

**Presentation title:** New HIV Prevention Technologies

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**Date:** 24<sup>th</sup> May 2022



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# HIV Situation in Kenya

- Kenya had a target of reducing new HIV infections to <22000 by 2020 but recorded 33,000 in 2020 (UNAIDS, 2020)
- 15 – 24years contributed 41% of all new infections among adult population with AGYW contributing two thirds (HIV Estimates, 2020)
- Kenya implements combination prevention (biomedical, behavioural and structural) interventions for HIV prevention
- Key populations (MSM, FSW, PWID, and Transgender) continue to be disproportionately affected by HIV
- Shortages of essential commodities like condoms and HIV test kits – a barrier to prevention
- Limited funding for HIV prevention (donor and national allocation)

## Why New HIV Prevention Products?



- Available methods have not slowed the epidemic among women
- Need for discreet options women can use on their own terms
- No one product will solve the HIV epidemic
- Women need multiple prevention options that make sense for their lives

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# What is the dapivirine ring?

- Flexible silicone ring which slowly releases the antiretroviral (ARV) dapivirine locally in the vagina, with minimal exposure elsewhere in the body
- User-inserted or inserted with support from a healthcare provider
- Long-acting
  - Kept in place for one month before being replaced with a new ring
- Discreet and does not interfere with sex



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# Why dapivirine ring?

No safety concerns to date

Shown to reduce HIV risk in clinical trials

Easy to use

Long-acting

Private

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# Reasons for Development

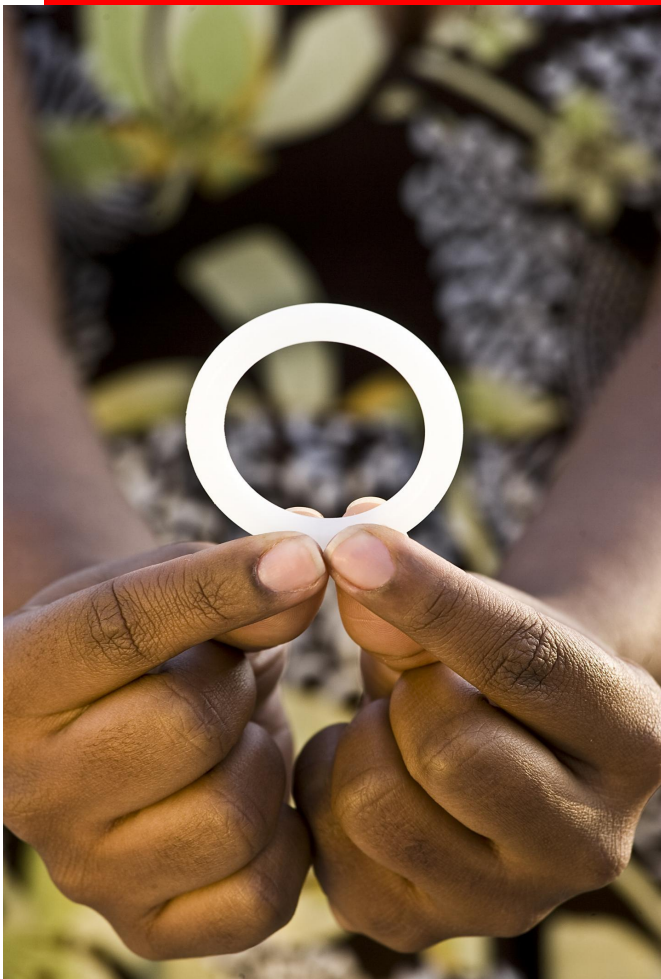
- Adolescent girls and women, particularly young women are disproportionately affected by HIV in sub-Saharan Africa
- Available HIV prevention products have not stopped the epidemic among these populations- no single product will
- People want HIV prevention options that are discreet, long-acting, and can be used without partner cooperation
- Lessons from contraception show that increased options lead to increased uptake – adding a new tool to the HIV prevention package could increase uptake of HIV prevention methods overall
- A product with few side effects that can be easily provided both within and outside of health facilities may reduce barriers to delivery and uptake



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# Efficacy



## Efficacy in Phase III trials

- 4588 participants ages 18-45 in Malawi, South Africa, Uganda, and Zimbabwe
- The ring reduced the likelihood of HIV acquisition by approximately 30% overall and was well-tolerated
- HIV risk reduction was likely greater among participants who used the ring at least some of the time
- Overall, HIV risk reduced by 40% among participants over 21; no reduction among participants under 21, who were more likely to show non-use of the ring

## Efficacy in open-label extension (OLE) trials

- 2790 former Phase III participants in Malawi, South Africa, Uganda, and Zimbabwe
- Taken together, modeling data from the two OLEs suggest overall likelihood of HIV acquisition among participants was reduced by about 50%, compared to about 30% in Phase IIIs
  - **Results are limited** due to lack of placebo comparison groups, but **indicate an encouraging trend**

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Study Name & Phase	Study population	Study Location	Key outcomes
<b>ASPIRE</b>  Phase 3	2,629 HIV-women aged 18-45	14 sites in Malawi, South Africa, Uganda, Zimbabwe	<ul style="list-style-type: none"> <li>• 27% overall reduction in HIV acquisition</li> <li>• 56% reduction in risk of HIV acquisition among women aged 21+</li> <li>• Large differences in risk reduction across age groups, likely due to adherence</li> <li>• Subsequent analysis showed a 65% reduction in risk of HIV acquisition among women who used the ring consistently</li> </ul>
<b>The Ring Study</b>  Phase 3	1,959 HIV-women aged 18 to 45	Seven sites in South Africa and Uganda	<ul style="list-style-type: none"> <li>• Ring use reduced HIV acquisition by about 30% overall</li> <li>• Ring use reduced HIV acquisition by 56% among those who used it most consistently</li> <li>• Ring safe and well-tolerated</li> </ul>
<b>HOPE</b>  Open label extension for ASPIRE	1,456 HIV-women (59% of those eligible from ASPIRE) 2 years of follow up	Same as ASPIRE	<ul style="list-style-type: none"> <li>• Ring safe and well-tolerated</li> <li>• 90% of returned rings were used at least some of the time</li> <li>• Estimated reduction in risk of HIV acquisition of 39% overall</li> <li>• Retention very high, with 98% completing all study visits</li> </ul>
<b>DREAM</b>  Open label extension for The Ring Study	941 HIV-women ages 20-50 from The Ring Study 12 months of follow up	Same as Ring Study	<ul style="list-style-type: none"> <li>• Ring safe and well tolerated</li> <li>• 95% of participants used the ring at least some of the time, an increase from 83% in Phase 3</li> <li>• Estimated reduction in risk of HIV acquisition 63% overall</li> </ul>



# European Medicines Agency (EMA)

- July 2020 - Positive Scientific Opinion
  - EMA adopted a positive opinion for use of the dapivirine ring outside of the European Union (EU) to reduce the likelihood of HIV acquisition during receptive vaginal sex, in combination with safer sex practices when oral PrEP is not used, cannot be used, or is not available

A screenshot of the European Medicines Agency (EMA) website showing the "Dapivirine Vaginal Ring 25 mg: Opinion on medicine for use outside EU" page. The page includes a "Table of contents" with links to Overview, Opinion details, Product information, and Assessment history. The "Overview" section is highlighted in blue and contains text about the ring's purpose and use. A grey box on the right indicates a "Positive opinion" for use outside the EU.

Dapivirine Vaginal Ring 25 mg: Opinion on medicine for use outside EU [Share](#)

*dapivirine*

Table of contents

- [Overview](#)
- [Opinion details](#)
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**Overview**

Dapivirine Vaginal Ring 25 mg is a vaginal ring used to reduce the risk of a woman getting infected with human immunodeficiency virus type 1 (HIV-1) through vaginal intercourse.

It is for use with safer sex practices (such as use of condoms) by women 18 years of age or above, when taking pre-exposure prophylaxis (PrEP) medicines by mouth is not feasible. It is intended for use outside the EU.

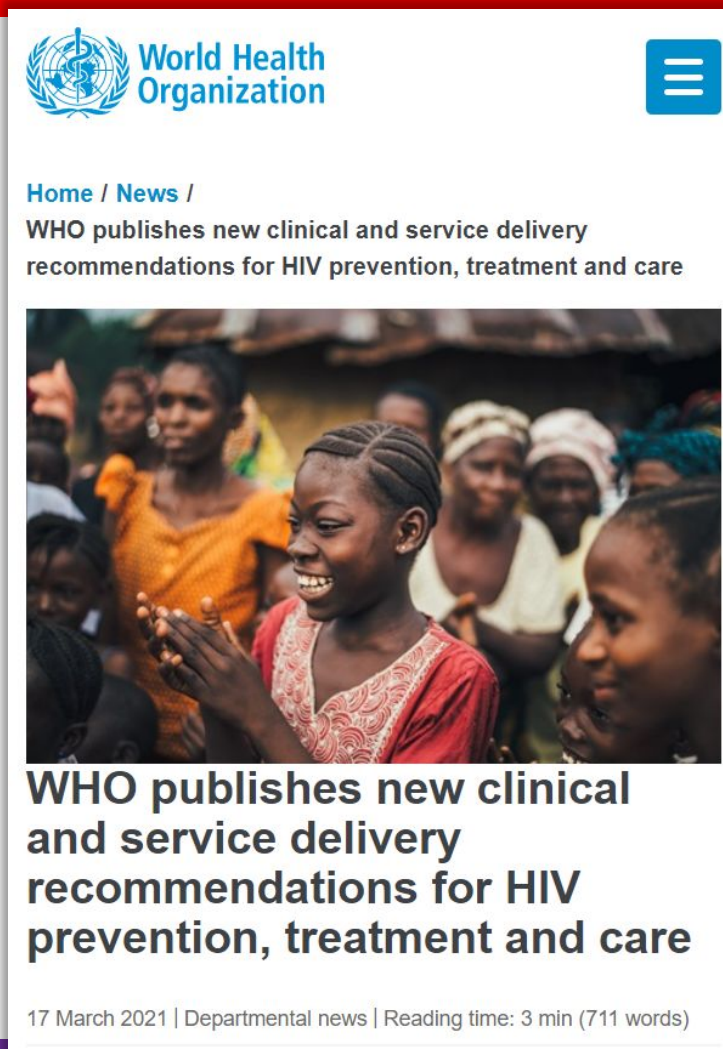
Dapivirine Vaginal Ring 25 mg contains the active substance dapivirine.

OPINION ON MEDICINE FOR USE OUTSIDE THE EUROPEAN UNION  
Positive opinion

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# World Health Organization (WHO)

- November 2020 - Prequalification received
  - WHO prequalification indicates that the ring meets global standards for quality, safety, and efficacy in reducing likelihood of HIV acquisition
- Jan 2021 – Conditional recommendation by the World Health Organization
  - WHO recommended the dapivirine ring as an additional choice for cisgender women who are at substantial risk for HIV acquisition and cannot or choose not to use oral PrEP, and as part of combination prevention approaches
- March 2021 - Clinical guidelines including the recommendation for the ring published



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- March 2021 - New Drug Application (NDA) accepted for review by the FDA
  - Unlike the EMA, which can give opinions on medicines intended for use in countries outside the EU, the FDA only gives opinions on medicines intended for use inside the United States
- December 2021 – IPM (ring developer) voluntarily withdrew NDA
  - During the FDA's review of the application, feedback indicated that current data are unlikely to support US approval given the context of the current HIV prevention landscape in the United States

## INCIDENCE DATA:

United States: In 2018, there were 36,400 new cases of HIV. Of those, 6700 (18%) were among women.  
(<https://www.cdc.gov/hiv/group/gender/women/incidence.html>)

East and Southern Africa: In 2018, there were 800,000 new cases of HIV. Of those, 208,000 (26%) were among young women (15-24).  
([https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview#footnote10\\_b8bow83](https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview#footnote10_b8bow83))

- Users find that the ring is an acceptable PrEP method for HIV prevention
- When used, the ring reduces likelihood of HIV acquisition during receptive vaginal sex by about 50%
- Use of the ring in settings with a high incidence among girls and women creates choice for people who do not, cannot, or are unable to use oral PrEP
- WHO through prequalification and recommendation of the ring indicate that the ring is safe and effective
- Countries that have approved use the Ring include: **Zimbabwe, Kenya and South Africa**



# Long-acting injectable Cabotegravir

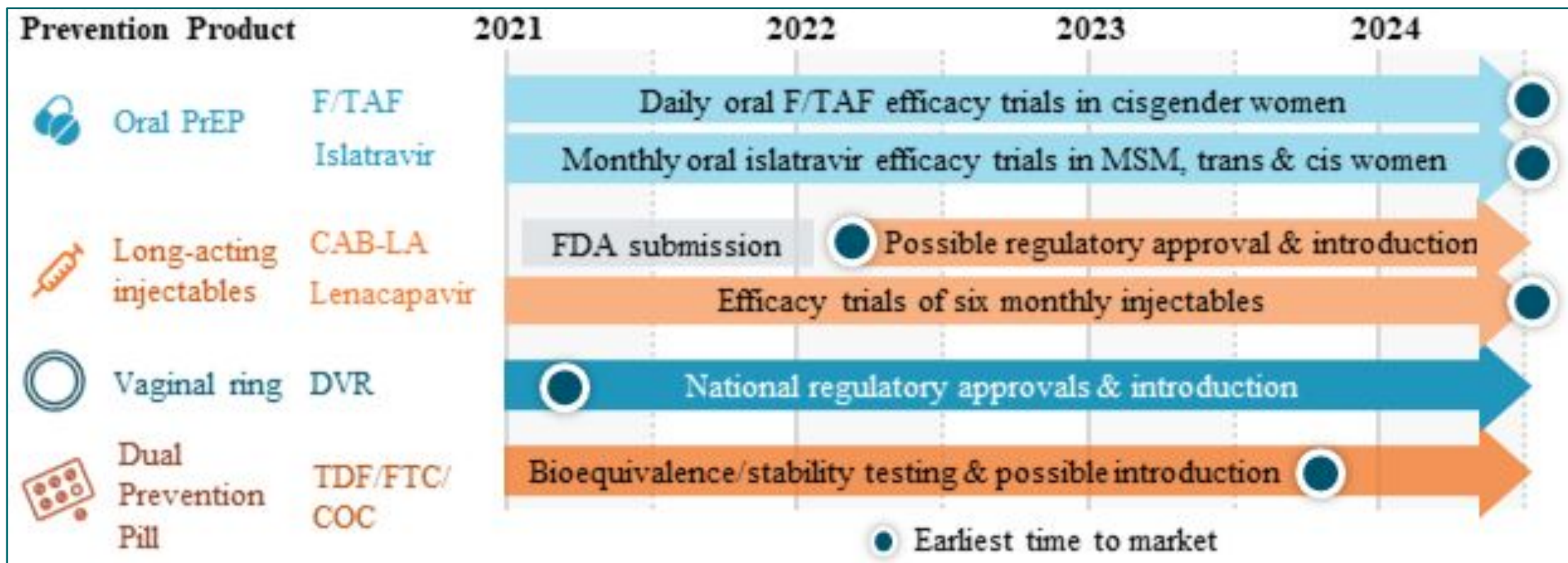
- CAB-LA, or long-acting injectable cabotegravir, is an antiretroviral drug formulated to be administered once every two months as an injectable form of PrEP.
- CAB-LA is an alternative, injectable PrEP option. Efficacy data from phase III clinical studies (HPTN 083 and HPTN 084) show it is safe, well-tolerated, and effective.
- Efficacy – Among MSM and transgender women (66%); among cis-gender women (89%)
- As of December 2021, CAB-LA was additionally approved by the US FDA for use as a prevention option.
- The developer (ViiV) has submitted new product application to the Kenya PPB for approval

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# Biomedical HIV prevention products

- Biomedical methods available in Kenya – PEP, Daily Oral PrEP

## Upcoming products



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## NEXT STEPS

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# MOSAIC

## Maximizing Options to Advance Informed Choice for HIV Prevention

*Our vision is that after five years women in sub-Saharan Africa will have access to multiple, effective biomedical prevention options that meet their changing needs and desires; that health systems will be enabled to support informed choice and effective use through policies, programming and differentiated service delivery; and that cost, impact and targeting guidance will be in place to support efficient use of resources.*

Countries with Mission concurrence:

- Eswatini
- Lesotho
- Kenya
- Namibia
- Nigeria
- South Africa
- Uganda
- Zambia
- Zimbabwe

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# MOSAIC

## Maximizing Options to Advance Informed Choice for HIV Prevention

### VALUES

Country-led

Women-focused  
with emphasis on  
AGYW

Informed choice

Equitable  
co-leadership

Intentionality

- 5-year global project funded by PEPFAR through USAID (2021-2026). Core partners – FHI360, LVCT Health, Wits RHI, PZT, AVAC and JHPIEGO
- Focus on research/research translation to support introduction and access for new biomedical prevention products to prevent HIV for women in sub-Saharan Africa
- Work across multiple countries to support evidence-informed and user-centered product introduction, research, research utilization, and capacity development
- Support a multi-product market with informed choice for HIV prevention as new products enter the market
- Collaborate closely with ministries of health, missions, implementing partners, civil society, end users, providers, other local and global stakeholders, and product developers

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# MOSAIC STRATEGIC PRIORITIES

## USER-CENTERED APPROACH

- Articulate, operationalize, and demonstrate accountability to principles of gender integration and meaningful youth engagement across MOSAIC

## PRODUCT INTRODUCTION RESEARCH

- Test novel PrEP indicators for monitoring and evaluation
- Design and initiate implementation studies for registered PrEP products
- Generate PrEP cost data
- Conduct systematic reviews and formative research on acceptability, values and preferences for new products
- Obtain program data and conduct secondary analyses



## PRODUCT INTRODUCTION POLICIES & PROGRAMS

- Pipeline management and market development
- Policy and program
- Civil society and advocacy
- Demand and marketing

## RESEARCH UTILIZATION & KNOWLEDGE MANAGEMENT

- Design and introduce research utilization and knowledge management strategies to support PrEP

## LOCAL PARTNER CAPACITY STRENGTHENING

- Strengthen local partner capacity to design and implement PrEP product introduction activities and research

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- **Goal:** To assess **feasibility, acceptability, uptake and patterns of use** with a PrEP service delivery package providing choice of oral PrEP, PrEP ring and CAB PrEP among women, especially AGYW, at PrEP delivery sites in Kenya, Lesotho, South Africa, **Uganda** and Zimbabwe
- **Program Design:** The study will implement an **enhanced PrEP service delivery package** that supports choice among the PrEP products that have regulatory approval in each country. The enhanced service package will include components at the **individual, provider, facility and community** levels and will use quality improvement methods to refine components and identify a core service delivery package for PrEP choice.
- **Study Design :** Prospective observational cohort and mixed methods process evaluation

- Counties - Nairobi, Mombasa and Kisumu
- Sites – 6 public health facilities (2 per county)
- Target – Young women (18+ years)
- Focus – offering women Choice
- Approach: 2 Phases:
  - Phase 1 – Participants offered Oral PrEP and Ring (12 months)
  - Phase 2 – Participants offered Oral PrEP, Ring and CAB-LA (12 months)



# Thank You

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