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Women-Controlled Methods for Preventing HIV other Sexually Transmitted Infections

"If the carnage of this pandemic has taught us anything, it's the terrifying vulnerability of women. I feel I must say that the greatest single international failure in the response to HIV/AIDS, is the failure to intervene, dramatically, on behalf of women."

- Stephen Lewis, United Nations Special Envoy for HIV/AIDS in Africa at the Third International Aids Society Conference, Rio de Janeiro, Brazil, July 2005

By Julia Matthews, MPH Project Manager | Ibis Reproductive Health

he HIV epidemic is affecting women and girls in increasing numbers. In sub-Saharan Africa, where nearly two-thirds of HIV-infected people live, women are more than 1.3 times more likely to be infected than men. Young women between the ages of 15 and 24 are at even greater risk. They are three times more likely to be infected than young men in this age group and make up approximately three-quarters of young people who are HIV-positive in sub-Saharan Africa. These startling statistics highlight the immense need for female-controlled methods of preventing HIV, including the female condom, microbicides and the diaphragm.

AN EXISTING METHOD: THE FEMALE CONDOM

The female condom is the only woman-initiated method that is known to be safe and effective in reducing the risk of pregnancy and the transmission of sexually transmitted infections (STIs). In addition, laboratory studies have demonstrated that the female condom blocks the passage of microorganisms, including HIV. The design of the female condom offers more protection to women than the male condom because the outer ring partially covers the external genitalia. The female condom also covers the vaginal area, which may offer more protection than the diaphragm, the sponge or the cervical cap which only cover the cervix. Studies in a variety of countries and cultures show that 50 to 93 percent of male and female participants found the female condom to be acceptable. For example, three-quarters of U.S. and Latin American women participating in a six-month contraception study stated that they liked the female condom

and half said they would continue using it.³ The most common complaints about the female condom – aesthetics, difficulty to insert and noise – typically fade with repeated use. However, new condoms are being developed that address these concerns and may also be less expensive.

NEW METHODS BEING TESTED: MICROBICIDES

Microbicides are a promising woman-controlled method currently under development. Microbicides are substances designed to reduce transmission of HIV and/or other STIs when applied vaginally and will likely come in a variety of forms including gels, creams, films, suppositories or vaginal rings. Microbicides generally work through one or more of the following ways by: I) boosting the body's natural defenses against infection; 2) damaging the surface membranes of pathogens (infectious agents) rendering them ineffective; 3) binding to a pathogen or healthy cell before they are invaded by an infectious agent; and/or 4) preventing viruses from replicating in a cell.

Currently, there are more than 60 substances that are being studied as possible microbicides. Because of their different modes of actions, some microbicides will reduce the risk of pregnancy and STIs, including HIV, while others will only prevent infection. Therefore, women who want to conceive would be able to protect themselves from disease. Five microbicides are currently in Phase III trials, the final stage of testing, which will determine how much they reduce the risk of HIV infection and how safe they are for long-term use. Continued progress in these trials means a microbicide may be available within the next five to seven years.

It is estimated that the first microbicides will be 50-60 percent effective in preventing HIV – much lower than the 90-95 percent effectiveness rate of male condoms. However, microbicides offer an important alternative in those situations when male condom use is impossible. For example, if only 20 percent of people at risk of HIV use a microbicide that is 60 percent effective in

protecting against HIV transmission, 2.5 million infections could be averted over three years. More than 60 studies have been conducted in developed and developing countries to determine the characteristics of an acceptable microbicide. Generally, findings show that interest in microbicides is higher in areas where women perceive their HIV risk to be greater. In addition, these studies indicate the need for a variety of products to meet the range of demands of a diverse consumer population.

AN OLD METHOD WITH NEW POTENTIAL: THE DIAPHRAGM

For thousands of years, women have used various forms of cervical barriers for reproductive health purposes. Women in ancient times used crocodile dung, lemon halves and beeswax plugs to prevent pregnancy. Developed in the late 19th century and widely used in the 1930s, today's contraceptive diaphragms are made of latex or silicone and are up to 94 percent effective at preventing pregnancy when used with a spermicide.

Globally, a small percentage of women using contraception choose the diaphragm. However, studies in the last decade show that despite low usage rates, it is a very acceptable form of contraception for women in a range of countries. Research conducted by Bulut et al. in Colombia, Turkey and the Philippines revealed that women liked the diaphragm because it was safe and free from side effects and because it was woman-controlled. For example, a focus group participant stated:, "I like it because I can manipulate it. I do not need to ask my husband. I am responsible."

This finding is supported by another study from Madras, India, which demonstrated that participants were motivated to use the diaphragm and capable of overcoming challenges such as lack of privacy and lack of support from their husbands. Women valued the diaphragm most for the absence of negative health consequences they had experienced with the pill and intrauterine device (IUD) including abdominal pain, nausea and headaches. New research is now re-examining the diaphragm

as a potential alternative for women to protect themselves from HIV and STIs for several reasons. First, recent evidence suggests that the surface of the cervix contains a high concentration of HIV-susceptible cells, resulting in a heightened vulnerability to HIV infection. Second, compared to the thicker cell lining of the vagina, the cervix is more fragile, covered only by a single layer of delicate cells. Thus, it is biologically more vulnerable to trauma, and therefore STI/HIV infection, than other areas of the reproductive system. Third, research shows that the cervix is the preferential infection site for many STIs, and the presence of STIs increases HIV transmission risk and vice versa. Finally, by shielding the cervix, the diaphragm may also reduce the transmission of STIs/HIV in the upper genital tract (uterus, fallopian tubes and ovaries).

In addition, several observational studies have demonstrated that use of the diaphragm is associated with a reduced risk of STIs and other long-term effects. For example, three studies showed that diaphragm users had a reduced risk of contracting gonorrhea compared to women who did not use the diaphragm. Two other research studies indicated a reduced risk of pelvic inflammatory disease (a consequence of STIs) in diaphragm users as compared to non-users. However, because the purpose of these studies was not to test the efficacy of the diaphragm for STI prevention, and none were randomized controlled trials, research directly examining this question must first be conducted. Also, in these previous studies, diaphragms were used with the spermicide Nonoxynol-9, which is no longer recommended for women at risk for HIV, because it was found to increase susceptibility to infection. Therefore, more data on diaphragms – whether used alone or in combination with a microbicide – is needed.

ATTITUDES TOWARD THE DIAPHRAGM AT FOLLOW-UP AMONG USERS

Variable	Percent at 6-month visit
Participant likes diaphram or condom	
better	
Diaphram	53.5
Condom	33.3
No preference	13.2
Participant finds diaphram or condom	
easier to use	
Diaphram	52.9
Condom	36.2
No preference	10.9
Partner knows when participant uses	
the diaphram	
Diaphram	10.9
Condom	63.8
No preference	24.7
Table modified from van der Straten, A et al., 2005.	

Before embarking on an effectiveness trial, a first step was to examine the acceptability of the diaphragm as a potential STI/HIV prevention method. In a recent study in Zimbabwe among 189 women ages 16-46 who were inconsistent condom users, the diaphragm in combination with KY jelly was well accepted. Uptake was high, with 98 percent using the method at least once during the first two months. ¹⁰ Findings (see table above) also showed that women who said the diaphragm was easier to use than condoms were three times more likely to be consistent diaphragm users. Women whose partner never knew when they used the diaphragm or whose partners always

knew when they used the diaphragm were more likely to be consistent users than women whose partners sometimes knew. Thus, a woman's ability to use her diaphragm discreetly or secretly (measured by her partner not knowing when she used the diaphragm) or completely openly was strongly associated with her consistent use of the method.

With the confidence that women are willing to use a diaphragm in a high HIV prevalence area, the University of California San Francisco (UCSF) is currently conducting a Phase III trial to investigate whether the diaphragm used with a lubricant gel could protect women against STIs/HIV. The study, *Methods for Improving Reproductive Health in Africa (MIRA)*, began in 2003 and is being conducted in South Africa and Zimbabwe. Enrollment is nearly complete and results are expected in 2007.

In collaboration with the MIRA partners, Ibis Reproductive Health is leading the effort to build awareness about research on the diaphragms and other cervical barrier methods. In 2004, the Cervical Barrier Advancement Society (CBAS) was established to raise the profile of cervical barriers and serve as a focal point for providing information and resources to media, organizations, and individuals interested in learning more about cervical barrier methods.

INCREASING AWARENESS ABOUT FEMALE-CONTROLLED METHODS

Women in particular need to have as many alternatives as possible at their disposal to protect themselves from infection and slow the advance of the HIV pandemic. Innovative and strategic education, marketing and distribution strategies are increasing demand for, access to and use of the female condom around the world. The microbicide community has mobilized resources for research and advocacy efforts with the aim of ensuring that when available, women will have access to a safe and reliable microbicide. Researchers are also taking a new look at the diaphragm to determine whether it may reduce women's risk of HIV infection. As women are increasingly affected by the HIV pandemic, the international health community must focus its energies and resources to ensure that women around the world have as many tools as possible at their disposal to protect their health.

For more information on Ibis, visit www.ibisreproductivehealth.org. For more information about cervial barriers, visit www.cervicalbarriers.org.

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