



# Microbicides for HIV Prevention

## An Introductory Factsheet

July 2020

*This fact sheet provides basic information on microbicides, a category of products that could provide additional tools to reduce the risk of getting HIV. For more basic fact sheets in this series on emerging HIV prevention strategies visit [www.avac.org/intro](http://www.avac.org/intro).*

### What is a microbicide?

Microbicides in HIV prevention are products designed to be applied in the vagina and/or rectum to reduce the risk of getting HIV during sex. Their name means they kill microbes — in this case, HIV.

No microbicides are on the market yet, but one may be available soon. The European Medicines Agency has issued a positive opinion of the dapivirine vaginal ring, triggering the next steps in a regulatory process. Find more information on the ring at [prepwatch.org/nextgen-prep/dapivirine-vaginal-ring/](http://prepwatch.org/nextgen-prep/dapivirine-vaginal-ring/).

The ring resembles the vaginal ring that some women use for birth control. The dapivirine ring is inserted into the vagina. A woman can insert and remove the ring herself. The dapivirine ring is designed to be changed monthly for continuous protection against HIV. In studies, most women who used the ring said it was very comfortable, and they report their partners rarely felt it during sex.

The dapivirine ring could be provided by community health workers, as well as in clinics. See more details on the dapivirine ring further down.

Microbicides are also being developed in other forms. A vaginal film that looks like a small piece of thin plastic, smaller than a stick of gum, could be inserted right before sex. The film dissolves in the vagina and could provide on-the-spot protection from HIV.

Other microbicides being tested known as multi-purpose technologies, or MPTs, would protect women from both pregnancy and HIV. Still others are designed to offer protection during rectal sex. These may look and feel like the douches and lubricants that many people already use before or during anal sex. The goal is to make products for safe sex that also protect against HIV and are comfortable. The vaginal ring may be ready to go on the market soon, but these other products, if effective, would not be available for many years.

### Why do we need microbicides?

Some people prefer to have protection from HIV throughout their bodies all the time. This is called systemic protection because the drug spreads through your whole body. Oral PrEP is one kind of systemic protection. Vaccines (when we have one for HIV) would also be systemic. These whole-body methods are also useful to people who use injected drugs because they can protect you no matter how HIV enters your body.

### Resources and links

AVAC ([www.avac.org](http://www.avac.org))

CONRAD ([www.conrad.org](http://www.conrad.org))

International Partnership for  
Microbicides  
([www.IPMglobal.org](http://www.IPMglobal.org))

International Rectal  
Microbicide Advocates  
([www.rectalmicrobicides.org](http://www.rectalmicrobicides.org))

Microbicide Trials Network  
([www.mtnstopshiv.org](http://www.mtnstopshiv.org))

Population Council  
([www.popcouncil.org](http://www.popcouncil.org))



Other people may prefer to use topical methods that provide protection in just one part of the body. Microbicides are products made to stop HIV just in the vagina or just in the rectum. They provide protection during sex without affecting the rest of the body. Some people call them “user-controlled” or “user-initiated” methods because they do not have to be inserted or removed by a doctor or health care worker. They are made for people who want protection that they can apply themselves, just when they need it.

Lessons learned from family planning show the benefits of having a lot of choices to offer when people are looking for protection. For example, some women like long-acting birth control methods, such as IUDs (some call this the loop), injectable products (like Depo Provera or Net-EN), or implants. Other women prefer user-controlled methods like birth control pills or rings or a diaphragm. Some women may like one strategy for a time and then change their preferences when conditions in their life change. Research shows that when people can choose their birth control method, the rate of accidental pregnancies goes down. HIV prevention can work the same way. We need choices—like microbicides, PrEP and vaccines—so people can choose the HIV prevention method they prefer and that will meet their current needs.

### What is the status of vaginal microbicide research?

Scientists have challenges to overcome in microbicide research: How can we use anti-HIV drugs and other products in the vagina or rectum safely to stop HIV without hurting any fragile tissues, and provide protection at the place where infection happens? How can we make products that stop HIV from infecting someone but do not disturb anything else during sex? And how do we make microbicides that people like to use?

In 2010, scientists showed that a vaginal gel containing 1% tenofovir (an anti-HIV drug) reduced women’s risk of HIV when they used it correctly. But too many women in the studies didn’t use the gel, for various reasons, so it was dropped as a potential microbicide.

In 2016, the dapivirine vaginal ring, created by the International Partnership for Microbicides (IPM) was shown to work. IPM and the Microbicide Trials Network (MTN) did two related studies. They were large studies, conducted over a four-year period to test how well the ring worked. Over 4,500 women in Malawi, South Africa, Uganda and Zimbabwe volunteered to use the ring. They also came in for regular check-ups and reported on how they felt about using it. The studies showed that using the ring as instructed lowered women’s HIV risk by more than half (56%). Women over 21 years old were more likely than the younger women to leave the ring in place as instructed. Women over 21 showed much better rates of protection against HIV than did younger women in the study.

Since 2016, social and behavioral research has been done to explore what younger women think about the ring and what could make it more attractive to them. IPM and MTN are also doing trials now to test if the ring can be changed less frequently, every three months instead of monthly. They’re also designing rings for women who are pregnant, breast-feeding or menopausal. These trials are ongoing.

The ring is not short-acting, which makes it different from other the microbicides being created. But it is user-controlled because a woman can remove the ring any time she wants. And its effect is limited to the vagina, so it does not affect the whole body.

IPM submitted its first regulatory application for the ring to the European Medicines Agency (EMA) through a process called Article 58, which allows the EMA to deliver a scientific opinion on a product’s use in low- and middle-income countries, in cooperation with the WHO. EMA began reviewing the application in July 2018.

IPM also has plans to apply to the South African Healthcare Products Regulatory Authority (SAHPRA) and the US Food and Drug Administration (FDA) for approval. If approved, the vaginal ring will be the first microbicide to become publicly available.

### What is the status of rectal microbicide research?

In 2016, we also got the first results from a Phase 2 rectal microbicide study. Called MTN 017, it was an “open-label” trial (participants know exactly what product they are getting) comparing people’s responses to:

- (1) using a tenofovir gel inserted rectally with an applicator, on a daily basis
- (2) using the gel and applicator “on demand” (before and after sex only)
- (3) using oral PrEP pills only, with no gel

The 195 MSM and transgender women participants spent eight weeks in each of these three categories. All three approaches were found to be safe but participants clearly preferred #2—using the gel when they needed it for sex but not every day.

The MTN 017 participants also told the researchers that they wanted simpler methods, products more like the lubes, douches and enemas they already know. This feedback came from both trial participants and community consultations.

As a result, researchers started MTN 026 (called the Adonis study) in 2017. It is a Phase 1 safety trial to test dapivirine (an anti-HIV drug) in lubricant form as a possible rectal microbicide. It will test the product's safety and also explore how participants feel about applying it like a lube (with fingers and/or penis), rather than with an applicator. The big challenge is to find a method that feels natural and gets enough drug in the right place to provide protection from HIV. Other early-stage studies are testing other anti-HIV gels and douches for rectal use.

### What other candidate microbicides are under study?

Numerous candidates are in the early phases of development—see more at [www.avac.org/trials/microbicides](http://www.avac.org/trials/microbicides).

*See also the fact sheet on Multipurpose Prevention Technologies (MPTs) for more information about development of additional, dual-purpose HIV prevention options ([www.avac.org/MPT](http://www.avac.org/MPT)). For related ARV-based prevention research, see AVAC's resources on long-acting injectable ARVs and pre-exposure prophylaxis at [www.avac.org/prep](http://www.avac.org/prep).*

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**About AVAC** | AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of new HIV prevention options as part of a comprehensive response to the pandemic.