## NEXT GENERATION HIV PREVENTION: THE DAPIVIRINE VAGINAL RING

PrEP Learning Network Webinar Series

# To receive a quarterly update on the dapivirine ring, join the new <u>Ring Network</u> <u>distribution list!</u>

Thank you to our speakers, Zeda Rosenberg from the International Partnership for Microbicides (IPM), Neeraja Bhavaraju from Afton Bloom, Taurai Bhatasara from the Zimbabwe Ministry of Health and Child Care, and Mary Mugambi from the Division of National AIDS and STI Control Program in Kenya, as well as attendees who participated in the fifteenth PrEP Learning Network webinar. In this webinar, we discussed the dapivirine vaginal ring (DVR), which recently received a positive scientific opinion from the European Medicines Agency (EMA) for use by cisgender women ages 18 and older in developing countries to reduce their HIV risk. During the webinar, we heard an overview of the DVR and plans for regulatory submissions in Africa, a framework for ring introduction as part of combination prevention, and national considerations for introduction in Zimbabwe and Kenya. In case you missed it, you can access <u>the webinar recording here</u>.

### **Top 14 Questions**

This topic generated a lot of discussion and questions! Below is a summary of the Q&A for those seeking more information on the DVR. Learn more by listening to the webinar recording, accessing complementary resources, signing up for future webinars, or visiting the <u>PrEP Virtual Learning Network</u> page.

Join us for the next webinar in the series.

### PREP FOR AGYW: EXPERIENCES FROM DREAMS PROGRAMS

22 October 2020

9:00-10:30 EDT

16:00-17:30 EAT Register Here

### **Top 14 Questions**

### 1. What is the dapivirine vaginal ring?

The dapivirine vaginal ring (DVR) is a vaginal ring made of flexible silicone that slowly releases an antiretroviral (ARV) drug called dapivirine over the course of one month to reduce the risk of HIV-1 infection in women. The ring is one-size-fits-all. A woman can insert the DVR herself; it does not need to be inserted by a health care provider. The woman should insert the DVR far enough into her vagina so that she can no longer feel it and she is comfortable, and leave it in place for one month.

#### 2. Who is the DVR for?

The DVR can be used by HIV-negative women ages 18 and older who are at risk for HIV and cannot or are unable to use oral PrEP. The recommended age range could expand in the future pending results from other research studies currently in progress.

### 3. How long does it take to reach maximum efficacy after insertion?

The ring should be in place for at least 24 hours for dapivirine to begin to help protect against HIV. However, it is the level of sustained-release achieved when the ring is in place continuously over the course of a month that helps reduce risk—which is why it is so important that women keep the ring in and replace it monthly.

### 4. Are there any side effects?

Side effects of the DVR are generally mild to moderate, such as UTIs, vaginal discharge or itching. In most cases, these issues resolve without interrupting ring use.

### 5. Does the DVR protect both partners or only women?

The DVR only reduces the risk of HIV-1 transmission via vaginal sex for an HIV-negative woman. It does not provide protection for male partners.

# 6. How long can a woman keep the DVR in place? Does it need to be removed during menses?

The ring is designed to be used continuously for 28 days. It does not need to be removed during menses. When the ring is not in place, the woman is not protected from HIV.

### 7. Can the DVR come out during sex? Can it be felt by a male partner during sex?

If placed correctly, the DVR should not come out during sex. During clinical trials, some men did report feeling it when asked during focus groups, but most men did not know the DVR was in place unless they were told it was there.









### **Top 14 Questions (continued)**

In fact, the overwhelming majority of women in ring studies reported that one of the most favorable characteristics is that it does not negatively impact the sexual experience for them or their male partners. Some women reported that the ring increased sexual pleasure for them and their male partners partly due to reduced anxiety about their HIV risk.

#### 8. Does the DVR protect women who engage in anal sex?

The DVR does not reduce the risk of HIV transmission via anal sex.

### 9. Does the DVR protect from unintended pregnancies and STIs?

The DVR does not prevent from unintended pregnancies or STIs. It is recommended that the ring be used with male or female condoms.

### 10. Will the DVR interfere with an intrauterine device (IUD)?

No, it does not interfere with IUDs/IUCDs. The ring can be used with some types of contraception but should not be used with other vaginal rings or diaphragms.

### 11. Can the DVR be used among pregnant and breastfeeding women?

The DVR is not contraindicated in pregnant and breastfeeding women. Pending country guidelines it will likely be the decision of healthcare providers whether to recommend the ring to a pregnant or breastfeeding woman, depending on her level of HIV risk. There are studies underway through to 2024 to collect data on the use of the DVR and oral PrEP among pregnant and breastfeeding women.

### 12. Is 35% of protection enough to recommend this product?

Yes. The EMA adopted its positive scientific opinion for the ring based on the 35% HIV risk reduction seen in The Ring Study, a Phase III trial, and on the urgency of the epidemic despite available options. As the EMA noted in its opinion, some women, particularly in sub-Saharan Africa, are at especially high risk for HIV because they cannot negotiate condom use or use oral PrEP. As a discreet and woman-controlled method, the DVR provides an additional HIV prevention option for women who cannot or choose not to use oral PrEP, or do not have access to it. In addition, The Ring Study was able to show an estimated 35% efficacy with only modest adherence, meaning that the ring's effectiveness may be higher. We are encouraged by results from subsequent open-label studies showing increased ring use and modeling data suggesting higher risk reduction—by more than 50%.



### **Top 14 Questions (continued)**

#### 13. Is there any required testing associated with the DVR?

A negative HIV test result will be required in order to receive a DVR prescription to ensure that any women who are HIV positive receive appropriate care and treatment, and to minimize any potential development of resistance to treatment regimens. Regular HIV testing every 3 months would be recommended, as with oral PrEP, but is subject to country guidelines. It will be essential to monitor any seroconversions and switch such clients to ART as appropriate.

### 14. How much will the DVR cost?

The goal is for the DVR to be publicly funded and provided to women at low or no cost. The cost of the ring will vary by country. IPM is working with donors, governments and key partners to keep the cost of the ring low.

### **ADDITIONAL RESOURCES**

For more further information on the dapivirine vaginal ring, please see the following resources:

- DVR Tools & Resources one-pager: A one-page document put together by the OPTIONS Consortium containing links to various DVR tools and resources such as blogs, videos, papers and peer-reviewed articles.
- **Ring Backgrounder** <u>fact sheet</u>: IPM's fact sheet providing an overview of the DVR, including the ring technology, key results, regulatory status and next steps.
- <u>**Ring Q&A:</u>** Frequently asked questions on the DVR, the EMA's opinion and next steps, including the ring's potential introduction (collated by IPM).</u>
- <u>Clinical Trial Results</u>: Find out more about the research, development and clinical history of the DVR. Learn about the results of the Ring Study and ASPIRE Phase III trials and the DREAM and HOPE open-label extension trials.
- <u>Manuscript on vaginal ring acceptability</u>: Vaginal ring acceptability and related preferences among women in lowand middle-income countries: A systematic review and narrative synthesis. PLOS ONE, 2019.
- <u>The Common Agenda</u>: A shared guide for stakeholders developed by OPTIONS and IPM on a wide array of activities required to accelerate potential introduction of the DVR, in line with key opportunities and considerations identified by national policymakers.
- <u>PROMISE/CHOICE 2-pager</u>: Read how the PROMISE and CHOICE projects are collaborating with IPM to support DVR introduction activities.

We hope you join us again on <u>October 22</u>! Our next webinar will focus on learnings from DREAMS PrEP programs. Learn more about current innovations to increase access, uptake, and continuation of oral PrEP among adolescent girls and young women. Visit the <u>PrEP Virtual Learning Network</u> for more information on previous or upcoming sessions.







