



What You Need to Know Microbicides: Prevention of HIV/AIDS, STIs, and Unintended Pregnancy



Microbicides are gels, creams, films, suppositories, and other products that reduce the risk of transmission of HIV/AIDS and/or sexually transmitted infections (STIs); some will also help prevent unintended pregnancy. More than fifty products are in various stages of development. While no microbicide products are currently on the market, they have the potential to allow millions of women around the world to more easily protect themselves from infection and pregnancy.

Patients seeking reproductive health services are often in need of dual protection from both STIs and unintended pregnancy. Although women are able to control their fertility through a variety of contraceptive methods, the condom is currently the only option available to women to protect themselves against infections. Microbicides could be applied in advance of sexual activity, and without the active involvement or even knowledge of the male partner.¹ When microbicides become available in the United States, providers will play a key role in counseling patients on this new technology and its potential to allow women to protect themselves against infection.

Overview of Microbicides

A microbicide is a substance that can significantly reduce transmission of HIV and/or viral, bacterial, fungal, or protozoan sexually transmitted pathogens when applied topically to genital mucosal surfaces. A microbicide could be produced in many forms, including gels, creams, suppositories, films, lubricants, or a sponge or vaginal ring that slowly releases the active ingredient. Microbicides can be contraceptive or non-contraceptive in functionality.

Mechanisms of Action

Most microbicides under development act through several possible mechanisms. Some are specific to HIV, others are not.

- Non-specific:
 - Blocking entry of the virus
 - Inactivating pathogen by breaking down its surface or envelope
 - Boosting the vagina's natural defenses
- Specific to HIV:
 - Inhibiting entry/fusion or replication

Current Status of Development

As of June 2008, 11 candidate microbicides were in clinical trials, three of which were in Phase II/IIB or III

trials,² with 50 additional products in preclinical testing.³ Results from current effectiveness trials could become available in 2009, but it will take additional time for the products to be reviewed and approved for licensure – at least 1-2 years. Thus, a microbicide could be ready for introduction in the next five years, but that would only be in a few countries, most likely through smaller scale introductory programs.

In 2007, the Phase III microbicide trial of cellulose sulfate was halted for concerns about safety.⁴ In February 2008, the results of the first Phase III trial of a candidate microbicide, Carraguard, were released. Although the trial demonstrated that Carraguard was safe for vaginal use, it provided no evidence of a protective effect.⁵ Research on rectal microbicides is not as far along as research for vaginal microbicides due to both political and scientific challenges, but preclinical and early safety testing are under way.

Preparing for Microbicide Access and Use

The face of AIDS is increasingly female, and the pandemic is having a disproportionate impact on communities of color. In the most recently available U.S. data from 2003, AIDS was the third leading cause of death among young African-American women aged 25–34 and the fourth leading cause of death for Hispanic women aged 35–44.⁶ Black women accounted for two thirds (66%) of new AIDS cases among women in 2005.⁷

The effects of microbicides on HIV infection rates will depend largely on the extent of their use. Modeling suggests that if a microbicide is used by 20 percent of women in 73 developing countries, even a microbicide that is only 60 percent effective against HIV could avert up to 2.5 million HIV infections over three years.⁸ Health care

Microbicides and HIV-Positive Patients

- By neutralizing pathogens in both semen and vaginal secretions, some microbicides may offer bi-directional protection for both partners.
- Some products may also be able to reduce a woman's risk of getting other STIs, bladder infection or yeast infections.
- Non-contraceptive microbicides could one day allow a sero-discordant couple to have children with less risk of sexual transmission.

providers will play an important role in determining the number of women who have information about and access to microbicides once they become available.

Health care providers need to be involved now in planning for how microbicides and other new prevention options, like vaccines, will be presented to the public in a way that doesn't discourage people from using condoms.

Acceptability of Microbicides

A nationally representative survey of 1,000 sexually active US women aged 18–44 found that an estimated 21.3 million US women have some potential current interest in using microbicides. These women are likely to be unmarried and of low income and less education, and are also more likely to have visited a doctor for infection symptoms.⁹ Growing evidence shows that:

- Individual women within and across cultures express different preferences for product formulation and other characteristics.
- Safety and effectiveness are regarded as most important.
- Primary concerns among women and men are about long-term side effects.
- Excessive “messiness” is a deterrent to use.
- Effect on sexual pleasure is an important consideration, with significant implications for product positioning, promotion, and marketing.

Use of Condoms

Scientists do not know exactly how effective microbicides will be. In order to be approved by drug regulators and accepted by policy makers, it is likely that microbicides would have to reduce risk of HIV by at least 40-50 percent. Although condoms provide the best form of protection for people who are sexually active, using a microbicide will be much safer than nothing for women for whom condom use is unlikely or impossible.

For some women and men, the contraceptive effect of condoms is a major deterrent to use; developing both contraceptive and non-contraceptive microbicides is important. Providers can counsel patients on the use of microbicides in conjunction with condoms for added protection, and as a “backup” method when condom use cannot or does not occur.

What Can You Do?

As a health care provider, you can help ensure that microbicides will be an option in the future.

1. Learn more

- Check out the latest news and advocacy updates from the Global Campaign for Microbicides and sign up for a free electronic newsletter at www.global-campaign.org.

- Find out about specific studies and sign up for a free electronic newsletter at the Alliance for Microbicide Development's Web site at www.microbicide.org.
- The Global Campaign for Microbicides offers a new online course, *Microbicides Essentials*. Users are able to earn continuing education credits, including CME. Check it out at www.hivpreventionresearch.org.

2. Advocate for microbicide research and development funding

- Write to your senators and representative by visiting www.global-campaign.org/legislativeadvocacy.htm.

3. Spread the word

- Host a talk about microbicides; presentations are available at the Global Campaign Web site.
- Share this microbicides information with colleagues.

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The Association of Reproductive Health Professionals (ARHP) is a multidisciplinary association composed of professionals who provide reproductive health services or education, conduct reproductive health research, or influence reproductive health policy. Founded in 1963, ARHP's mission is to educate health care professionals, public policy makers, and the public. The organization fosters research and advocacy to promote reproductive health. www.arhp.org

The Global Campaign for Microbicides is a unifying umbrella for activism to build support among policymakers, opinion leaders, and the general public for the ethical development of and increased investment in microbicides and other user-controlled HIV and STD prevention options. Through the shared commitment and collective agenda of its 300 endorsing groups worldwide, the GCM amplifies the voices of advocates by equipping them with a growing body of free resources and materials, supporting their efforts through sub-grants and offering guidance for effective awareness-raising, media cultivation and lobbying strategies. www.global-campaign.org