AN EXISTING METHOD: THE FEMALE CONDOM

The female condom is the only female-initiated method (women instigate use but need co-operation of their partner) that is known to be safe and effective in reducing the risk of pregnancy and the transmission of sexually transmitted infections (STIs). The design of the female condom offers more protection to women than the male condom because the outer ring partially covers the external genitalia. Studies in a variety of countries and cultures show that, on average, 50 - 70% of male and female participants found the female condom to be acceptable. An acceptability study in South Africa found that 30% of the female participants used the female condom at least once, and of these 86% said they would use it again and 95% said they would recommend it to friends.

In terms of pregnancy prevention, the female condom is comparable to the male condom. Twenty-one per cent of women using the female condom will become pregnant in the first year of use compared with 15% of male condom users. With correct and consistent use, 5% of female condom users and 2% of male condom users will experience a pregnancy in the first year of use. More recent studies in China, Panama and Nigeria showed higher effectiveness rates of 94 - 98% for the female condom compared with 92 - 96% for the male condom. Regarding prevention of STIs, a systematic review found that female condoms confer as much protection from
STIs as male condoms. In addition, laboratory studies have demonstrated that the female condom blocks the passage of microorganisms, including HIV.12

Currently, the only female condom that is approved by the US Food and Drug Administration and procured by large donor agencies is the FC Female Condom® produced by the Female Health Company; two other female condom brands are marketed outside the USA. The most common complaints about the female condom – aesthetics, difficulty with insertion and noise – typically fade with repeated use. Nevertheless, several new condoms are being developed that address these concerns and may also be less expensive. The World Health Organization announced in August that the second generation FC2 Female Condom, made of nitrile, a latex derivative, had met international standards for dual protection against pregnancy and STI/HIV infection and will be cheaper to produce.13

Since the female condom entered the market in 1992, more than 100 million have been distributed in more than 90 countries.14 Since the female condom was introduced into the country in 1998 through a national pilot programme, South Africa has become the second-largest distributor of female condoms globally (following Brazil) with procurement of female condom programming in at least 23 countries. Finally, the Global Female Condom Initiative, which aims to scale up condom programmes. In September 2005, a global consultation was held in the USA to develop a plan of action for garnering international support for the female condom. Also in 2005, the United Nations Population Fund launched the Global Female Condom Initiative, which aims to scale up female condom programming in at least 23 countries. Finally, the recently launched Prevention Now! Campaign is working to promote universal access to female condoms and other existing STI/HIV prevention options.

**TABLE I. MICROBICIDES IN ADVANCED CLINICAL TRIALS**

<table>
<thead>
<tr>
<th>Mechanism of action</th>
<th>Candidate product</th>
<th>Developer</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal defense enhancers</td>
<td>BufferGel®</td>
<td>ReProtect, Inc.</td>
<td>Phase 2/2B</td>
</tr>
<tr>
<td>Entry/fusion</td>
<td>Carraguard®</td>
<td>Population Council</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Cellulose sulfate gel (CSI)</td>
<td>PRO 2000</td>
<td>Indexus Pharmaceuticals, Inc.</td>
<td>Phase 3</td>
</tr>
<tr>
<td>PRO 2000</td>
<td>Indevus Pharmaceuticals, Inc.</td>
<td>Phase 3</td>
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</tbody>
</table>

Because of their different modes of action, some microbicides are designed to reduce the risk of pregnancy and STIs, including HIV, while others aim only to prevent infection, enabling women who want to conceive to protect themselves from disease.

It is estimated that the first microbicides will be 50 - 60% effective in preventing HIV – much lower than the approximate 90% 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% of people at risk of HIV use a microbicidal gel that is 60% effective in protecting against HIV transmission, 2.5 million infections could be averted over 3 years.

More than 60 studies have been conducted in developed and developing countries to determine the characteristics of an acceptable microbicide. 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. In South Africa, qualitative research revealed support for microbicides stemming from respondents’ concerns around the HIV epidemic, rape, sexual coercion and unplanned consensual sex.

Microbicides have garnered much greater attention in the past few years. After the record-level attendance for the Microbicides 2006 conference in Cape Town, South Africa, microbicides again took center stage at the recent XVI International AIDS Conference in Toronto, Canada. Bill Gates opened the conference by stating, ‘We need to put the power to prevent HIV in the hands of women’.
Greater attention and advocacy has increased funding for microbicide research and development with annual global investment rising from US $65 million in 2000 to US $163 million committed for 2005. Public-private partnerships have played a critical role in advancing microbicide research. Commercial investment has been sorely lacking, while funding from national level sources is increasing. Experts agree that despite increased investment a global funding shortfall remains and that US $280 million is needed on an annual basis.

**NEW POTENTIAL OF OLD METHODS: CERVICAL BARRIERS**

For thousands of years women have used various forms of cervical barriers for reproductive health purposes. For example, the contraceptive diaphragm was developed in the late 19th century and by 1930 was the most frequently prescribed contraceptive method in the USA. Diaphragms and cervical caps were also popular contraceptives in the early 1900s in Europe, including Holland, Germany, England and France.

Cervical barrier methods when used with spermicide have proven contraceptive benefits. However, internationally few women rely on cervical barrier methods for contraception. According to the United Nations Population Division, only 0.5% of women (married or in partnerships currently using contraception) aged 15 - 49 years use vaginal barrier methods, including the diaphragm, cervical cap and spermicidal foams, jelly, cream and sponges. (see Fig. 1 for worldwide use).

Although the diaphragm was previously available in South Africa, it is not currently available in either the private or the public health care sector. Despite this lack of availability, 16.4% of all women surveyed in the 1998 Demographic and Health Survey had knowledge of the diaphragm as a contraceptive method and 0.8% of women had ever used the method. Among women currently using contraception, unsurprisingly, none reported use of the diaphragm.

Although not yet proven, cervical barriers may also provide some protection against HIV and STIs. Prior observational studies indicate that women who used a diaphragm with spermicide had a reduced risk of acquiring STIs and associated long-term sequelae. All of the studies compared diaphragm users with non-users, and all used some type of multivariate analysis to control for known co-factors or confounders such as socioeconomic status or age. Because these studies were not designed to test the efficacy of the diaphragm, and because they are all observational studies and therefore subject to biases, there results must be considered as suggestive rather than definitive. Clinical trials are currently underway to investigate whether the diaphragm may reduce STI/HIV transmission.

Indeed, there is biological plausibility that the diaphragm may also decrease risk of HIV acquisition. Several characteristics of the cervix may mean it is more vulnerable to STIs/HIV than other areas of the female reproductive tract. First, recent evidence suggests that the cervix has a high concentration of...
Health care providers are at the forefront in the fight against putting the tools of prevention in women’s hands. Because provide women with more alternatives to protect themselves address the root causes of women’s vulnerabilities, they will HIV infection. Second, compared with the thicker cell lining of the vagina, the cervix is more fragile, covered only by a single layer of cells. It is therefore biologically more susceptible to trauma, and therefore STI/HIV prevention, than the vagina. Third, research shows that the cervix is the preferential infection site for many STIs, including gonorrhea, chlamydia, and human papillomavirus (HPV), and the presence of STIs increases HIV transmission risk and vice versa. Finally, the cervix is the entryway to the upper genital tract, which may also be an important site for HIV infection. Demonstrating the increased activity and interest in cervical barrier methods, the Microbicides 2006 conference featured nearly 30 presentations reporting on research aiming to determine the safety and acceptability of diaphragms and other cervical barriers as potential STI/HIV prevention methods. For example, one study among US women found that two candidate microbicides, Acidform™ and BufferGe® were safe when used with a diaphragm. In addition, researchers at the University of California, San Francisco and University of Zimbabwe found that Cellulose Sulfate gel, another potential microbicide, when used with the diaphragm was shown to be safe. Another research trial demonstrated that the BufferGe® Duel™, a cervical barrier that is combined with the candidate microbicide BufferGe®, was easy to insert and remove, validating the idea that a cervical barrier can be prepackaged with a microbicide. One of the most exciting pieces of news were the results presented by the University of Pennsylvania showing that BufferGe® used with the diaphragm is as effective as the diaphragm used with nonoxynol-9 (N-9) spermicide for contraception. Having an N-9 alternative is a significant advance, because N-9 is not recommended for women at high risk of HIV. For more information on research and issues related to cervical barriers, visit the Cervical Barrier Advancement Society (CBAS) website at www.cervicalbarriers.org.

CONCLUSION

Although female-controlled HIV prevention methods cannot address the root causes of women’s vulnerabilities, they will provide women with more alternatives to protect themselves from infection. No one method will be right for every woman or girl, but reproductive health and rights are advanced by putting the tools of prevention in women’s hands. Because health care providers are at the forefront in the fight against HIV, they play a key role in educating clients about available options, such as the female condom, staying informed about the development of new promising methods such as microbicides and cervical barriers, and supporting women in their method choice.

REFERENCES

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