

EAST AFRICAN COMMUNITY
SEXUAL AND REPRODUCTIVE HEALTH BILL, 2021
New biomedical HIV prevention product-introducing
Dapivirine ring as a women control technology and
self-initiated HIV prevention option among adolescent,
girls and young women as part of combination HIV
prevention approach.

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Outlines:

- Introduction
- Overview of Vaginal Dapivirine Ring
- Research findings
- Methods
- Result
- Conclusion
- Recommendation



INTRODUCTION

- Integration of sexual and reproductive health services in Partner State universal health coverage –
- Sexual and Reproductive Health for Adolescents and young people, in relation to Access to sexual and reproductive health services (Clause 6 and 11 - page 2).
- Other Sexual and Reproductive Health Services and related services (item 19) Protection from HIV and AIDS and sexual transmitted infections.
- Although demand and access to daily oral PrEP is increasing around Tanzania, a daily pill is not a suitable or desirable prevention method for everyone. Today, women and girls account for more than half of all people living with HIV globally, and face persistently high HIV-infection rates.
- Experience introducing oral PrEP in many countries has revealed that women face unique challenges when it comes to adhering to a daily pill due to gender inequity, social norms and other barriers.
- **Page 9 (item h) Accessibility, availability and education on contraceptives and other biomedical HIV prevention products – Dapivirine Vaginal Ring.**

An additional user controlled HIV* prevention options for those who cannot O Choose Not to Use Oral PreP



Flexible, one-size-fits-all vaginal ring developed by the International Partnership for Microbicides (IPM)

Slowly releases an anti-retroviral (ARV) called dapivirine into the vagina over the period of one month

The first long-acting HIV prevention product

User-controlled HIV prevention method

Research findings

- Efficacy data shows that the ring reduces HIV risk by 35 percent, with recent data from open label extension studies suggesting a greater reduction in HIV risk by about half.
- Modelling has shown that even a partially effective prevention option can have an important protective impact for women and their communities as part of a comprehensive HIV prevention strategy

The Ring Fills Gaps in the Current Portfolio

	Current options			Innovation
	Condoms	Treatment as Prevention	Oral PrEP	Dapivirine Ring
Frequency	At time of sex	Daily	Daily	Monthly
Site of action	Non-systemic	Systemic	Systemic	Non-systemic
Role of male partner in use	Male partner consent required	Controlled by partner living with HIV	User-initiated	User-initiated

Method:

- The OPTIONS Consortium conducted secondary research and interviews with key stakeholders in several countries to understand about the ring and processes for introducing new biomedical HIV prevention products.
- Tanzania was prioritized for analysis in May 2018 due to the state of the HIV epidemic in the country and experience with ring trials.
- Interviews comprised a mix of policymakers, civil society representatives, donors, implementing partners and trial contributors.
- new option, Dapivirine Vaginal Ring efficacy data shows that it reduces HIV transmissions but it shows 0% efficacy among AGYW because they did not use it, however in the open label study they used it and efficacy increased to 50%.

Dapivirine Ring Trials

Malawi, South Africa, Uganda, Zimbabwe

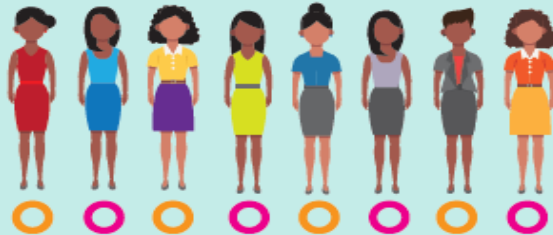
Phase III



ASPIRE

4500

Women did not know if they're receiving the dapivirine ring or a placebo ring



Placebo

What we saw in Phase III trials

HIV risk was lower with dapivirine ring use in the Phase III trials



35%
27%

Adherence was about 80% in Phase III trials

80%

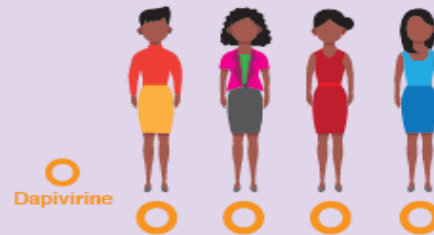
No safety concerns were seen with use of the dapivirine ring in the Phase III trials

Risk Reduction

Adherence

Safety

Open-Label



Dapivirine



HOPE

HIV Open-label Prevention Extension
Out of ASPIRE, there is HOPE

2400

Former Phase III participants

All women know they're receiving the dapivirine ring (there was no placebo group)

What we saw in Open-label studies

63%
39%



Modeling data suggest HIV risk was reduced by about half with ring use across both studies

90%+

More than 90% of women used the dapivirine ring at least some of the time

The dapivirine ring's safety profile in the open-label studies was similar to the strong profile seen in the Phase III trials

WHAT WE KNOW

01 The Phase III trials showed that HIV risk was reduced in women who used the dapivirine ring

02 Open-label study results suggested that the dapivirine ring reduced HIV risk by about half across both studies, an encouraging trend

03 Adherence was higher in the open-label studies

04 The dapivirine ring had a strong safety profile in all the Phase III and open-label studies, with no safety concerns

05 The open-label study results suggest that when women are aware that the dapivirine ring reduced HIV risk in large clinical trials, they are more likely to use the product and see greater protection

The Ring: Rollout Milestones as of March 2021

Positive Opinion:

European Medicines Agency
July 2020

Added to prequalification list:

World Health Organization
November 2020

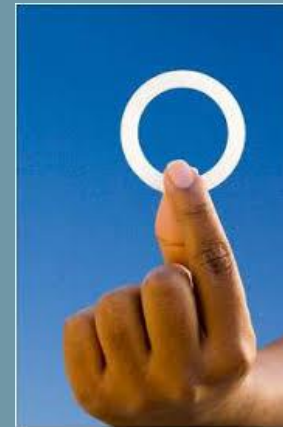
Recommendation:

World Health Organization
January 2021

Inclusion in HIV Prevention Guidelines:

World Health Organization
March 2021

The World Health Organization recommends that the ring be offered as an option for women in need of HIV prevention methods as part of combination prevention approaches.



IPM has applied for regulatory approval in many countries, including the United States and South Africa. Some countries have already approved the ring, and more country regulatory responses are anticipated in 2021 and 2022.

Result:

- TNW+ managed to meet a total of 305 AGYW from all diversity and educated about the Dapivirine Ring through a workshop held at Dar es salaam and WAD in Moshi 2020.
- Dapivirine ring messaging in Swahili language were displayed. Additional awareness by marching almost 5km was done.

Result

- All groups of AGYW, FSW, Trans Women and IDUs were interested to understand the concept of Dapivirine Virginal Ring.
- Further more other organizations working on health perspective are now started to create demand by sensitizing the women and girls on understanding the concept of DVR. (DWWT)



Results:

- The ring is currently under review by National Medical Regulatory Authorities in Kenya, Malawi, Rwanda, South Africa, Tanzania, Uganda, Zambia, Zimbabwe although COVID-19 may cause delays.
- In Tanzania delays of adoption is due to a policy environment and a slow pace of product introduction that may delay the launch of a demonstration project for the ring.

Result...

- There was interest from all stakeholders to provide another HIV prevention option.
- One of the ten sites of the study was in Tanzania. The study site was the Kilimanjaro Christian Medical Centre (KCMC) in Moshi, Tanzania, and the site enrolled 9 of the 280 women that participated in the study.
- IPM colleagues shared that Tanzania was not included in the phase III studies because the prevalence at the study site was not considered to be high enough.

Challenges

- While some stakeholders in other countries involved on the research were familiar with the ring, Tanzania has not been involved in any phase III or OLEs for the ring.
- Protracted process and expressed skepticism about Tanzania's ability to move quickly on the ring based on the lengthy process to introduce oral PrEP.

Conclusion:

- The daily oral PrEP is an effective HIV prevention method to Women and AGYW however adherence and other factors may contribute to inconsistent use.
- Dapivirine ring is a long acting HIV prevention option that AGYW can use when unable to use other methods. Now it's a time to start thinking about how to pair the PrEP work we've done with the introduction of the Dapivirine Ring.

Recommendation

- The ring might take a similar process of introduction to PrEP and self-testing. If we get prepared and involve the policymakers now, it might be able to shorten the process after those two products.
- CSO, KVP's ,AGYW and FBO 's should joint together with NSA's to make sure the DVR introductions is fasten.
- We may learn from other countries processes which shows good development.

- The introduction of the Dapivirine Ring has been well received by AGYW and some policy makers, hence there is a need for continued awareness raising, demand creation, availability, and affordability.
- The use of translated information in Swahili plays a critical role in enforcing messaging to targeted groups waiting for the introduction in the country.
- Policy makers and USAID/PEPFAR missions in most countries advised that a demonstration in each country addressing local conditions and concerns is the best way to expedite inclusion of the ring in national policies and plans.

REFERENCE.

- *OPTION data*
- *TNW+ implementation report*
- *International Partnership Microbicides journal*
- *PrEP watch*