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Microbicides [1]

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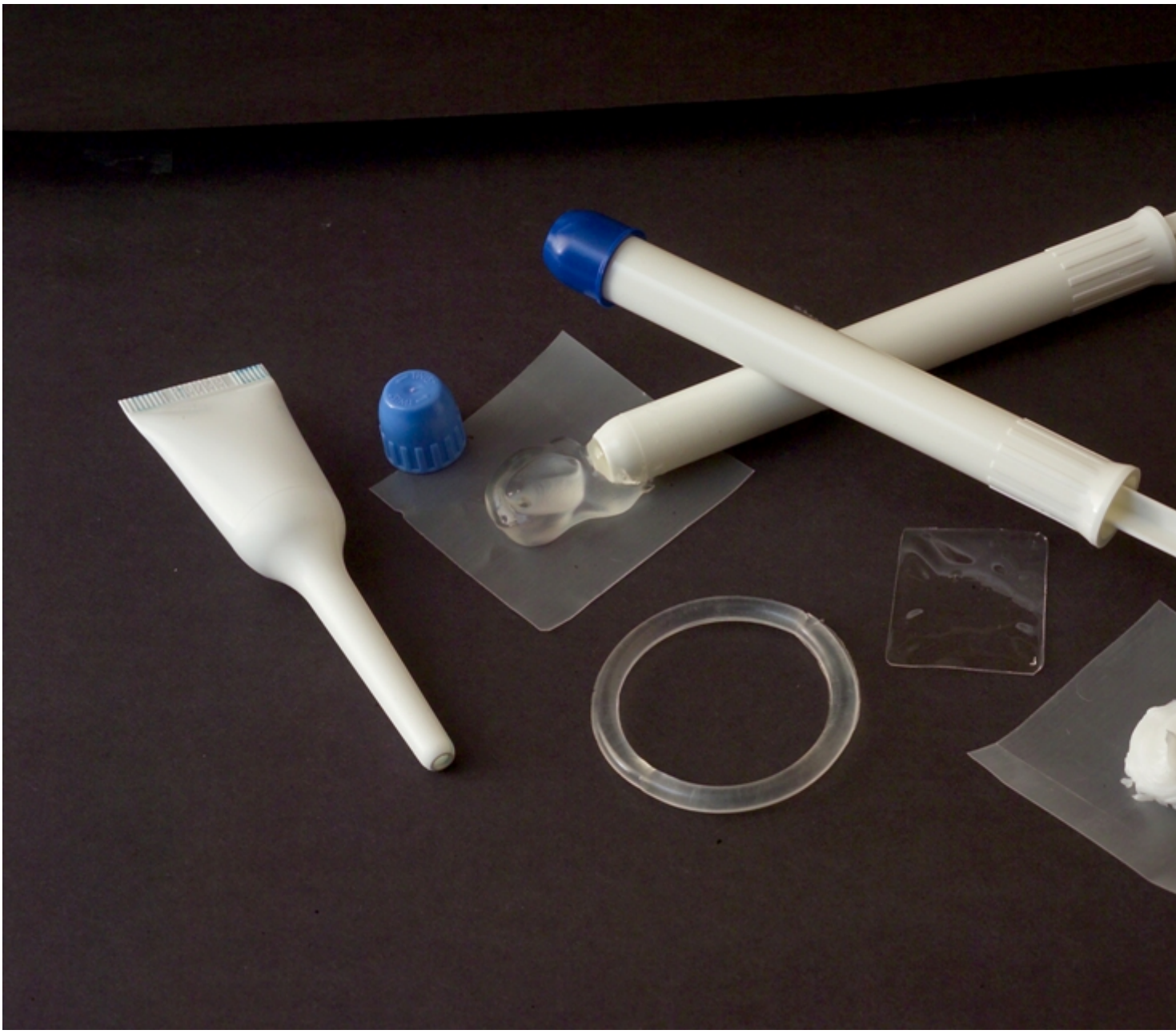

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What are microbicides?

Microbicides are products being developed to reduce the spread of HIV and other sexually transmitted infections or diseases (STIs or STDs) [2]. Microbicides could come in many forms, including gels, creams, suppositories, films, lubricants, sponges, or vaginal rings. They could be used in the vagina or rectum.

How would microbicides work?

Microbicides could work in different ways:

1. Killing germs such as bacteria and viruses or making them inactive
2. Changing the condition of the vagina or rectum to make infection less likely
3. Blocking infection by creating a barrier between the germ and the cells of the vagina or rectum
4. Preventing the germ from spreading after it has entered the body

Are microbicides currently available?

No. Scientists are testing many products to see whether they help protect against infection with HIV and/or other sexually transmitted infections. Some of these products have proven safe enough in lab studies that they are now being tested in people. However, no safe and effective microbicide is currently available to the public.

What is happening in microbicide research?

Microbicides have been in development for more than 15 years. A number of studies conducted on the early products failed to find an effective microbicide. However, there is hope that a new group of microbicides that contain HIV drugs will be more effective. These microbicides come in several different forms ? gels, rings, films ? and may serve as

multipurpose prevention technologies (MPTs), which address two or more sexual health issues at one time (e.g., HIV and pregnancy [3]).

Vaginal Rings

There is also hope that vaginal rings containing HIV drugs can prevent the spread of HIV. The ring is flexible and can be inserted by the woman herself deep inside the vagina against the cervix (entrance to the womb). The ring is comfortable and rarely felt by the woman herself or her sexual partner(s). It needs to be replaced once every one to two months. This is different from vaginal gels, which need to be inserted directly before or at the time of a sexual act. Women are in control of the use of both rings and gels. However, with the ring, women do not need to plan for sex, which can allow sex to be more spontaneous.

One of the largest announcements at the 2016 Conference on Retroviruses and Opportunistic Infections [4] involved results from two studies that looked at the effectiveness of an intravaginal dapivirine-containing ring. The two studies ? the ASPIRE study and The Ring Study ? enrolled more than 4,500 HIV-negative women in South Africa, Uganda, Malawi, and Zimbabwe ages 18 to 45 years. They shared a very similar design, which assigned half of participants to receive a ring containing the study drug - dapivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI [5]) - and half to receive a ring containing no dapivirine (the placebo). The rings were inserted into the vagina every month for two years.

Both studies showed a modest reduction in HIV infection among women who used the dapivirine ring. The trials were also similar in that younger women saw little or no benefit from using the ring. The difference in effectiveness in age groups has to do with adherence [6]. Younger women were less adherent in using the ring, and consequently saw less protective benefit. Interestingly, adherence increased over time, suggesting that women may have needed some time to become familiar with the new technology.

As a result, researchers are now conducting open-label extensions on The Ring and ASPIRE studies. These extension trials are designed to gather information about how the ring works for women who are aware of its potential benefit and may shed some light on challenges with adherence.

Vaginal and Rectal Gels

Promising results were reported a few years ago from a study of HIV-negative women in South Africa. It showed that when women used a one percent gel version of the HIV drug Viread (tenofovir) inside the vagina, two out of every five HIV infections were prevented. These study results provide early proof that HIV drug-based microbicides, in particular tenofovir gel, can help protect women against HIV.

Unfortunately, a similar study of tenofovir one percent vaginal gel among more than 5,000 HIV-negative women in Uganda, South Africa, and Zimbabwe was not successful. This study, called the VOICE study (MTN 003), was stopped in the fall of 2011 because it did not work to prevent HIV infections. The gel did not work largely because women did not use it as directed. However, the tenofovir gel appeared to be safe, without major side effects [7]. While it is encouraging that tenofovir-containing gels appear effective when used as directed, researchers will be shifting their focus to understanding why so few women choose to use these gels so that more acceptable and effective prevention methods can be identified.

Researchers also tested a version of tenofovir gel designed for rectal use. This study (MTN 017) explored the safety and acceptance of the rectal gel in transgender women and men who have sex with men in Peru, South Africa, Thailand, and the US. It found that the rectal gel was safe and well-tolerated, and that participants were highly adherent overall. Adherence was higher among those who used the product before and after sex compared to those who used it on a daily basis.

Rectal gels containing dapivirine and maraviroc are currently in development and under investigation. Scientists are also studying vaginal gels containing dapivirine, dapivirine plus maraviroc, and dapivirine plus darunavir.

Vaginal Films

Scientists in the FAME-02 study found that a vaginal film containing dapivirine delivered enough drug to vaginal tissue to prevent HIV infection when tested in the laboratory. Study of a vaginal film containing dapivirine is ongoing.

Multipurpose Prevention Technologies

MPTs provide ways of preventing more than one thing in one device. For example, MPTs may prevent pregnancy and HIV, or they may prevent HIV and several other STIs. Having methods that combine prevention of pregnancy and STIs (including HIV) would be more convenient, and likely lead to more consistent and therefore more effective use.

Researchers are studying several methods for combining prevention technologies, including a vaginal ring containing both a hormonal contraceptive (to prevent pregnancy) and an HIV drug (to prevent HIV; a form of Pre-Exposure Prophylaxis, or PrEP [8]). It can be inserted well before sex, stay there for up to three months, and is not usually felt by either partner. Vaginal gels that may prevent pregnancy and HIV are also under investigation.

Would microbicides eliminate the need for condoms?

No. When used consistently and correctly, male or female condoms are likely to provide better protection against HIV and other STIs than microbicides, so they are still the best choice. But for people who do not have access to condoms, or who cannot or will not use condoms, microbicides would provide another option. This is especially true for women whose male partners refuse to use condoms [9]. Microbicides could be used without the knowledge of women's sexual partners, thereby putting the power of prevention directly in women's hands. Using microbicides could save lives and have a major impact in reducing the spread of HIV.

Would microbicides protect against all sexually transmitted infections?

Many of the microbicides being tested work against HIV. In time, a product may be developed that combines different microbicides and could prevent a wide range of STIs, including HIV (see multipurpose prevention technologies, or MPTs, above).

What if a woman wants to get pregnant?

Many of the microbicides being studied would allow a woman to get pregnant. These are called non-contraceptive microbicides. They would offer women the option of getting pregnant while still protecting themselves from infection ? an option that is not available with condom use. The tenofovir one percent gel tested in the CAPRISA 004 study and mentioned above is one example of a non-contraceptive microbicide. Contraceptive microbicides or MPTs would prevent pregnancy as well as HIV and, ideally, other STIs. It is important to have both types available.

Would microbicides be safe?

Any new product must go through strict safety testing before becoming available to the public. Health activists and researchers are closely watching over the clinical testing of microbicides to make sure that the testing is being done correctly.

How would microbicides benefit men?

It is possible that the male partner of a woman living with HIV might be protected from infection if she used a vaginal or rectal microbicide. However, this would need to be tested in clinical trials [10]. The safety and effectiveness of vaginal microbicides must be tested separately from rectal microbicides.

How would microbicides benefit women with HIV?

Microbicides could help protect women living with HIV from re-infection with other HIV strains, from other STIs, and from pregnancy.

Why do we need microbicides if we will eventually have a vaccine to prevent HIV?

Research on developing a vaccine [11] to prevent HIV infection has not been successful so far. Microbicides may be available sooner than a preventive HIV vaccine. Even if a safe and effective vaccine is discovered, vaccines and microbicides will both have roles to play in the prevention of HIV.

How much will microbicides cost, and will people be able to afford them?

Advocates are working with researchers and policy makers to make sure that any approved microbicide will be as affordable and accessible as possible.

What about Nonoxynol-9 (N-9)?

N-9 products are sold over the counter as spermicides that can prevent pregnancy. They cannot prevent the transmission of HIV or other infections. In fact, when used more than once a day, N-9 contraceptive products may actually increase HIV risk by irritating the lining of the vagina. Other studies show that N-9 is even more irritating to the rectum than to the vagina.

According to the World Health Organization (WHO):

- N-9 is not effective at preventing the transmission of HIV or other STIs. It should NOT be used for disease prevention.
- Women at risk for HIV, especially those having sex more than once a day, should NOT use N-9 for birth control [12].
- Condoms with N-9 provide no more protection against pregnancy or infection than plain lubricated condoms. Since N-9 condoms may cause irritation, they should not be used.
- Products with N-9 should NEVER be used for anal sex.

Taking care of yourself

Until microbicides are available, the best way to protect yourself and your partner from sexually transmitted infections, including HIV, is to use a male or female condom [9] and use PrEP for the HIV-negative partner. It is also important to avoid the use of nonoxynol-9 products if you think there is any chance you may be exposed to HIV. Getting tested for STIs regularly and getting treatment quickly if you have an STI will also help reduce your risk of HIV infection if you are exposed to HIV.

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Additional Resources

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Multipurpose Prevention Technologies (WHO) [31]
Why Microbicides? (IPM) [32]
Microbicides: The Basics (AVAC) [33]
Microbicide Trials Network (MTN) [34]
NIAID Research on Microbicides (NIH) [35]
Microbicides (AIDS InfoNet) [36]
Vaginal Rings Containing Antiretroviral Moderately Effective in Preventing HIV ? But Not in the Youngest Women (AIDSmap) [37]
Move On Down the Road: The Dapivirine Ring Will Enter Open-Label Extension Trial (AVAC) [38]
'On-Demand' Rectal Microbicide Gel Has Reasonable Tolerability and Acceptability (AIDSmap) [39]
Microbicides to Block Transmission of HIV (NIAID; NIH) [40]
Microbicides (AIDS.gov) [41]
Multipurpose Prevention Technologies (AVAC) [42]

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[37] http://www.aidsmap.com/Vaginal-rings-containing-antiretroviral-moderately-effective-in-preventing-HIV-but-not-in-the-youngest-women/page/3037926/
[38] http://www.avac.org/blog/move-down-road
[39] http://www.aidsmap.com/On-demand-rectal-microbicide-gel-has-reasonable-tolerability-and-acceptability-daily-less-so/page/3040354/
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