

# Why Microbicides for Women?



INTERNATIONAL  
PARTNERSHIP FOR  
MICROBICIDES

Women are at disproportionate risk for HIV infection—and urgently need new tools they can use to protect their own health. Products called microbicides are being developed as vaginal rings, films and tablets and as rectal and dual-compartment gels that could be used both vaginally and rectally to help prevent sexual transmission of HIV. These products are based on the same types of antiretroviral (ARV) drugs already being used successfully to treat and prevent HIV.

## Women and Girls Bear the Burden of the HIV/AIDS Epidemic

- **HIV/AIDS is one of the world's leading causes of death in women ages 15-49.**<sup>i</sup> Over half of all adults living with HIV/AIDS are women.<sup>ii</sup> The epidemic takes a disproportionate toll in sub-Saharan Africa, where six of every 10 adults living with HIV/AIDS are women.<sup>iii</sup>
- **New HIV infections among women and girls continue at an alarming rate.** Each day, more than 1,800 women and girls acquire HIV.<sup>ii</sup> In sub-Saharan Africa, 63% of all new HIV infections are among women and girls, and young women ages 15-24 are three times as likely to acquire HIV as young men.<sup>iii</sup>
- **Women are particularly susceptible to HIV.** Heterosexual sex remains the primary mode of HIV transmission in sub-Saharan Africa, and a combination of biology and gender inequities, including gender-based violence, renders women more susceptible to HIV infection than men.

In sub-Saharan Africa, young women ages 15-24 are *more than three times as likely* to acquire HIV as young men of the same age.<sup>iii</sup>

- **Caregiving for those living with HIV/AIDS often falls to women and girls, limiting their opportunities.**<sup>vi</sup> Many female caregivers have little extra time to earn money, produce food or attend school while supporting their families. Consequently, these women

and girls, along with their families, are more likely to be malnourished, in poor health and impoverished—all factors that further increase susceptibility to HIV infection.



*Reducing maternal mortality is difficult in countries hit hard by HIV, a contributor to death in pregnant women and new mothers.*

- **HIV/AIDS has a significant impact on the health of pregnant women and new mothers.** Women of reproductive age are at high risk for HIV infection, and women may be two to four times as likely to acquire HIV during pregnancy and the postpartum period.<sup>iv</sup> Pregnancy also exacerbates the symptoms and effects of HIV, and many women living with HIV in developing countries learn that they are infected only after they become pregnant. Globally, a substantial proportion of deaths among women living with HIV occur during pregnancy or postpartum,<sup>v</sup> and a study of three African sites estimated that women living with HIV faced a more than fivefold risk of maternal death than HIV-negative women.<sup>vi</sup> New woman-centered prevention tools would help reduce maternal mortality.

## New Woman-controlled Prevention Options are Urgently Needed

**A range of prevention choices are needed to control the epidemic among women.** Many women are unable to negotiate with their partners to use condoms, or to even plan the timing of sex. In addition, while daily ARV pills called PrEP (or pre-exposure prophylaxis) are also highly effective and being made available in many countries, some women are not able to—or choose not to—use a daily pill or future methods like an injectable. Controlling the epidemic will require a range of options so a woman can choose the product that best meets her individual needs and life circumstances.

**Microbicides could offer women discreet methods to protect their sexual and reproductive health on their own terms.** One microbicide has been found to reduce women's HIV risk in large clinical trials: the monthly dapivirine vaginal ring. The nonprofit International Partnership for Microbicides (IPM) designed the flexible silicone ring to slowly release the ARV dapivirine. Women insert the ring themselves and replace it each month. The product received a positive opinion from the EMA in 2020 and a recommendation from the WHO in 2021. IPM is seeking regulatory approvals for the ring's use in countries in eastern and southern Africa where HIV incidence among women is high and they urgently need new prevention choices. Regulatory approval was received in Zimbabwe and several other countries in the region in 2021, with additional reviews underway.

**Microbicides that combine an ARV with a contraceptive are also being developed to protect against HIV and unintended pregnancy, a major contributor to maternal mortality.** Together, HIV and maternal mortality are two of the leading risks to women's health worldwide. Among such multipurpose products in development is IPM's three-month ring designed to slowly release dapivirine along with the contraceptive hormone levonorgestrel. Encouraging results from two safety clinical trials supported the product's continued development. In addition, IPM reformulated the ring to increase its firmness due to some participant reports of slippage and is planning a Phase I trial of the reformulated ring in 2022.

**Microbicides would complement existing HIV prevention methods.** The dapivirine microbicide ring would help fill a gap by adding a long-acting method designed specifically for women to a comprehensive HIV prevention toolkit that currently includes condoms, daily oral PrEP, treatment-as-prevention and male circumcision. Other promising tools in development include ARV-based injectables and implants, long-acting oral PrEP, rectal and dual-compartment gels and vaccines.

**Modeling studies show that a combination approach is needed to end the epidemic—and that microbicides like the dapivirine ring could have a meaningful impact as part of that approach.**

**Realizing the promise of microbicides requires continued support.** Between 2018 and 2019, global investment in overall microbicide research and development fell 6%, from US\$163 million to US\$154 million.<sup>vii</sup> Sustained funding to develop a diverse product pipeline that uses new mechanisms of actions and different formulations is critical to meeting the urgency of the epidemic and staying ahead of the virus. Safe and effective microbicides would help empower women to protect themselves from HIV/AIDS and alter the course of the epidemic.

<sup>i</sup> UNAIDS. "We've Got the Power: Women, Adolescent Girls and the HIV Response". 2020.

<sup>ii</sup> UNAIDS. Core epidemiology slides. 2021.

<sup>iii</sup> UNAIDS. AIDSinfo database. <http://aidsinfo.unaids.org>, accessed December 7, 2021.

<sup>iv</sup> Thomson KA, J Hughes, JM Baeten, G John-Stewart, C Celum, CR Cohen, et al. Increased risk of HIV acquisition among women throughout pregnancy and during the postpartum period: A prospective per-coital-act analysis among women with HIV-infected partners. *J Infect Dis* 2018 Jun 5;218(1):16-25.

<sup>v</sup> GBD 2015 Maternal Mortality Collaborators. Global, regional, and national levels of maternal mortality, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet*. 2016 Oct 8;388(10053):1775-1812.

<sup>vi</sup> Calvert C, M Marston, E Slaymaker, AC Crampin, AJ Price, N Klein, et al. Direct maternal deaths attributable to HIV in the era of antiretroviral therapy: evidence from three population-based HIV cohorts with verbal autopsy. *AIDS*. 2020 Jul 15;34(9):1397-1405.

<sup>vii</sup> Resource Tracking for HIV Prevention R&D Working Group. "HIV Prevention Research & Development Investments." <http://www.hivresourcetracking.org>, accessed March 23, 2021.