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## **Dapivirine Levonorgestrel Vaginal Ring: A multipurpose prevention ring for HIV and contraceptive protection**

IPM South Africa

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# DAPIVIRINE LEVONORGESTREL VAGINAL RING

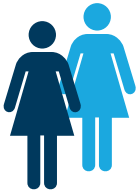
A MULTIPURPOSE PREVENTION RING FOR HIV AND CONTRACEPTIVE PROTECTION

## ABOUT THE DAPIVIRINE-LEVONORGESTREL VAGINAL RING

Leveraging our experience developing the monthly dapivirine vaginal ring (DVR or “PrEP ring”), which received a positive opinion from the European Medicines Agency in 2020 for women’s HIV risk reduction, the Population Council is developing a 3-month multipurpose vaginal ring to help women protect against both HIV and unintended pregnancy. This ring is designed to slowly release the antiretroviral (ARV) drug, dapivirine and the contraceptive hormone, levonorgestrel.

## KEY ISSUES

Women’s sexual and reproductive health needs do not exist in isolation, and meeting those needs is essential to supporting women’s overall health. New products that simultaneously address both issues could help keep women healthy so they can reach their full potential.



- **Women are disproportionately affected by HIV/AIDS due to biology, gender inequities and cultural norms.** In sub-Saharan Africa—where the epidemic’s main driver is heterosexual sex—women account for nearly **63%** of new HIV infections. Young women in the region are more than twice as likely to acquire HIV as young men.



- **In developing countries, a lack of access to contraception is a major contributor to maternal and newborn deaths,** largely due to complications during pregnancy and childbirth. Worldwide, **43%** of all pregnancies are unintended. An estimated **214 million** women have an unmet need for contraception — one-quarter of whom are living in sub-Saharan Africa.



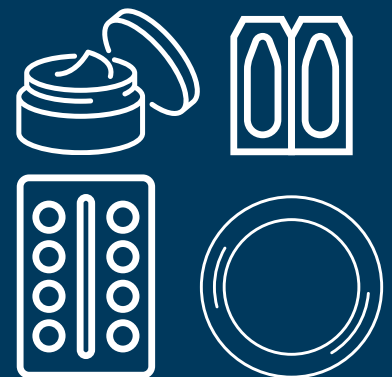
- **Women face dual risks.** Women in areas with high rates of HIV often have the greatest unmet need for modern contraception. Recent research also suggests that women’s risk for HIV is up to **three times higher** during pregnancy, and HIV/AIDS is one of the leading causes of death among pregnant women in developing countries.

## MULTIPURPOSE PREVENTION

Although condoms are highly effective multipurpose prevention technologies (MPTs), it is often difficult for women to negotiate condom use with their partners. New MPTs are in development to protect users against multiple indications simultaneously (i.e. sexually transmitted infections, HIV, and/or contraception) to improve:

- Choice
- Convenience
- Cost

MPTs can come in a variety of delivery systems, including topical gels, vaginal rings, oral pills, and fast dissolving vaginal or rectal inserts.



## THE DAPIVIRINE-LEVONORGESTREL VAGINAL RING

Building on the successful development of the one-month DVR for HIV prevention, the Population Council is developing a dual purpose vaginal ring with dapivirine for HIV prevention and levonorgestrel for contraception. This ring is an ethylene vinyl acetate core-sheath vaginal ring designed to slowly release the two active products. Women would insert the ring themselves into the vagina and replace it every three months, offering them a user-controlled, long-acting dual prevention option.



### INTEGRATED SOLUTIONS MAKE SENSE

- **Discreet, woman-initiated** protection against HIV and unintended pregnancy can help reduce maternal and newborn deaths
- **Long-acting** options are convenient and may help encourage consistent use
- 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
- **Combined protection** may be more appealing to women versus HIV/STI prevention products alone because women's perceived risk of HIV is often lower than their perceived risk for pregnancy. Women in multiple studies have shown strong interest in and willingness to use multipurpose products versus HIV/STI prevention products alone.

### THE PROGRESS

Two phase 1 studies (MTN-030/IPM 041 and MTN-044/IPM 053/CCN019), were led by our partner, the Microbicide Trials Network (MTN). These studies found the ring to be well-tolerated, and encouraging drug levels were seen in blood and vaginal fluid. Together with the National Institute of Child Health and Human Development, a Phase 1b trial of the ring is ongoing.

Pending the results of the Phase 1 trials of the ring, it may be possible to conduct trials that would supplement data from previous efficacy trials of dapivirine and levonorgestrel. Such “bridging studies” could reduce the timeline by requiring fewer subsequent clinical trials. This approach would be determined in consultation with health and regulatory authorities.