Please join us

8:30 AM to 10 AM ET

March 3

The Dapivirine Ring

Giving Women Hope and Choice in HIV Prevention

Thank you for joining us today!

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THE CHOICE AGENDA
HIV prevention research – a new forum for advocacy on the latest

Thank you for all the great questions and comments you shared when you registered for this webinar.

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TCA Radio

3.3.26
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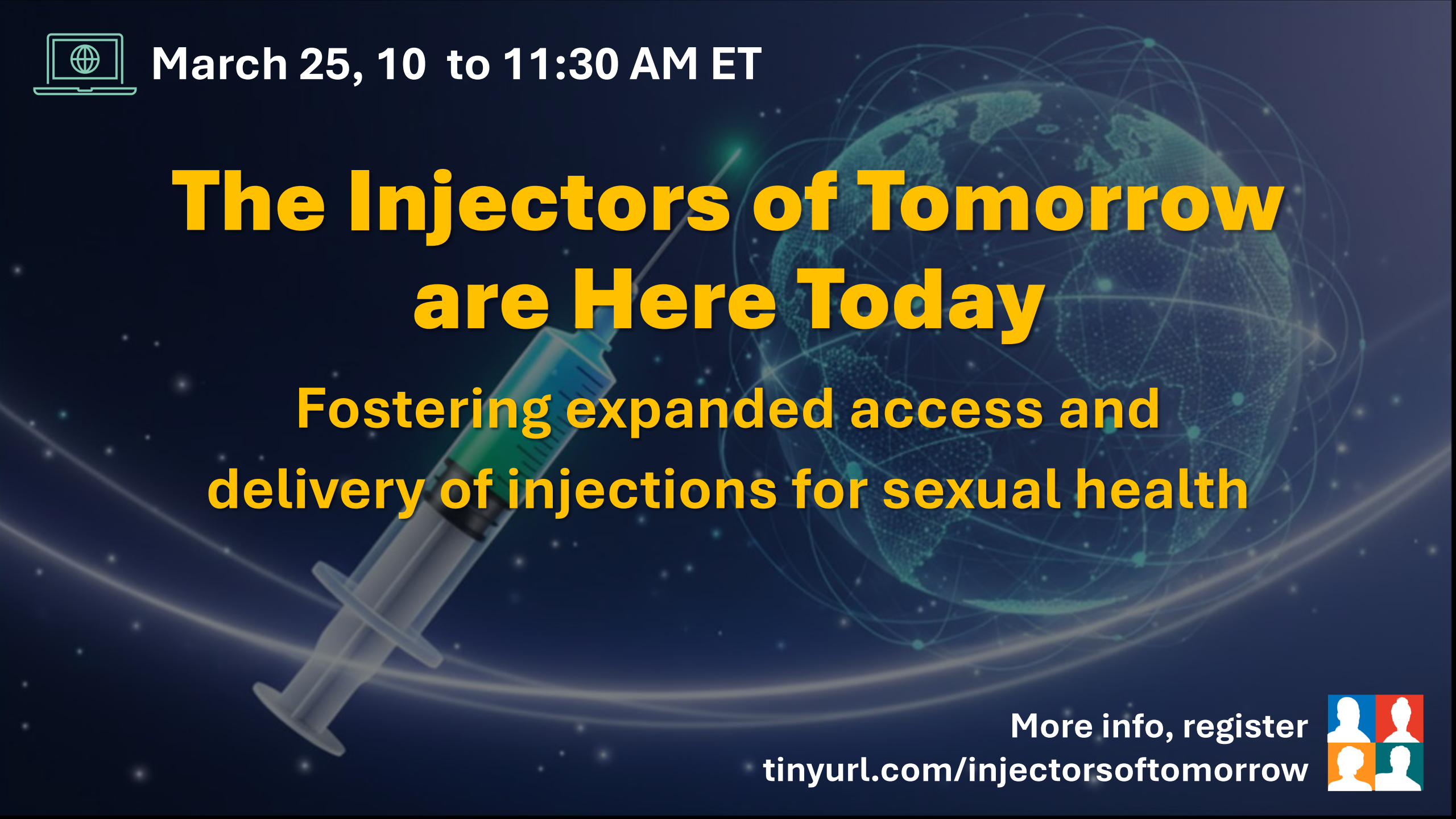
single ladies
/beyonce, dave aude remix

bliss
/tyla

on time
/nikita kering

wale wale
/zuchu


March 25, 10 to 11:30 AM ET
The Injectors of Tomorrow are Here Today
Fostering expanded access and delivery of injections for sexual health
More info, register
tinyurl.com/injectorsoftomorrow

Speakers

Diantha Pillay, IPM South Africa

Emily Dorman, Population Council

Chilufya Kasanda, Ascend Futures Foundation

Yvette Raphael, Advocacy for Prevention of HIV and AIDS

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THE DAPIVIRINE VAGINAL RING

Giving Women Hope and Choice in HIV Prevention

The Choice Agenda Webinar – March 3, 2026

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Presenters

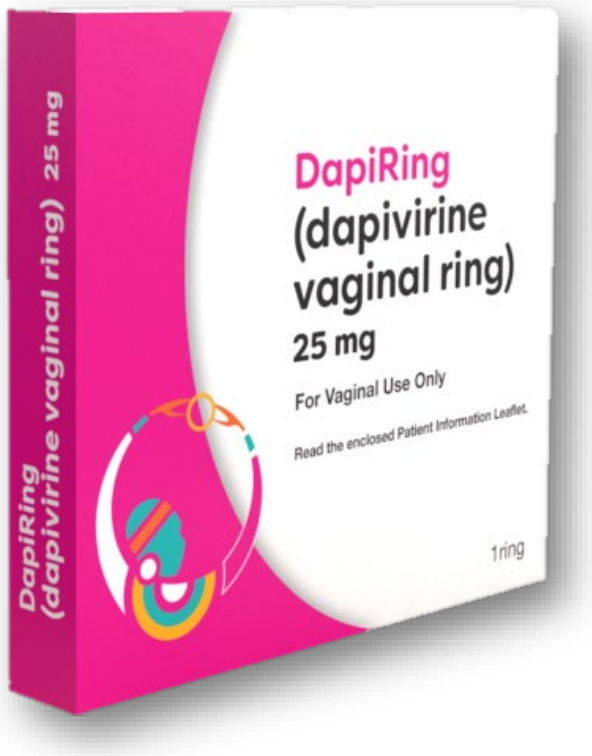
Diantha Pillay - Director, Global Product Access & Medical Science Liaison, IPM South Africa

Yvette Raphael - Co-founder and Executive Director, Advocates for Prevention of HIV and AIDS

Chilufya Kasanda - Executive Director, Ascend Futures Foundation

Emily Dorman – Senior Project Manager, Center for Biomedical Research at the Population Council

Presentation Overview



- Overview on the monthly DVR
- Efforts to maximize implementation of the DVR
- The future of the DVR
- Advocate voices

Overview of the Dapivirine Vaginal Ring (DVR)

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Monthly DVR Characteristics

Dosing

1 ring every month, inserted vaginally

25mg dapivirine released locally in the vagina

Population

HIV-uninfected women **16 years and older,** including breastfeeding population

Efficacy

Phase 3 trials: ~30%

Open-label extension: >50%

Sub-analyses/ modeling: 63% to 91%

Safety

Very favorable safety profile

AEs similar to placebo

No impact on fertility

Subsidized price per ring = $5,90

Monthly DVR Characteristics

Overview of DVR Safety

- Dapivirine has a very favourable safety profile
- DVR results in very low systemic exposure to drug:
  - Allows for minimal toxicity monitoring during use
  - Results in low potential for systemic drug/drug interactions DDIs and AEs related to interactions.
- Frequency of AEs did not increase over time with continuous ring use, making long-term use favourable
- No new safety concerns have been identified in subsequent studies in special populations (breastfeeding women, women from 16 years old, pregnant women)

Efforts to maximize access & implementation of the DVR

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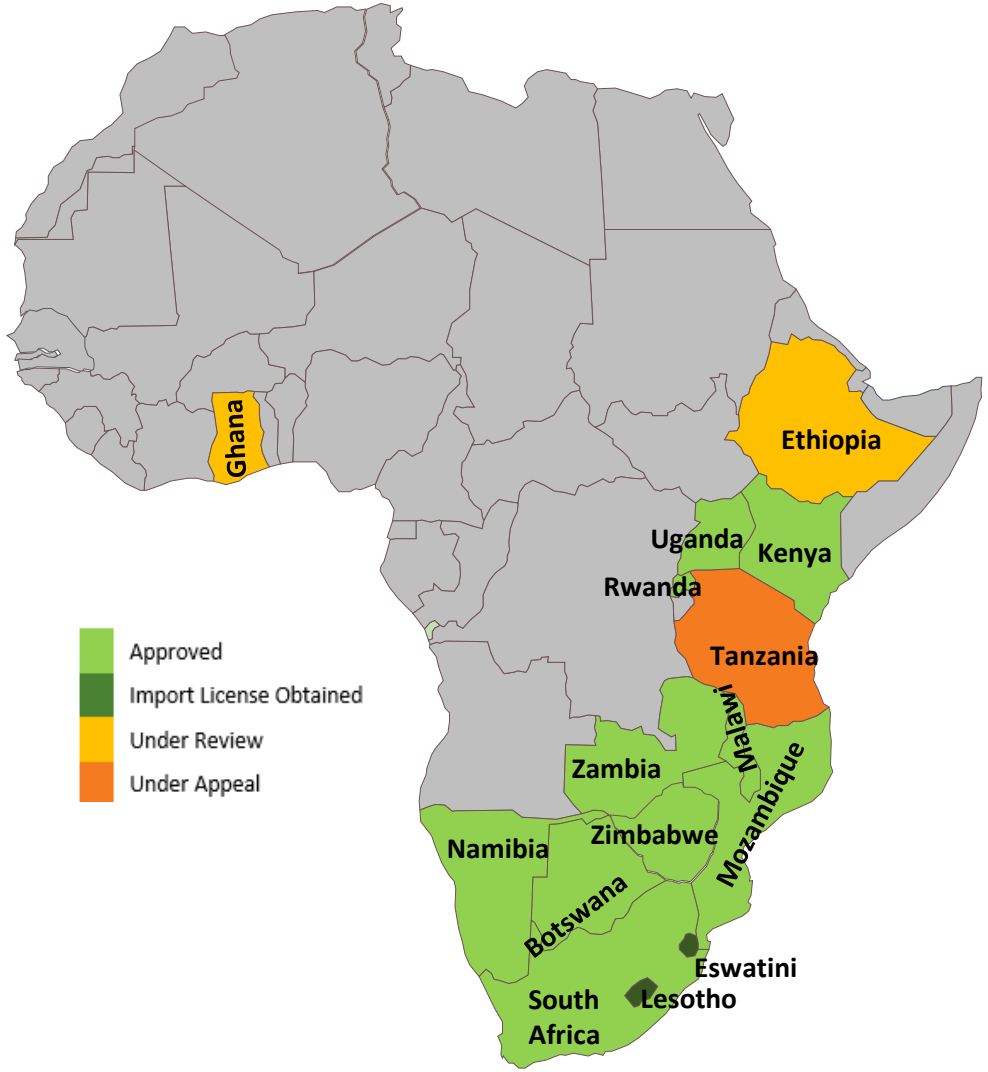
Monthly DVR Registrations – 12 countries



Country	Status
Zambia	Product Registration May 2021
Malawi	Product Registration May 2021
Kenya	Product Registration July 2021
Zimbabwe	Product Registration July 2021
Uganda	Product Registration October 2021
South Africa	Product Registration March 2022
Botswana	Product Registration December 2022
Rwanda	Approved February 2023
Namibia	Product Registration July 2023
Eswatini and Lesotho	Import licenses have been issued
Mozambique	Product Registration December 2024
Ghana	Under Review
Ethiopia	Under Review
Tanzania	On April 2022 TMDA rejected the registration An appeal was submitted.

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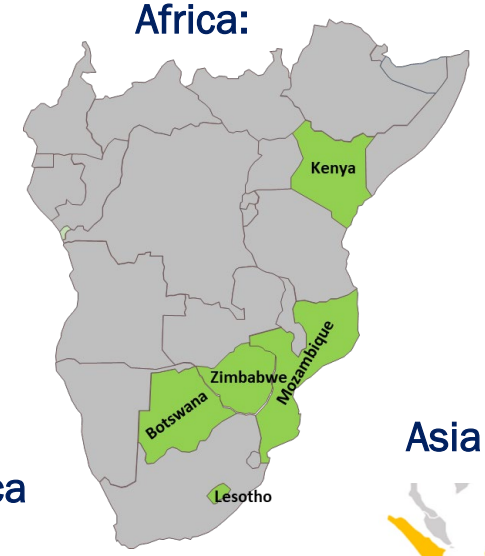
Monthly DVR Global Implementation

Planned & Ongoing Implementation Studies

Africa:

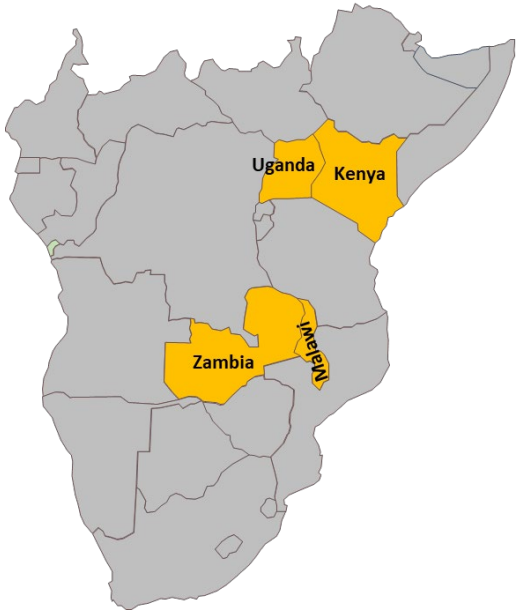


Central America

Asia Pacific:

Planning for Rollout

Africa:



Public Health Roll-Out

Africa:

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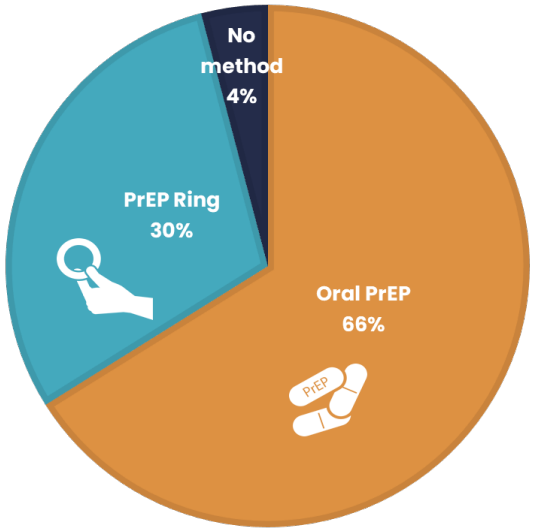
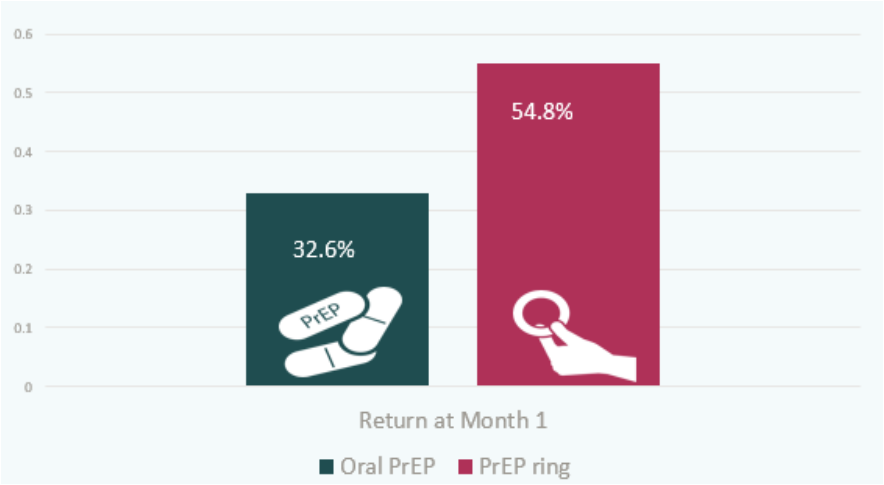
CATALYST Implementation Study

The CATALYST study provided both oral PrEP and the DVR and included 27 PEPFAR/USAID-supported public health facilities across Kenya, Lesotho, South Africa, Uganda and Zimbabwe.



Uptake of oral PrEP and DVR



Patterns of PrEP use among women in the context of choice

Results showed:

- DVR was chosen due to ease of use (56.9%) and not needing to swallow pills (53.0%).
- Month 1 return was 32.7% for oral PrEP and 55.2% for the ring.
- DVR users reported higher adherence as compared to oral PrEP users ($p < 0.001$).

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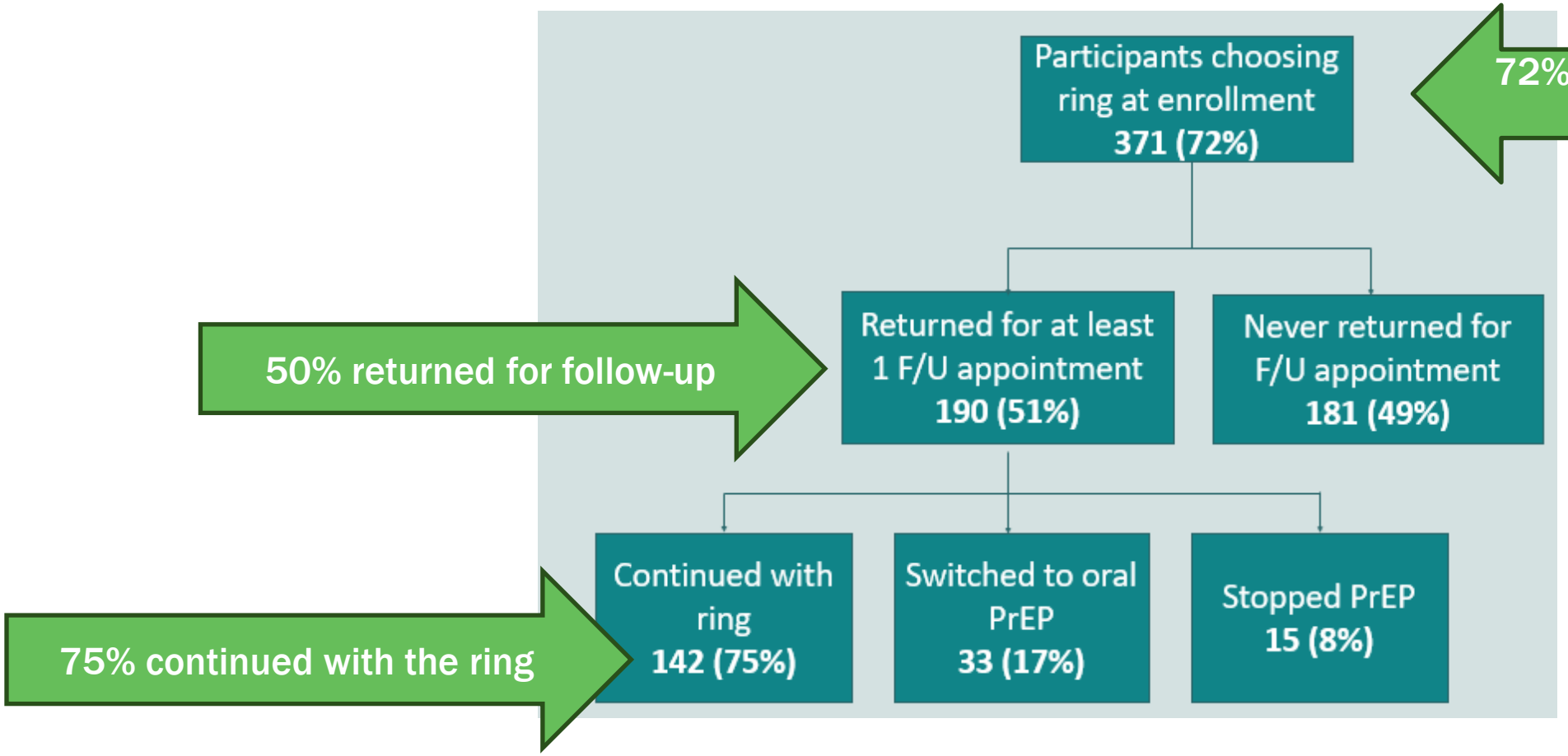
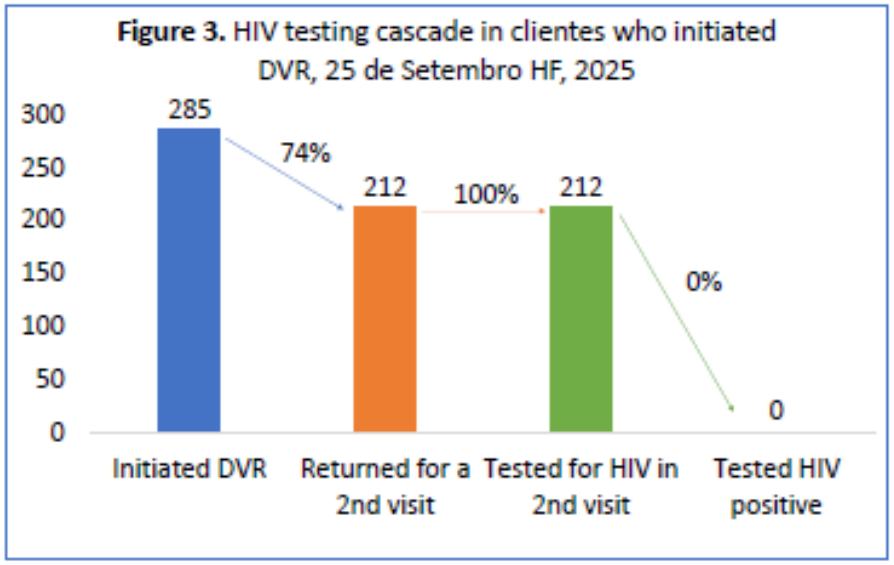
MOSAIC Eswatini Implementation Study



Results showed even higher choice and continuation of the ring.

ICAP Mozambique Implementation Study

- DVR was offered integrated into the existing PrEP services at youth friendly clinics, delivered by national health system staff in Nampula Province
- From March to August 2025, 396 AGYW were offered DVR, with 285 (72%) clients initiating
- Among the 285 initiators, 279 (98%) were PrEP naïve.
- The return rate for the 2nd follow-up visit was 74% (212/285).



- High acceptability demonstrated amongst AGYW
- The absence of HIV seroconversions during follow-up and complete adherence to HIV testing protocols highlight the feasibility and safety of DVR delivery in real-world settings.
- These findings support the DVR as a valuable addition to the PrEP choice mix for AGYW in Mozambique

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Spotlight on Eswatini and Zambia Rollout

Eswatini

- Current public health rollout since 2024 through primary healthcare clinics
- Three months PrEP ring dispensing at initiation visit with distribution of an HIVST to conduct at M1.
- 6-month dispensing of the ring allowed from the 2nd F/U visit with HIVST to conduct after 3 months
- Community initiation and refills by HTS counsellors and peer educators after confirming HIV negative test result
- No restrictions for use of the PrEP ring in pregnant and breastfeeding women.
- Ring allowed from age 16 and above

Zambia

- National PrEP Task Force planning phase 1 implementation
- To commence with 1200 donated rings from IPM/PC to PPAZ (Lusaka and Livingstone)
- Ordered over 21 000 rings through the CIFF/GF EMAV – awaiting rings
- Expanding use of social media and digital solutions for demand creation

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Challenges (and Progress) Towards Ring Adoption

Limited Population	Price	Efficacy	Global Funding Losses
• Ring not approved for critical subpopulations	• $12,98/ring not cost-effective compared to other options	• Modest Phase 3 trial efficacy	• Significant loss of foreign assistance for health programmes
↓	↓	↓	↓
Label Expansions	Ring Price Subsidy	Sub-analyses and RWE	Ring Donations

Label Expansions

Label expansions now under review by local regulators

Breastfeeding Women:

- Favorable safety profile and previous data showing low drug transfer to breastmilk supports updates of WHO to include breastfeeding women
- **EMA approved expansion of the product label for the breastfeeding population in 2024**

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
- **EMA approved ring use for adolescents (aged 16 and above) in 2025**

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

Pregnant Women: Interim findings

- Three cohorts have completed the study and no safety concerns
- Infant follow-up is concluded (final report in development)

Ring Price Subsidy

- The DVR is a critical option in the HIV prevention tool kit: entirely woman controlled, discreet, and very safe and simple to implement
- Price reduction of >50% lowers barriers at a critical time when global HIV prevention infrastructure has been disrupted
- $5.90/ring pricing will bring the DVR closer in-line with the cost of oral PrEP and with the expected annual cost of the more efficient, convenient 3-month DVR

Dapivirine Vaginal Ring price drops by over 50%, bringing more affordable HIV prevention options to women and adolescent girls in Africa and beyond – Population Council

"Reducing the price of the DapiRing is more than a financial decision, it is a moral necessity. No woman should ever be denied protection simply because it is not affordable; affordability is the gateway to equity. Until every prevention product is priced within reach, our work is not done," **said Joyce Nganga, Senior Policy Advisor and Programme Coordinator, WACI Health and Member, African Women Prevention Community Accountability Board.**

"Choice in HIV prevention is essential and making products more affordable improves access to the products that fit their lives and that they want to use. By reducing the cost of the one-month Dapivirine Vaginal Ring, the Population Council is really prioritizing the equitable delivery of PrEP to women and girls. With the extraordinary challenges we are facing in the current HIV response, it is encouraging and a reason for optimism to see organizations step up to fill gaps in access," **said Jim Pickett, Director, The Choice Agenda and Senior Advisor, AVAC.**

DVR Efficacy – Sub-Analyses & Real-World Data

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

- **Phase III trials:** DVR reduced women's risk of HIV-1 infection by about 30%. Modeling data in one of the trials suggests efficacy may be as high as 75-91% when the ring is used consistently.


BROWN ER et al. *Journal of the International AIDS Society* 2020, **23**:e25634
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25634/full | https://doi.org/10.1002/jia2.25634

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

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,§], Craig W Hendrix[3], Ariane van der Straten[4], Flavia M Kiweewa[5], Nyaradzo M Mgodi[6], Thesla Palanee-Philips[7], Mark A Marzinke[3], Linda-Gail Bekker[8], Lydia Soto-Torres[9], Sharon L Hillier[10], Jared M Baeten[11] and the MTN-020/ASPIRE Study Team

- **Open-Label Studies:** Increased ring use and greater risk reduction —by over 50%.

- **Secondary analysis** indicates consistent ring use was associated with a 63% per-sex-act HIV-1 risk reduction; Consistent use significantly correlates with HIV-1 protection


The Journal of Infectious Diseases

MAJOR ARTICLE

IDSA Infectious Diseases Society of America | hivma hiv medicine association | OXFORD

Assessing Per-Sex-Act HIV-1 Risk Reduction Among Women Using the Dapivirine Vaginal Ring

Randy M. Stalter,[1] Tracy Q. Dong,[2] Craig W. Hendrix,[3] Thesla Palanee-Phillips,[1,4] Ariane van der Straten,[5,6] Sharon L. Hillier,[7,8] Flavia M. Kiweewa,[9] Nyaradzo M. Mgodi,[10] Mark A. Marzinke,[3] Linda-Gail Bekker,[11] Lydia Soto-Torres,[12] Jared M. Baeten,[1,13] and Elizabeth R. Brown[2,14]; for the MTN-020/ASPIRE Study Team

Demand Creation

- **Information Education and** Communications (IEC)
  - Instructional videos (translated)
  - Merchandise
  - Information pamphlet
  - FAQ
- **Global HPC Training Package**
  - Modules
  - Counseling tools
  - Demo rings
- **Social Media**

www.prepringinfo.org

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Social Media

- Launched various prep.ring platforms in December 2025
- Collaborate with partners to create country specific content

In-country Advocacy Partners

- Formal agreement with local partners where there are plans for DVR introduction
- Budget depends on availability of funding from donors
- Experienced with HIV prevention advocacy, awareness, demand creation programs
- Stakeholder engagement, advocacy and awareness generation
- Currently collaborating with 8 partners

The Future of the DVR

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A Pipeline of Women-Centered Prevention

Monthly DVR

- 25mg DPV; silicone matrix design
- HIV prevention
- Commercially available (12 African countries; 2 pending review)

3-Month DVR

- 100mg DPV, silicone matrix design
- HIV prevention
- Line extension; intended to replace monthly DVR
- EMA positive opinion expected 2026

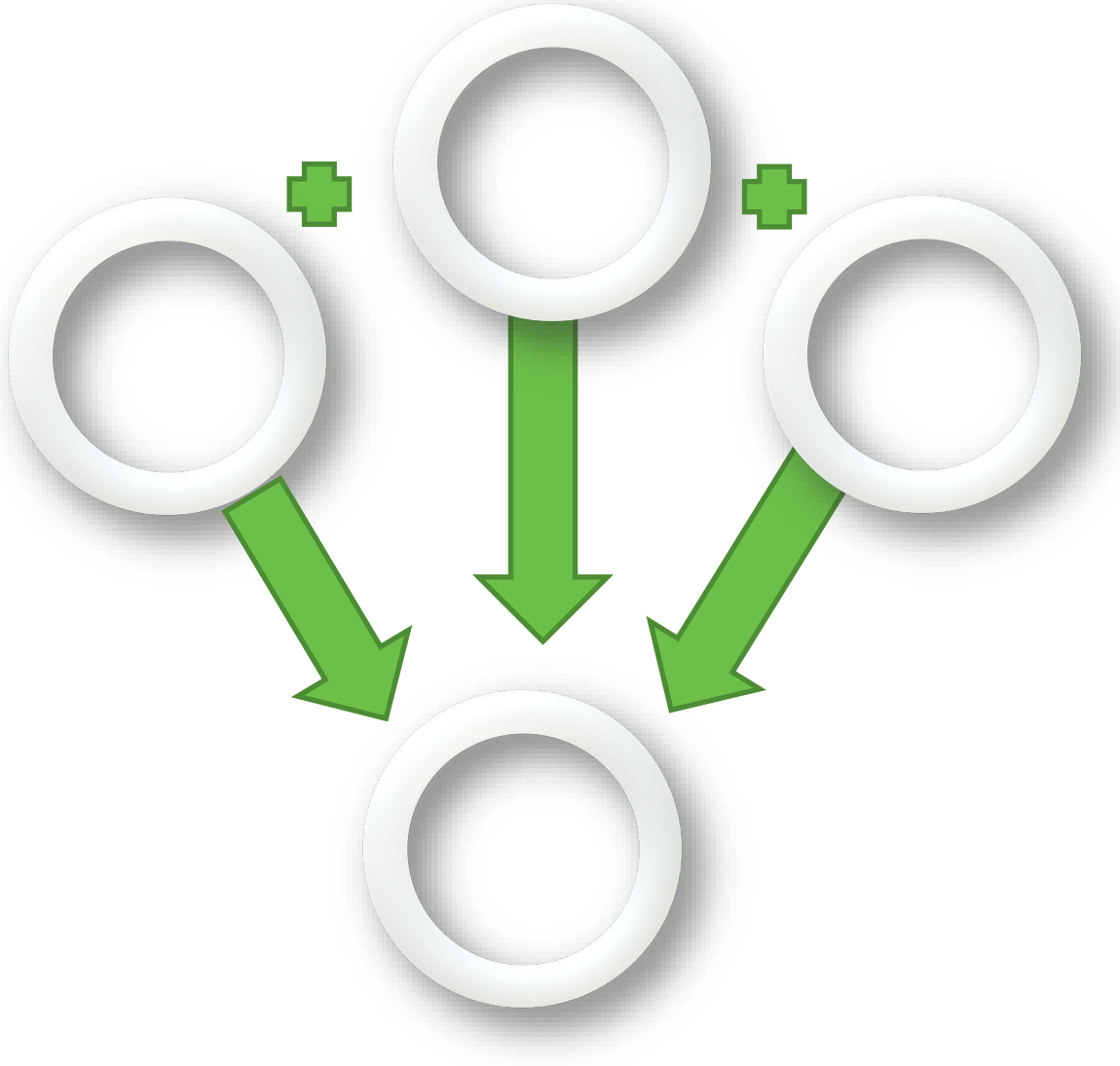
Dapivirine Contraceptive Ring

- 3-monthly; dapivirine and levonorgestrel, EVA core-sheath design
- HIV and pregnancy prevention
- To bridge to the efficacy of the 25mg DVR

Why a Three-Month DVR?

3-month formulation provides several advantages over monthly DVR:

- Only 4 rings required per year versus 12
- Reduced cost, waste, and environmental impact
- Increased convenience for the user
- Potential for increased adherence



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Three-Month Ring Bioavailability Trial

Phase I trial (n=124) at FARMOVS, South Africa comparing:

- Monthly DVR (inserted every 30 days)
- 3-month DVR (inserted for 90 days)

Primary Objective

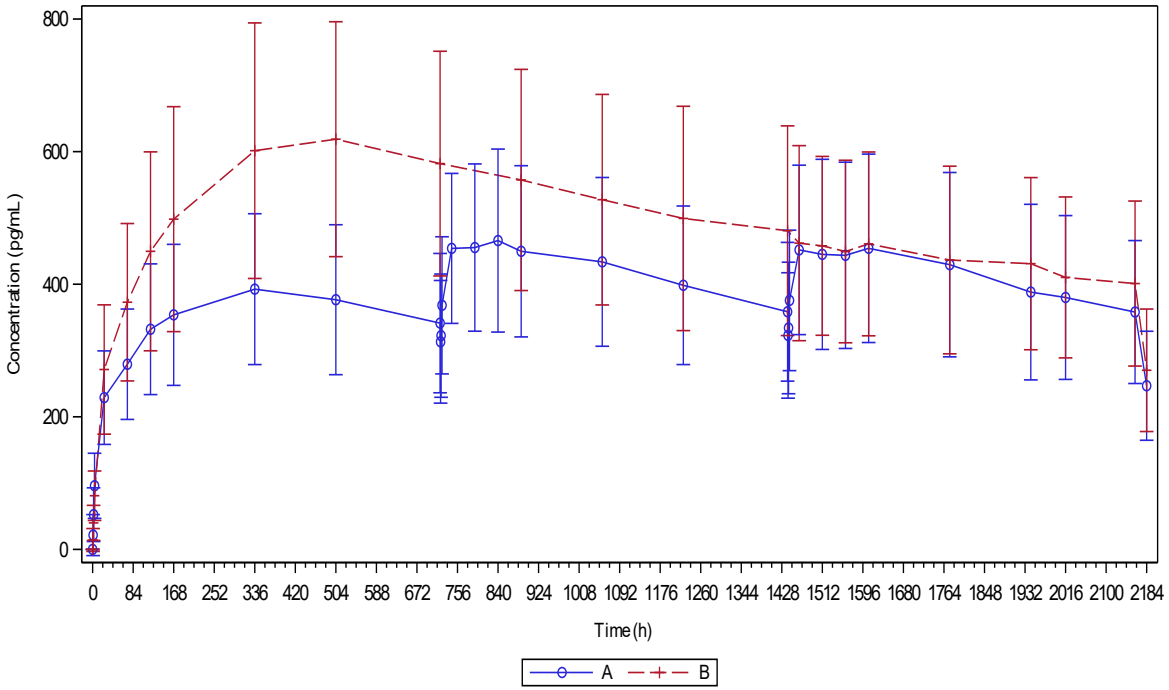
- Relative bioavailability of 100 mg ring compared to 25 mg ring by Dapivirine plasma PK parameters

Secondary Objectives

- Safety of the two ring formulations used continuously for 90 days
- Vaginal microenvironment over the course of 90 days of ring use

Exploratory Objective

- Understand women's perceptions of and overall acceptability of both rings



Conclusions

3-month ring non-inferior to monthly ring
3-month ring superior to monthly ring

Nuttall J, Haddad L, Plagianos M, Kriel W, Visser J, Solai L, Garg A, Steytler J, Devlin B. Pharmacokinetic Superiority of a 3-month Dapivirine Vaginal Ring (100 mg) Compared to the 1-month Dapivirine Vaginal Ring (25 mg). Late breaker Oral Presentation, HIVR4P, Lima, Peru, October 6-10, 2024.

Women's Acceptability of 1- vs. 3-Month Rings

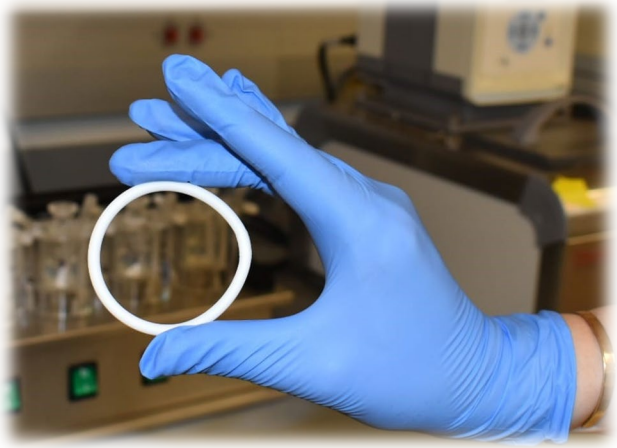
- Majority of participants interviewed preferred the 3-month ring, driven by greater convenience.
- Most participants would consider using the DVR in the future.
- If only the 3-month ring were available, most women would be willing to switch.

Progress Towards the 3-month DVR

- Regulatory review by European Medicines Agencies (EMA)
  - The line extension application for the 3-month DVR submitted to EMA November 2025
  - A positive opinion expected in 2026
- Further cost-efficiencies are being incorporated via manufacturing improvements in 2026.
- Commercial license:
  - In November 2025, **a commercial licensing agreement** was signed between PC and **Kiara Health**, a Black-owned, South Africa-based pharmaceutical company.
  - This fulfills our long-held mission to transfer the leadership of the DVR to a locally-based group.

Overview of the Dapivirine Contraceptive Ring

- **Goal**: a single, convenient, long-acting product containing dapivirine (DPV) and levonorgestrel (LNG) that provides HIV risk reduction and contraception
- **Product design:**
  - Made of ethylene vinyl acetate (EVA)
  - Core-sheath design, manufactured through co-extrusion
  - process
- **Target product profile highlights:**
  - Dosing frequency: 90 days
  - Attributes: Flexible, white/off-white ring (comparable mechanical properties and dimensions to NuvaRing®)
- **Clinical status:**
  - Phase 1b Study (IPM-056) completed, demonstrating safety, bleeding pattern, and DPV release in-line with monthly DVR
  - Next steps: to establish the relative bioavailability vs. the monthly DVVR



Key Takeaways

- The PrEP ring is truly a **woman-centered intervention** – as it is fully female-controlled, long-acting and discreet
- Although the **efficacy** demonstrated in Phase III was around 30%, sub-analysis amongst higher adherers showed a potential for efficacy between **75-91%**, and open-label extension studies showed increased efficacy levels > 50% and modeling suggested even greater risk reduction is achieved when the ring is used consistently
- PrEP ring **fulfils an important need** in the prevention toolkit - only approved product that is locally active, women centered, and safe for breastfeeding women and adolescents (16 and above) with label expansion in progress to include pregnant women
- The introduction of the monthly PrEP ring **paves the way for other long-acting products** – like the 3-month ring (under regulatory review) and the Dapivirine contraceptive ring
- When given the option women chose and retain the PrEP ring in real-world settings – highlighting the need for more awareness and demand creation in the community

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Advocate Voices

Yvette Raphael –

Co-founder and Executive Director, Advocates for Prevention of HIV and AIDS

Chilufya Kasanda –

Executive Director, Ascend Futures Foundation

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Thank You

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