

Microbicides: What Do They Mean For Women?

What is a “microbicide”?

“Microbicide” (mī-KRO'-bi-sīd) just means anything that kills microbes (like bacteria and viruses). In connection with HIV prevention, a microbicide is any substance that can substantially reduce the risk of getting or transmitting sexually transmitted infections, including HIV, when it is inserted in the vagina or rectum. **No proven microbicides are on the market yet.** But several candidate products are in clinical trials and the search to find one that is both safe and effective is ongoing.

What will microbicides look like and how will they work?

Some of the microbicide candidates look just like over-the-counter vaginal products—the gels, foams, films, and suppositories that are already sold for birth control or to treat vaginal infections. The difference is that microbicides are designed to stop HIV, instead of treating infections or preventing pregnancy.

Scientists are also developing some new formulations that can be used without an applicator and that women will be able to leave in place for weeks. A hollow vaginal ring (similar to the NuvaRing® contraceptive device), for example, might release the microbicide slowly for up to a month and provide round-the-clock protection.

Almost all candidate microbicides being tested right now are made with antiretroviral drugs, (ARVs¹). These are the same types of drugs people who are HIV-positive use for treatment. They are re-formulated in lower doses as gels, films, etc. so they can be applied as a microbicide.

How effective would a microbicide be?

Male and female condoms are by far the most effective tools for preventing HIV infection when used consistently and correctly. But they often are not. Mathematical modelling² has shown that, if a woman uses a 50% effective microbicide at least 50% of the times she has sex, her risk of HIV would be lower overall than if her partner uses a condom only once in a while (for example if he uses it only two out of every ten times they have sex).

The effectiveness of a method is shaped by: (1) how effective the prevention tool is and (2) how often people use it. Less effective methods used regularly protect better than more effective methods used occasionally.

Microbicides will likely be much less effective than condoms (perhaps in the 40% - 60% range) on a “per sex act” basis. But people who do not use condoms every time—especially women whose partners often refuse condoms—could benefit from a microbicide that they could apply, themselves, every time they have sex.

Prevention tools are just one part of what is needed for women to protect themselves from HIV. More work must also be done on the structural issues that make it hard for women to insist on condoms in the first place—like not having the economic opportunities and social autonomy to make their own choices about sex.

When and how will microbicides be available?

When: Developing new drugs is a complicated process. It often takes more than a decade to find one that is both safe and effective. At each step along the way, potential products are dropped because they fail to meet the necessary standards. Only about one out of 100 original candidates make it to the final stages of testing.

¹ To learn more about how ARV-based microbicides fit into broader ARV-based prevention, see GCM's fact sheet on “ARV-Based Prevention, “What Does It Mean for Women” at <http://www.global-campaign.org>.

² “Mathematical modelling” is a scientific technique that uses various mathematical structures to represent real world situations and analyse them. A description of how this model on women's HIV risk works is available at http://journals.lww.com/aidsonline/Fulltext/2003/05230/Shifts_in_condom_use_following_microbicide.15.aspx#

The trial results of a candidate microbicide called tenofovir will be announced in 2010. If the trial shows that tenofovir gel is effective, it will likely take another larger trial to confirm the product is effective. The current trial is a phase IIB, and regulators may require a phase III trial to confirm the results. Even after a successful phase III trial, it could take two to three years for the product to be reviewed and licensed in countries where it would be first introduced. Several candidates are already in the testing pipeline but have not yet progressed to full-scale effectiveness trials.

How: How a microbicide is made available will depend partly on whether it is ARV-based or non-ARV-based. ARV-based microbicides are likely to be more potent against HIV and may be longer-lasting. But they also might cause more side effects, including a particular problem called drug resistance³, if they are accidentally used by someone who is HIV-positive already. For this reason, women will have to see a health care provider and get an HIV test before receiving these products. They will only be available by prescription.

Non-ARV-based microbicides may be less effective against HIV than ARV-based products. And they may have to be used closer to the time of sex (likely within a few hours) because they may be harder to put into time-released devices like vaginal rings. But it is likely that non-ARV-based microbicides could be available over-the-counter in shops, without a prescription. Each type of product has advantages and disadvantages.

What could microbicides mean for women?

The possibility of a microbicide offers real hope to women who want to have their own HIV prevention tools, as well as to both women and men who have anal sex and want additional methods of protection.

Many women participating in microbicide trials have said that they would probably tell a male partner if they were using something for HIV prevention—even if the method is not as obvious to him as condoms. But, unlike male and female condoms, microbicide use wouldn't require a partner's active cooperation. Talking about microbicides could be a one time conversation and does not have to happen right before sex. After that, the woman could use them on her own without need to "negotiate" or interrupt sexual spontaneity every time.

Here are some other questions women have raised about microbicides:

- ***"If my man knows I am using microbicides to prevent HIV, will he still use condoms?"*** His refusal to use one could *raise* her risk, even if she has a microbicide. On the other hand, women in some microbicide trials report that using a lubricating gel along with condoms makes sex more pleasurable for both partners. Some say this actually makes negotiation for condom use easier for them (that is they can say to their partners "I will use the gel if you use the condom").
- ***"What will people say about me if they find out I'm using a microbicide?"*** Even if she is at high HIV risk, a woman may choose not to use a microbicide if she fears that doing so will make people will think she is promiscuous. So messages to promote them must steer around this kind of stigma.
- ***"How much will it cost and where will I get it?"*** In many countries, it will be essential for governments and development agencies to purchase microbicides in bulk and distribute them through public health agencies and social marketers at little or no cost. No matter how well it works, a microbicide that costs much more than a male condom will not be within reach of all women who need it.

What are the advocacy issues?

Collectively, we need to advocate for stronger support for the research and development of both ARV-based and non-ARV-based microbicides. We also need much more data on some important questions, such as how these products will affect pregnancy, breast-feeding, and the lives of women already living with HIV. Most importantly, we need to start addressing the cost and access issues now while research is still underway. Those who will eventually use microbicides must be involved in setting research priorities and helping to find answers to these questions. After all, microbicides are all about putting HIV prevention into women's hands.

³ To learn more about this, see GCM's fact sheet, "Understanding Drug Resistance", available at [http://www.global-campaign.org/clientfiles/FS-DrugResistance\[E\].pdf](http://www.global-campaign.org/clientfiles/FS-DrugResistance[E].pdf).