViiV and other stakeholders; support training of trainers to roll out national trainings as needed

HIV Prevention Ambassador Training & Toolkit

Uptake & Effective Use

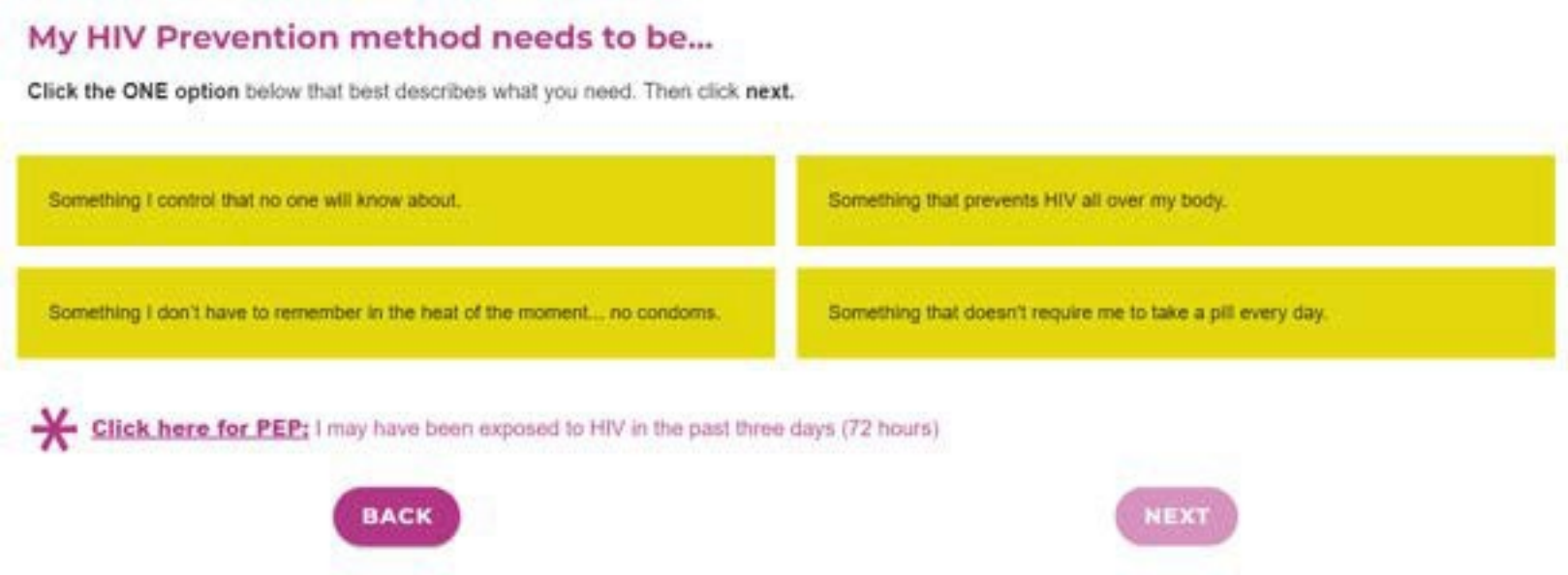
- This [training and toolkit](#) are designed to engage adolescent girls and young women (AGYW) as HIV prevention ambassadors to support PrEP uptake and continuation and includes up-to-date information on oral PrEP, **PrEP ring** and CAB PrEP.



MOSAIC TA: Conduct facilitator trainings for implementers to expand reach of the training package

HIV Prevention Journey Tool

- The [HIV Prevention Journey Tool](#) was developed to support adolescent girls and young women to explore methods that would align with their lifestyle, needs and personal preferences; and support healthcare providers to provide informed counseling based on client needs. The tool has paper-based and digital options.



MOSAIC TA: Adapt the Journey Tool for a specific country context and support uptake of the tool across program implementers in, as desired.

ACKNOWLEDGMENTS

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Photo Credit: MOSAIC Consortium



Questions