TuSalud

Vaginal Ring Will Be Available in 11 African Countries—But Not the U.S.

Effective oral and injectable PrEP have put a damper on development of alternative HIV prevention methods, but women need a variety of options.

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The dapivirine vaginal ring, an alternative HIV prevention method for women, will soon be available in nearly a dozen countries in Africa. This is welcome news, as adolescent girls and young women are among the groups most at risk in sub-Saharan Africa. But the ring is not available to women in the United States, who also need more prevention options.

The antiretroviral ring is now approved or authorized for use in 11 countries in East and Southern Africa, according to a November 30 announcement from the Population Council and IPM South Africa. It is currently being offered through more than 30 implementation and pilot studies in Eswatini, Kenya, Lesotho, South Africa, Uganda and Zimbabwe, and it will soon be available in Botswana, Malawi, Namibia, Rwanda and Zambia. More than 113,000 rings, marketed as DapiRing, have been sold as of September. The ring is currently produced by a company in Sweden, but Kiara Health, a South African pharmaceutical company, aims to set up local manufacturing capability, which should improve access and lower costs.

“Women have told us they want more options in the future, and we’re responding,” said Anita Bhatia Garg, the Population Council’s senior director for strategy and commercial relations, who has been involved in the ring’s development for more than 15 years. “Women need different choices for HIV prevention at different stages of their lives, and the ring could be a critically important option. It complements existing HIV prevention tools and circumvents well-documented challenges that adolescent girls and young women face in taking pills on a daily basis.”

The flexible silicone ring, which is worn in the vagina for a month at a time, slowly releases dapivirine, a non-nucleoside reverse transcriptase inhibitor. Research has shown that the ring is safe, including recently published results from the DELIVER trial, which found that adverse pregnancy outcomes and complications were rare among women who used either the ring or daily pre-exposure prophylaxis (PrEP) pills during the third trimester of pregnancy. The study is ongoing to evaluate outcomes when these products are used earlier in pregnancy.

Studies have shown that the dapivirine ring—the first long-acting HIV prevention tool designed

specifically for women—is moderately effective. Results from the ASPIRE trial (MTN-020), presented at the 2016 Conference on Retroviruses and Opportunistic Infections (CROI) and reported in The New England Journal of Medicine, showed that the ring reduced the risk of HIV acquisition by 27% overall compared with a placebo ring. But efficacy rose to 56% for women older than 21. The Ring Study (IPM 027) yielded similar results. Adherence was higher in the follow-up open-label HOPE (MTN-025) and DREAM (IPM 032) trials, and the risk of HIV acquisition was reduced by around 40% to 60% compared with the expected rate if women did not have access to the ring. Studies suggest that effectiveness can reach 75% with optimal adherence.

More recently, the REACH study (MTN-034) randomly assigned 247 young women (ages 16 to 21) in South Africa, Uganda and Zimbabwe to use the vaginal ring or daily tenofovir disoproxil fumarate/emtricitabine PrEP pills (TDF/FTC; Truvada and generic equivalents) for six months. They then switched to the other method for another six months; for the final six months, they used the method of their choice. As reported at CROI 2022 and in The Lancet HIV, moderate product-related adverse events were more common with TDF/FTC compared with the ring (54 versus five events), but there were no serious events with either method. More than half (57%) of participants in both groups achieved high adherence. Four women acquired HIV, none of whom used their assigned method consistently. After using both methods, 67% chose the ring, 31% chose oral PrEP and 2% chose to use neither.

Earlier this year, researchers presented some of the first real-world data from Zimbabwe, showing that the chances of HIV acquisition were similar for women who used either the dapivirine ring or PrEP pills.

But the HIV prevention landscape has changed dramatically since the development of vaginal rings began nearly two decades ago. The Food and Drug Administration (FDA) approved TDF/FTC for PrEP in 2012. Another daily pill containing tenofovir alafenamide/emtricitabine (TAF/FTC; Descovy) followed in 2019. Long-acting injectable cabotegravir (Apretude), which is administered by a health care provider every other month, was approved in late 2021.

Daily TDF/FTC PrEP is now thought to be around 99% effective for gay and bisexual men and transgender women who use it consistently, though the pivotal iPrEx trial saw an overall efficacy of just 44%—within the same range as the vaginal ring studies. TDF/FTC was less effective for cisgender women in clinical trials, likely due to suboptimal adherence. TAF/FTC is also highly effective for gay and bi men and trans women, but, due to insufficient data, it is not yet approved for people exposed to HIV via vaginal sex. Injectable cabotegravir was found to be substantially more effective than PrEP pills for both gay and bi men and trans women and for young cisgender African women.

American Women Need More Options Too

As oral and injectable PrEP have raised the bar, vaginal rings and other topical microbicide products don't appear to be in the same league. For this reason, the International Partnership for Microbicides (IPM) withdrew the dapivirine ring from FDA consideration last year, after receiving feedback that current data are unlikely to support U.S. approval. (The ring and other IPM assets

were acquired by the Population Council in 2022.)

“IPM is disappointed that the HIV prevention portfolio in the United States will not include the monthly dapivirine ring as an option for women who cannot or choose not to use systemic PrEP but still need a way to reduce their risk,” the organization said in a statement at the time. “IPM, which developed the monthly dapivirine ring, remains dedicated to expanding women’s HIV prevention options and will continue its efforts to make the ring available to women in countries and communities where the need is greatest.”

Researchers and advocates stress that women need multiple HIV prevention tools—especially discreet options they can control themselves—as they now have for contraception. “The ring is very private,” Jeanne Marrazzo, MD, MPH, the new director of the National Institute of Allergy and Infectious Diseases, told NPR. “The male doesn’t necessarily even know it’s there.”

Some women find it difficult to take a PrEP pill every day, or they may not want to have pill bottles that could reveal they’re concerned about acquiring HIV, potentially subjecting them to stigma or even violence. Others, especially those in poor or rural areas, may not be able to attend a clinic for PrEP shots every two months.

“Because of economic disparities and uneven power dynamics within sexual partnerships, women and girls are often unable to negotiate safer sex or even choose when or with whom they have sex,” Diantha Pillay, of the Population Council’s South African affiliate, said in the recent announcement. “These factors also drive gender-based violence, which further increases women’s risk of HIV infection. Therefore, there is a need for comprehensive prevention strategies that include options that women control.”

In 2021, the World Health Organization recommended the dapivirine vaginal ring as one prevention method for women at substantial risk for HIV after a systematic review found that the benefits of the ring outweighed its harms. The European Medicines Agency has given a positive opinion on the ring for cisgender women ages 18 and older in high-prevalence countries, though it is not marketed in Europe.

While adolescent girls and young women in Africa face the greatest HIV burden, women in the United States also need new prevention options.

A decade after the FDA approval of TDF/FTC, PrEP has not reached its full potential. Although uptake of oral PrEP has been high (94%) among eligible white gay and bisexual men, it remains low for Black and Latino men (13% and 24%, respectively) and for women of all racial/ethnic groups (15%), according to the Centers for Disease Control and Prevention. Use of injectable PrEP lags overall, in part because it is more expensive and not yet widely covered by insurance, though that could soon change.

Research suggests that the dapivirine ring would be a welcome addition to the prevention tool kit for women in the United States. The MTN-023 study found that U.S. adolescent girls and women

under age 18 achieved good adherence, and more than 90% said they liked the ring and found it easy to use.

The HIV Prevention Choice Manifesto for Women and Girls in Africa, launched in September 2023 by a broad consortium supported by UNAIDS, underlines the need for choice in prevention methods and the importance of empowering communities to reduce women's risk. The manifesto asks policymakers, governments and donors to enable women to choose from an array of prevention tools and calls for research and development to add more options to the mix.

To that end, the Population Council is developing a longer duration dapivirine ring that can be used for three months, significantly lowering the annual cost and offering greater convenience, as well as combination antiretroviral and contraceptive rings. The organization expects development of the three-month ring to be completed in the next 12 to 18 months.

MATRIX, a project focused on developing innovative HIV prevention products for women, is working on a dapivirine-containing vaginal film that is designed to slowly dissolve over the course of a month. Some women may find it easier to insert and use than a ring. The MATRIX-002 study, launched last month in Kenya, South Africa, Zimbabwe and at the University of Pittsburgh in the United States, is evaluating the safety, acceptability and usability of two prototype films that do not contain the active drug. Results are expected by the end of 2024, and the first clinical trial of a dapivirine-containing film could start the following year. A dual-purpose antiviral and contraceptive film is also in development.

Another potential future option is a fast-dissolving insert containing tenofovir alafenamide and the integrase inhibitor elvitegravir (TAF/EVG). Developed by CONRAD, the bullet-shaped tablet is designed to be used as an "on demand" method around the time of sex. It could be an appealing option for people who have sex infrequently or for other reasons prefer not to use a daily or long-acting prevention method.

Laboratory and animal studies showed that the insert provided protection against both vaginal and rectal HIV exposure. Results from early human studies, presented at CROI 2023 and reported in Frontiers in Cellular and Infection Microbiology, look promising.

The recently launched MATRIX-001 trial, which aims to enroll 60 women in Kenya, South Africa and Norfolk, Virginia, in the United States, is evaluating multiple doses of the TAF/EVG insert or an inactive placebo insert. The participants will insert the first tablet at a study site with the guidance of clinic staff and thereafter will do so on their own, first once daily for three days and then every other day for two weeks. Results are expected in mid-2025.

"Existing methods aren't enough to meet women's varying needs and lifestyles," trial investigator Nelly Mugo, MBChB, MPH, of the Kenya Medical Research Institute, said in a news release. "A product that's intended to be used at the time of sex, like the fast-dissolving TAF/EVG vaginal insert, would fill an important gap as an alternative approach for women wanting protection only when they feel they need it."

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