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Microbicides

Today, women represent the fastest growing group of new HIV infections internationally. 6,300 women worldwide become infected with HIV everyday. In the U.S., the Centers for Disease Control and Prevention (CDC) estimates that as many as 160,000 women are living with HIV. Consistent and correct use of a condom is the most effective method to prevent sexual transmission of HIV and other sexually transmitted diseases (STDs). Cultural, social and political norms can make condom use impractical or impossible, especially when a woman attempts to initiate the use of a condom. The inability to convince a male partner to utilize condoms places women at an increased risk for HIV infection, other sexually transmitted diseases or an unplanned pregnancy. Consequently, alternative methods of female-controlled protection are needed.

Effective microbicides will allow women to protect themselves from becoming infected with HIV or other STDs. Roughly three out of every four new HIV infections among women are related to heterosexual sex. Transmission of HIV from men to women during male-female sexual contact is more likely to occur than transmission from women to men. Additionally, men who have sex with women who also engage in high-risk behaviors can place women at further risk. Women who believe they are in a monogamous relationship may become infected with HIV as a result of their partner's risky sexual or substance using behavior. If a woman is unaware or misled about the sexual or injection drug use behaviors of her partner, she may not feel the need, and subsequently not require, her partner to use condoms during sex. Subsequently, long-term relationships and marriages are not protection against HIV infection.

Gay men and other men who have sex with men could use a microbicide as well. In addition to the rapid increase in HIV infection among women, men who have sex with men continue to be disproportionately infected with HIV. For many gay

men, the constant pressure to use condoms consistently is becoming more challenging. Additionally, many younger men who have sex with men and did not witness the peak of the AIDS epidemic in the gay community in the 1980's and early 1990's are less likely to use condoms consistently. Condoms are the most effective method of HIV prevention; however, microbicides could be used as a secondary HIV prevention method.

What are Microbicides?

A microbicide is a substance that prevents the transmission of diseases. Microbicides work by killing or disabling a germ or virus. Microbicides can be administered via a gel, cream, suppository, film, sponge, wipe, and vaginal or rectal ring. To date there are no microbicide products that prevent HIV or STDs.

Microbicides that prevent HIV or STDs could be used without a condom or with a condom as extra protection. While microbicides may never be as effective as consistent and correct condom usage for HIV prevention, they may provide a prevention method for people who use condoms inconsistently or do not control the decision to use condoms.

There are different forms and applications that microbicides may take, and there are also different ways in which a microbicide can work. One way a microbicide can work is by killing the bacteria or virus. Alternatively, a microbicide may prevent the replication of the virus or bacteria after infection has occurred. A microbicide could also use the barrier method by serving as an "invisible condom" applied to the vagina or rectum to block infection by bacteria or a virus. A microbicide could enhance the vaginal environment in order to optimize the inherent capacity of the female reproductive tract to protect itself from foreign substances.

Risk Factors

Microbicides could reduce the risk of transmission of HIV and other sexually transmitted diseases by providing women and gay men with alternatives to condoms. An ideal microbicide could be applied up to several hours before sex without a partner's knowledge, reducing or eliminating the need for condoms. Prior application of a microbicide would allow for individuals to anticipate sexual activity and lessen the probability of decision-making in haste or under the influence of alcohol or other substances. Microbicides could give people an opportunity to protect themselves against HIV and STDs proactively.

Women who could face the fear of reprisal or abuse for asking their sexual partner to wear a condom could use a microbicide unbeknownst to their partner. Additionally, studies indicate higher rates of consistency and effectiveness when a woman is in control of contraception and/or HIV prevention methods. Researchers believe that microbicides would be used consistently by women (given the history of women's use of contraceptive devices such as the birth control pill) because they would not be dependent on their partners.

Research and Resources

Currently, there are roughly 60 microbicide products and compounds under investigation in small biopharmaceutical companies, nonprofit organizations and smaller public companies. A barrier to microbicide research and development is the lack of interest and investment by large pharmaceutical companies. Larger companies are not interested because "first generation" microbicides may not be highly profitable. The United States government currently invests \$23 million a year in microbicide research, equivalent to one percent of the total AIDS research budget. This funding is primarily distributed internationally.

Given the ongoing microbicide research, there probably will not be any microbial products available to consumers for several years. Microbicides, like any new product or treatment, must demonstrate successful clinical trials prior to approval by the Food and Drug Administration.

The general public is unaware of the existing research on microbicides and the potential they have for HIV prevention. People, especially women, need to become familiar with the concept of microbicides so they can encourage the development of microbicides as an additional health promotion strategy. Public awareness is needed to support and promote the research and development of microbicides.

Ideal microbicides would include a microbicide that would prevent the transmission of HIV and other STDs while still allowing a woman to become pregnant, balanced with microbicides that will prevent pregnancy as well as HIV and STDs. Numerous acceptability studies have been conducted internationally and have found that an ideal microbicide would be purchased over the counter, effective when applied several hours before sexual intercourse, could be used several times a day, and would be fast acting, odorless, colorless and tasteless. The majority of women surveyed showed interest in a microbicide that would provide protection against sexually transmitted diseases and HIV.

Conclusion

The Microbicide Development Act of 2002, pending in the U.S. Congress, intends to encourage the development of microbicides and provide funding for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to expand and coordinate microbicide research activities. The proposed legislation also requires a report to Congress and requires both NIH and CDC to coordinate with other federal agencies working on microbicides research. Finally, the Microbicide Development Act authorizes the appropriation of necessary funding to support microbicide research for the next two years.

Microbicides are a promising venue for HIV prevention, especially for women and gay men. Without a vaccine or a cure for HIV/AIDS, HIV prevention remains the most effective defense against AIDS. In order to fight the epidemic, decrease the number of new HIV infections and save lives, time and money must be invested. Currently, available protection methods are not equally available to both men and women. Microbicides can bridge the gender gap and help women protect themselves.