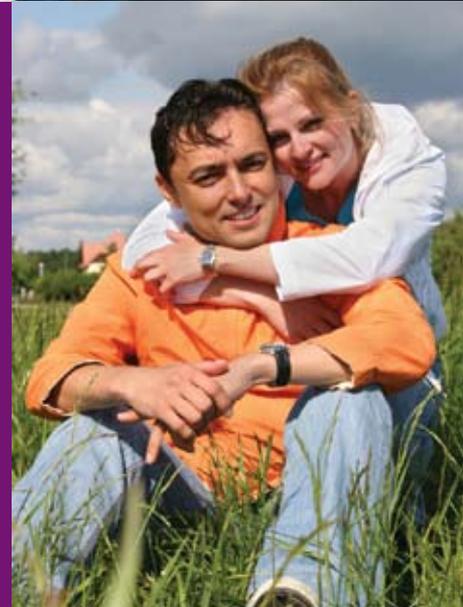




# Female Condom

A Powerful Tool for Protection



## About this document

After more than ten years on the market and despite the clear need, the supply and adoption of female condoms is low—significantly below the levels needed to have an impact on the HIV/AIDS epidemic. More than 100 experts from 15 countries met in Baltimore, Maryland, in September 2005 at the Global Consultation on the Female Condom (GCFC) to discuss the status of the female condom worldwide and to develop a plan of action to build support for the method.<sup>1</sup> A key goal of this plan is to gather the support of donors, policymakers, and women’s health advocates worldwide to make the case for immediate, widespread promotion and distribution of female condoms as an important way to protect women, men, families, and communities around the world. This document answers key questions about the female condom and builds on the momentum created at the GCFC by presenting evidence of the female condom’s effectiveness and impact, identifying current challenges to wider use, and indicating the steps that need to be taken now to develop strong female condom programs worldwide.

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# Broad support from the global health community

“Female condoms are of enormous importance to the fight against AIDS because they are the only existing, effective female-controlled preventive tool against HIV and other STIs. However, their use has remained frustratingly and tragically low, despite growing demand from women themselves. The barriers of price and supply must be overcome. Female condoms must be brought within the reach of all women as a core part of the world’s commitment to moving towards universal access to HIV prevention, treatment, care, and support.”

— Dr. Peter Piot, Executive Director, UNAIDS

“The female condom works. It is effective in preventing pregnancy and STIs, including HIV. When it is offered with good counseling and support, female condom availability results in significantly safer sex ... More choice equals more protection. It’s that simple. Increased choice helps to empower women. As part of a rights-based approach to health care, women should by right have access to female condoms.”

— Dr. Steve Sinding, Director General, International Planned Parenthood Federation

“We must increase access to female-controlled methods of prevention to ensure that women have life-saving tools, such as female condoms.”

— Dr. Thoraya Obaid, Executive Director, UNFPA

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## Overview

Millions of couples worldwide need effective protection against sexually transmitted infections (STIs), including HIV, and pregnancy. Treatment and care efforts are expanding worldwide, but they cannot keep up with the spread of the HIV/AIDS epidemic, especially among women and girls. The female condom is an effective STI and pregnancy prevention technology available now that enables couples to reduce their risks. Research shows that the method is comparable to the male condom in its effectiveness in preventing pregnancy and STIs. Access to the female condom can increase the proportion of couples having protected sex and offers a lifesaving alternative when male condoms are not used.



Although female condoms have been introduced in many countries, their supply and uptake in countries hardest hit by the HIV/AIDS epidemic is woefully inadequate. In 2005, only 14 million female condoms were available for distribution, while 6 to 9 billion male condoms were provided worldwide. Greater investment by the private and public sectors and support from the donor community are urgently needed to make the female condom an affordable option. While new female condom products being developed offer more choice and may overcome some of the problems reported by current users, these products face financial and regulatory barriers that slow their path to market. Advocacy for the female condom, from the community level upwards, is needed to stimulate demand and increase access and availability. Research that provides more data on the method's impact and cost-effectiveness will help promote the female condom.

The female condom is not a promise on the horizon, but an effective, female-initiated method available now that can protect women from pregnancy and STIs. It is an important technology that needs to be given a more prominent role in reproductive health programs and included in STI/HIV and pregnancy prevention efforts worldwide.



## UNPRECEDENTED NEED

# Is there a need for the female condom?



**Yes.** The need for effective alternatives to the male condom is critical to protect women and couples from STIs and unintended pregnancy.

Millions of women worldwide suffer from STIs—all of which are preventable, but many of which are not curable. Almost half of the 39 million adults around the world infected with HIV are women—up from about one-third in 1985.<sup>2,3</sup> Young women are most at risk. Half of all new HIV infections occur in young people (15 to 24 years old). Other STIs also take a toll worldwide, and some can make those infected more vulnerable to HIV infection. According to the latest World Health Organization (WHO) estimates, 340 million new cases of curable STIs occur every year.

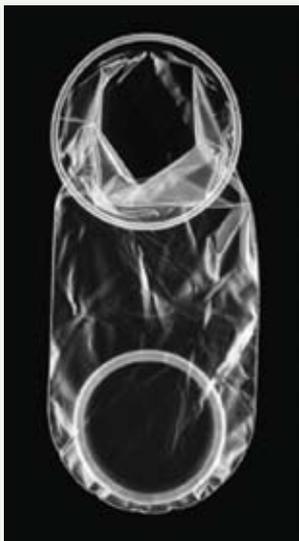
Biology, gender roles, sexual norms, and inequalities in access to resources and decision-making power put women and girls at greater risk of infection than men and boys. Many women have insufficient information about sexual and reproductive health and do not understand the risks associated with their own or their partners' sexual behaviors. Many of those who do recognize their vulnerability are powerless to protect themselves. Women who receive information and counseling, and who learn to use the female condom, can protect themselves even if their partners refuse to use a male condom.

“A place for female condoms?  
It is not whether there is a place  
but WHAT is the place?”<sup>4</sup>

– UK Department for International  
Development Health Advisor in China

The need for effective options to protect women’s health and future fertility is urgent. Currently, the only protective methods against STIs are the male and the female condom. Since the advent of the HIV/AIDS epidemic, the female condom is the only new technology developed and approved that protects against STIs (see box). Not only can effective female condom programs help women and

couples reduce their risks for diseases and unintended pregnancies now, strong introduction programs can also help pave the way for the introduction of other new protection methods, such as cervical barriers and microbicides, which will become available in the next decade.



## The female condom

The most widely distributed female condom, the FC Female Condom<sup>®</sup>, is the only female condom currently approved by the US Food and Drug Administration and distributed by major donor agencies.<sup>5</sup> It is a soft, strong, transparent polyurethane sheath about the same length as a male condom, but with flexible rings at both ends. It can be inserted into the vagina several hours prior to sexual intercourse and can remain in place after ejaculation. It provides a protective barrier between the penis and the cervix, the vagina, and parts of the external female genitalia. Polyurethane is a thin, odorless material that transfers heat better than latex. The female condom is prelubricated with a silicone-based, non-spermicidal lubricant. It has a shelf life of five years.

Studies show that some women like the female condom because it gives them greater control over safe-sex negotiation, is effective for STI and pregnancy prevention, is easy to use, increases sexual pleasure, and is a good option for men who do not like male condoms. However, other women report dissatisfaction with the female condom because of discomfort during sex, the need to get a partner’s consent, difficulties in use, aesthetic concerns, noise, sensitivity to polyurethane, and/or cost. New female condom designs that address these problems are being developed. A new condom from the Female Health Company, FC2, may be available in 2006; other new designs are several years away.

FC Female Condom is a registered trademark of Female Health Company.

## Can all women use the female condom?



"This female condom in question ... I have been hearing of it but I don't actually believe it exists ... I want to be convinced there is something like the female condom."<sup>6</sup>

— Chinazo Nkechi

**Yes.** All women at risk for STIs and/or pregnancy are appropriate users of the female condom. It is especially suitable for women who are unable—for a variety of reasons—to depend on male condoms and who need protection from STIs.<sup>7</sup>

Women want the means to protect themselves from unplanned pregnancy and STIs, and they are eager to try products that offer protection. Early female condom introduction efforts were targeted to commercial sex workers (CSWs), because they are at high risk for HIV and other STIs and have an obvious need for a female-initiated method of protection. The female condom is well accepted by CSWs in many countries, especially as an option when clients refuse to use male condoms. Training that includes insertion practice has contributed to acceptance of the female condom by CSWs.

As the global HIV/AIDS epidemic has evolved, so too have the populations at risk. About three of every four HIV infections in developing countries are transmitted through heterosexual intercourse. The majority of new HIV infections in women occur within marriage or long-term relationships with primary partners.<sup>2</sup> In southern India, a significant proportion of new infections occurs among married women, many of whom have been infected by husbands who frequented CSWs.<sup>2</sup> Male clients of CSWs are infecting their wives and girlfriends in Thailand, where

as many as one-half of new HIV infections each year occur within marriage or regular partnerships.<sup>2</sup> Almost seven in ten young women surveyed in Zimbabwe and South Africa reported having one lifetime partner, and eight in ten had abstained from sex until at least age 17. Nonetheless, four in ten of these young women were HIV positive.<sup>2</sup> Young, married women are the fastest-growing group of HIV-positive people, and it is urgent to reach them with preventive measures. Reaching out to these couples with unbiased, culturally appropriate information is an increasingly important focus of female condom programs.

Married women can use the female condom's effectiveness in pregnancy protection to promote its use to their husbands, who may be reticent to use a condom, or who may associate condom use only with extramarital sex. In Zimbabwe, the female condom has been marketed successfully to couples as the "Care Contraceptive Sheath," thus distancing the product from any stigma associated with male condoms and STIs and building an image of acceptability of this method among couples who "care."

## REDUCING INFECTIONS

# Does the female condom prevent transmission of STIs?



**Yes.** Evidence from laboratory and population-based studies shows the female condom is at least as effective as the male condom at preventing STIs.

Several laboratory studies show that the material used in female condoms, polyurethane, is an effective barrier against many common STIs, including HIV. A test simulating sexual intercourse found the female condom was impervious to HIV.<sup>8</sup> A test of the permeability of female condoms to gas, liquid, and the  $\phi$ X174 virus (a virus smaller than HIV) similarly found them to be impermeable barriers.<sup>9</sup> Based on these laboratory tests, the study authors concluded that female condoms can provide a highly protective barrier for STI prevention and contraception.

An additional estimate of the effectiveness of female condoms in preventing HIV transmission has been derived from the method's effectiveness for pregnancy prevention and estimates of the risk of HIV infection per act of sexual intercourse. According to one such scenario, perfect use of the female condom for a year by a woman having sexual intercourse

“... the female condom is not a luxury to many women, especially in Africa and probably elsewhere too. It is a necessity that determines life or death.”

— Daisy Nyamukapa, UNFPA Zimbabwe

twice a week with an HIV-infected partner could reduce her risk of acquiring HIV by more than 90 percent.<sup>10</sup> Even if the woman only used a female condom half of the time, her risk of HIV infection in one year would still be reduced by 46 percent.

Several small studies, including the few randomized, controlled trials on female condom use, indicate that female condoms confer as much protection from STIs as male condoms. Studies in Kenya, Thailand, and the United States found that the prevalence of STIs declined by about the same amount among women who were given female or male condoms as among those who were given only male condoms.<sup>11-13</sup> The additional protection offered by female condoms is shown in recent data from Madagascar, where STI prevalence declined by 13 percent among sex workers a year after female condoms were added to the distribution

of male condoms.<sup>14</sup> Consistent use of the female condom by women in the United States provided complete protection from trichomoniasis reinfection.<sup>15</sup>

A review of studies of the male condom determined that, in typical use, the male condom results in an 80 percent reduction in HIV incidence.<sup>16</sup> While no studies have evaluated the specific HIV prevention effectiveness of the female condom, it is likely that the female condom provides at least the same level of protection as the male condom. Because it covers the base of the penis and some of the external female genitalia and is more resistant to tears, the female condom may offer better protection against genital ulcer diseases.

## DUAL PROTECTION

**Does the female condom offer dual protection against pregnancy and STIs?**



**Yes.** The female condom is the only woman-initiated method of dual protection against STIs and pregnancy available.

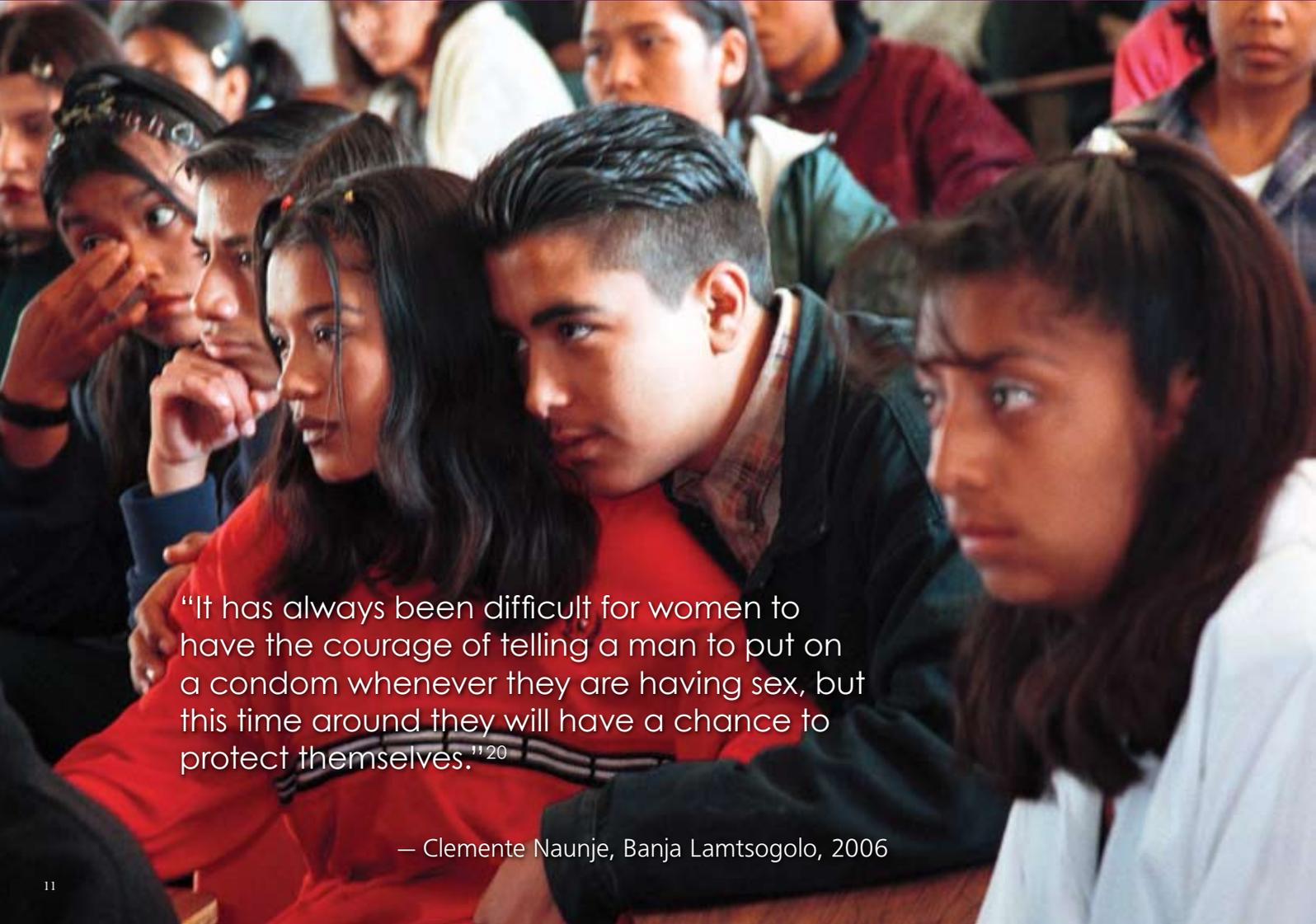
Several studies show that the female condom provides about the same protection from pregnancy as the male condom. WHO-supported studies comparing the effectiveness of female and male condoms show that the two types of condoms are substantially equivalent in preventing unintended pregnancies. Effectiveness rates for typical use among study participants in China, Panama, and Nigeria ranged from 94 to 98 percent for the female condom and from 92 to 96 percent for the male condom.<sup>17</sup> Previous studies had estimated the female condom to be 79 percent effective in typical use, compared to 85 percent for male condoms, 80 percent for diaphragms, and 71 percent for spermicides.<sup>18</sup> Promotion of female condoms for dual protection is particularly relevant in countries where married women are increasingly at risk of infection. The female condom expands the opportunities for lifesaving dual protection.

## UNFPA Global Female Condom Initiative

The most comprehensive program to promote the female condom as a dual protection method is the Global Female Condom Initiative launched by UNFPA in 2005, which aims to scale up female condom programming in at least 23 countries.<sup>19</sup> At the country level, UNFPA has helped establish condom technical working groups and is working with government and other stakeholders to develop and implement country-driven strategies for integrating female condoms into a wide range of reproductive health services. The goals of the Female Condom Initiative are to (1) expand access to female condoms and (2) integrate female condoms as an essential component of national HIV/AIDS policy guidelines and reproductive health programs. The Initiative aims to:

- Increase uptake of female condoms.
- Empower women to negotiate safer sex with their partner(s).
- Promote correct and consistent use of female condoms for HIV prevention.
- Advocate for the inclusion of female condoms in the WHO essential drug list.

## Does the female condom have an impact on levels of protected sex?



“It has always been difficult for women to have the courage of telling a man to put on a condom whenever they are having sex, but this time around they will have a chance to protect themselves.”<sup>20</sup>

— Clemente Naunje, Banja Lamtsogolo, 2006

## Yes. Effective female condom interventions can increase the proportion of protected sex acts and decrease STI prevalence.

The contribution of the female condom to overall increased protection and decreased prevalence of STIs depends on who uses it, how correctly and consistently it is used, and whether it is a substitute for the male condom. Many studies show that providing the female condom (as part of a comprehensive prevention strategy) results in increased levels of protection.

Protected sex among women in studies in the United States and Brazil doubled after they received female condoms and counseling on their correct use.<sup>21,22</sup> In Madagascar, protected sex increased by 10 percent among CSWs due to their use of the female condom.<sup>14</sup> Other studies of female or male condom use in Kenya, Zambia, the United States, Zimbabwe, South Africa, and Nigeria found that encouraging use of either method contributed to increases in the proportion of protected sex acts.<sup>23-29</sup> When both types of condoms are available, consistent condom users often switch between use of female and male

condoms. These studies provide important evidence that the female condom is not just a substitute for the male condom, but is complementary and contributes to increased use of both types of condoms.

As has been shown for male condoms, female condoms likely offer some protection against chlamydia, gonorrhea, herpes simplex, syphilis, and human papillomavirus infections.<sup>30</sup> Because the female condom covers more of the external female genitalia than the male condom does, it may be even more effective at preventing genital ulcer diseases—all of which can increase risk for HIV infection. Female partners of male condom users are less likely to get cervical cancer, and it is plausible that the same protection is provided by female condoms.<sup>31</sup> More research is needed to determine the disease-specific protection offered by the female condom, especially to safeguard the reproductive health and future fertility of young women.

COST-EFFECTIVENESS

## Is the female condom cost-effective?



**Yes.** Modeling exercises have shown that when the female condom is offered as part of a well-planned STI and pregnancy prevention program, it is a cost-effective public health intervention.

Health economists have developed models to estimate the relative benefit of female condom investment compared with other costs of STI/HIV prevention and treatment. Such models can help donors, health decision-makers, and program managers better understand the potential contribution of female condoms to safeguarding health and reducing negative impacts of unprotected sex. In one such model commissioned by the Female Health Company, substantial cost savings to the health sector were estimated based on different use scenarios in South Africa and Brazil of their new female condom, FC2.<sup>32</sup> For example, the model estimated that in South Africa, assuming a low uptake of 4 million (at an estimated unit cost of US\$0.77 for product, distribution, training, and education) the female condom would prevent 1,740 HIV infections, with a net savings to the health care system of about \$980,000. Another type of model estimates that an investment of \$4,000 for female condoms distributed to 1,000 CSWs in rural South Africa would prevent many cases of HIV, syphilis, and gonorrhea, yielding net savings to the health sector of just over \$9,000.<sup>33</sup>

These types of models suggest that female condom programs can be highly cost-effective

and offer significant protection to women and men. The additional benefits associated with prevention of pregnancy—and prevention of mother-to-child transmission of HIV—have not been quantified in these models, but they would make the cost-benefit analysis of the female condom even stronger.

In recent years, the international community has focused on improving access to treatment of HIV. While the gains made in treatment are laudable, they should not come at the expense of prevention services, which are estimated to be 28 times more cost-effective than treatment.<sup>34</sup> Female condom programming is far less expensive than many other HIV/AIDS program inputs, such as antiretroviral therapy, which, at commercial prices, can cost US\$300 to \$1,200 per user per year in developing countries.<sup>35</sup> Even at greatly reduced prices for antiretroviral therapy, such as those negotiated by the Clinton Foundation HIV/AIDS Initiative, the costs associated with treatment will grow substantially. The female condom is an important prevention tool, and its use along with antiretroviral therapy is one way to efficiently and effectively combine prevention and treatment.

## CHALLENGES

# Are there challenges to increasing access to and use of the female condom?



"... the biggest challenge [to female condom promotion] is not the noise or the way to use it—but that men are afraid it will make women promiscuous."<sup>6</sup>

— Manju Chatani, African Microbicides Advocacy Group

**Yes.** Expectations of uptake and impact may have been too optimistic, given the challenges of introducing a new product.

With so many women's lives depending on an effective prevention option, hopes and expectations for the female condom have been high. While research shows that the female condom does provide STI and pregnancy protection, like all user-dependent methods, its effectiveness relies on correct and consistent use and good communication between partners. As with all new methods, counseling, practice, and peer support lead to greater comfort and confidence in use of the female condom. Experience in many diverse settings shows that women have learned to use the female condom successfully for protection.

The challenges of introducing the female condom have been compounded by negative perceptions of barrier methods. Some donors, program managers, and providers think that women are not willing to learn the steps necessary for insertion, including touching their genitals, or to talk with their partners about condom use. Similar obstacles were proposed for other vaginal products, such as tampons, (the feminine hygiene product designed to absorb menstrual blood), which took almost 20 years to be widely accepted.<sup>36</sup> The tampon faced preconceived health care provider

biases and slow user uptake similar to those associated with the female condom, but it is now a well-accepted product used by many women. These potential obstacles could be viewed as opportunities for women to learn about their anatomy and become comfortable with their bodies.

By teaching women to become familiar with their bodies and to gain confidence using vaginal methods, the female condom can ease the acceptance of other female-initiated products currently being developed, such as new cervical barriers and microbicides, which also will require insertion into the vagina. Providers influence acceptance of new methods by their attitudes and by the type of information they provide to clients. Stronger efforts must be made to ensure that providers convey accurate, unbiased information about female condoms to their clients.

Another challenge cited as hindering the uptake of the female condom is the product cost, especially compared to the male condom (see boxes, next pages). New methods often cost more than existing products, especially until demand reaches a level that encourages

## Cost of the Female Condom

One of the obstacles to more widespread distribution and use of the female condom is the high cost of the current product, especially compared to the male condom. The FC Female Condom is available to donor programs through an agreement with the Joint United Nations Programme on HIV/AIDS at a cost of £0.38 per unit (~US\$0.66), or 22 times the cost of a male condom (\$0.03 per unit). The discrepancy is somewhat less when the costs of delivering female and male condoms through a comprehensive STI/HIV prevention program (training, advocacy, promotion, marketing, distribution, and monitoring) are added. For example, using data from all its social marketing programs, Population Services International (PSI) estimates that the “fully loaded” unit cost (product and program costs minus income generated) for the female condom in 2005 was \$1.28, 12 times greater than the fully loaded cost for the male condom (\$0.11).<sup>37</sup>

The good news is that whereas the fully loaded cost for male condom programming has stabilized, the program cost for female condoms continues to drop. The current cost of \$1.28 is a decrease of almost two-thirds from the \$2.96 cost to procure and program female condoms in 2000. Programming costs tend to decrease over time, as programs mature and products gain familiarity and wider distribution. PSI's social marketing programs sold 867 million male condoms in 2004, a volume that allowed immense cost efficiencies, in comparison with sales of only 2 million female condoms. As the demand for female condoms increases worldwide, so will sales, reducing the unit cost of purchasing female condoms. And as programs mature and product awareness grows, the need for intensive promotion should lessen, further decreasing the cost of delivering female condoms to populations where they are needed.

economies of scale in production and stimulates competition. Until this occurs for the female condom, stakeholders need to advocate for sufficient financial support to make the method widely available at low cost. Other new prevention methods under development, such as microbicides, are also expected to cost substantially more than male condoms, especially for packaging and applicators. However, research and development proceed, because the need is so great, and it is assumed that governments will provide production incentives and that donors and governments will purchase in bulk and build on existing distribution systems for product delivery.

Given the small-scale programming of the female condom to date, it has been difficult to show the method's public health impact. However, pilot projects do show that making the female condom available within the context of a well-supported prevention program increases use of both female and male condoms.

The female condom can contribute in many ways to improved health if programmed appropriately.<sup>38</sup> In addition to reducing a woman's risk of disease and pregnancy, it can lead to women's increased knowledge of their bodies, improved sexual communication and negotiation skills, and empowerment. These benefits are difficult to measure, but they can have significant impact on women's overall quality of life.

“If we have this new condom, we will get our men to use it ... It will help us a lot.”<sup>39</sup>

— Female participant in group discussion near Durban, South Africa, 1995

“We can create providers ... who understand how to talk to women about their bodies [and] we can train women about their bodies ... We can do that with the female condom today and it will benefit male condom programs, female programs, and microbicides introduction.”<sup>40</sup>

— Key informant, 2004



## Reuse of the female condom

Reuse of the female condom has been proposed as a way to make the method more affordable now and increase its acceptability. Although the FC Female Condom is designed as a single-use product, there have been reports of reuse. In Zimbabwe, 2.2 percent of users in a study reported reusing the female condom for reasons of cost, inadequate supply, saving time, and mere experimentation.<sup>41</sup> In 2000, WHO developed a draft protocol for reuse and commissioned research to test the safety and effectiveness of reused female condoms. Two years later, WHO issued a statement saying it does not recommend or promote reuse of female condoms, but it did publish a draft protocol that includes disinfecting, washing, drying, storing, and relubricating female condoms intended for reuse.<sup>42</sup> While not advocating reuse, WHO has said the final decisions must be made locally, given the diversity of cultural, social, and personal factors that influence use. It is unclear how much reuse currently takes place worldwide—and whether there is any increased risk for the woman and/or her partner—but more research on this option, including simplified disinfection protocols and the potential for reuse of the new FC2, are needed. Studies are under way to evaluate a simplified cleaning protocol.

## INCREASING DEMAND

# Are there feasible strategies for increasing demand and access?

A photograph of two women in Senegal. The woman on the left is wearing a vibrant, multi-colored headwrap (blue, orange, pink, and white) and a matching patterned top. The woman on the right is wearing a blue headwrap and a black top. They are standing against a light-colored, textured wall.

“In Senegal, the [female] condoms are sold with noisy bine bine beads, an erotic accessory that women wear around their hips. The rustle of the polyurethane during sex is now associated with the clicking of the beads—and so, a turn-on.”<sup>43</sup>

— *The Sunday Independent*, 2005

**Yes.** Increased promotion, wider distribution, better integration with other health programs, and reaching out to at-risk couples will stimulate demand for female condoms and contribute to improved access.

Worldwide orders for female condoms have not changed significantly during the last three years, as evidenced by steady sales data from Female Health Company.<sup>5</sup> But consistent, large sales in South Africa and Brazil show what is possible with investments in programming (see boxes, next pages). There is a need for greater demand at the community level to gain the attention of local decision-makers who handle procurement and programming.

Private- and public-sector donors, as well as ministries of health and program managers, need to hear from those who stand to benefit from use of the female condom. The experience in Zimbabwe—where women’s groups collected more than 30,000 signatures from women demanding access to the female condom, resulting in the government’s importation of the female condom—shows the power of local groups.

Global and grassroots advocacy strategies are needed to make the case for female condoms. Well-coordinated efforts to reach decision-makers with key messages are needed to

raise awareness and respond to questions and concerns. Involving professional health associations, policymakers, program managers, service providers, community leaders, and local women’s and youth groups in coordinated efforts to advocate for increased funding, support, and programming for the female condom will better voice the need for this type of protection.

Far greater education and outreach is needed to increase the demand for female condoms by potential users. This involves reaching out to women and men who are not normally the focus of condom promotion. Targeting the female condom to young people can help them incorporate this risk-reducing strategy early in their sexual experience to protect against pregnancy, disease, and infertility (a sequela of STIs such as chlamydia). Men need to be included in female condom education and outreach efforts to help overcome partner opposition, an important reason given by some women for discontinuing use of the method.

## Promoting dual protection in South Africa

South Africa has one of the largest female condom programs in the world. In 2004, 1.4 million female condoms were distributed through the national program. The female condom was introduced in the country in 1998 through a pilot program targeting distribution through family-planning clinics, CSW sites, and a social marketing program in eight of nine provinces.<sup>28</sup> The introduction strategy included provider training, information pamphlets for clients, monitoring and analysis of condom distribution, and quality assurance and supervision visits. Interviews with female condom users following the introduction showed that most female condom accepters were young (age 20 to 29), were current users of hormonal contraceptives, and mainly adopted the female condom for the additional benefit of STI/HIV protection.

The female condom program in South Africa is guided by a government barrier methods task force that includes all the key female condom stakeholders and works to ensure consistent supply of high-quality condoms to all provinces. The program's success is also due to the coordinated, structured introduction strategy; well-monitored and controlled supply of female condoms; and comprehensive training of providers on female condom and dual protection. The program is now working to keep pace with demand, as well as stimulate greater involvement from the private sector.

Focusing on these groups and others who may be at risk, such as women with multiple partners, intravenous drug users, HIV-discordant couples, and HIV-positive women, as well as couples in stable partnerships, can increase the demand and provide increased protection to the most vulnerable populations.

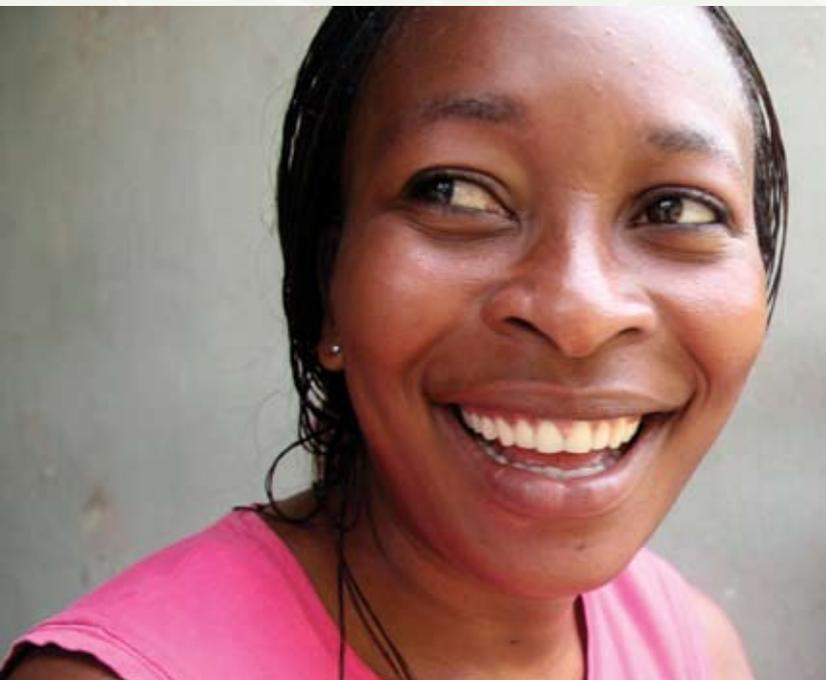
Integrating female condom programming with other services, including family planning, reproductive health, voluntary HIV counseling and treatment, preventing mother-to-child transmission of HIV, antiretroviral treatment programs, and antenatal care, can be cost-efficient and increase access to the method for these potential users. The combined forces of these programs can build capacity and help institutionalize female-initiated methods and facilitate the introduction of other women's protection options as they become available.

All women need access to a range of methods to protect themselves from unintended pregnancy and STIs. Decades of family-planning research have shown that increasing the choice of methods leads to increases in overall use. The greater the number of choices, the greater the likelihood that couples will use protection for every sexual act. Supporting female condom programming efforts that include information, practical training, and low-cost supplies will help make the female condom acceptable and available to all who can benefit from its protection.<sup>38</sup> It is not a question of whether the female condom is a better method than

the male condom, diaphragm, or other family-planning method, but of how to give a woman options. With more than one option, she can choose the method that best fits her (and her partner's) reproductive health needs.

“... there is generalized lack of political commitment on the part of national leaders to support the procurement, distribution and promotion of female condoms ...”<sup>6</sup>

— Maxwell Madzikanga



## Reaching out to high-risk women in Brazil

The female condom is a widely recognized STI/HIV prevention method in Brazil. The government first introduced female condoms following a large-scale acceptability study in 1999, targeting the most vulnerable groups, including CSWs, HIV-positive women, women with STIs, female drug users, and women at risk from violence. Social marketing of female condoms had begun two years earlier in the private sector by DKT do Brasil. In 2000 and 2001, almost 2 million female condoms were distributed at no or low cost through the public and private sectors.

After five years, knowledge and acceptance are widespread, and distribution of the female condom has been highly effective in specific groups, like CSWs. Training service providers how to introduce and demonstrate use of the female condom and reaching out to women and men through community-based organizations have been key elements in the successful introduction of the female condom in Brazil.

The program is now faced with the challenge of increasing distribution to meet the urgent need to protect vulnerable populations. Although 4 million female condoms were distributed in 2003 and 2004, Ministry of Health officials believe that distribution should increase five-fold to better meet the need.<sup>44</sup>

## PROSPECTS FOR NEW PRODUCTS

# Are there prospects for new female condom products?



“We call on governments to ensure that the female condom is marketed to women in local communities and promoted as an effective method to prevent HIV/AIDS and sexually transmitted infections.”<sup>45</sup>

— Dr. Musimbi Kanyoro, World YWCA

**Yes.** Two new female condom models are in limited distribution, and a second-generation condom (FC2) will soon be available. Three new products are in development but will not be available for several years.

Most global experience and published information currently available about the female condom comes from just one product, the FC Female Condom, manufactured by the Female Health Company (FHC). Two other female condoms, the V'Amour Female Condom and the Natural Sensation Panty Condom, are in limited marketing outside the United States, but they have not been approved by the US Food and Drug Administration or included in procurement by major donor agencies.<sup>46</sup> FHC has developed a second-generation female condom, the FC2, made of synthetic latex, which should allow for price reductions as production volumes increase. At the request of the Joint United Nations Programme on HIV/AIDS, UNFPA is negotiating a price agreement with FHC for large-volume procurement of FC2. FHC hopes to develop a coalition of regional buyers to enable cost savings through bulk regional procurement. Nonetheless, to achieve even a 50 percent price reduction (US\$0.31), global sales and bulk purchasing will have to increase to 200 million units—more than 14 times the total 2005 sales of the FC Female Condom (14 million units). This will require a substantial increase in global demand.

Three additional female condom products—the Woman's Condom, the Silk Parasol Female Panty Condom, and the Belgian Female Condom—are in various stages of design, testing, and regulatory approval. Regulatory approval of these products is contingent on the developers receiving adequate funding for clinical trials and regulatory applications. It will be several years before any of these new products are available.

The availability of more female condom products will yield many benefits for current and future users of the female condom. New products may improve acknowledged problems with the first-generation product and therefore better meet users' needs. Less-expensive design and manufacturing and market competition may result in lower product costs and therefore greater access. The regulatory approval pathway these new products must follow is costly and difficult, however, and can keep viable new products from reaching users. Amending the clinical trial requirements and streamlining the regulatory approval processes for female condoms in the United States may help bring innovative products to market.

## PRIORITIES

**Are there clear priorities for taking action now to increase access to and use of female condoms?**



**Yes.** The female condom is poised for greater use and impact. The need for effective disease protection is great, and female condoms have the potential to protect the health of millions of couples worldwide.

The female condom is a key technology in the fight against HIV/AIDS that awaits the full support of the global community. There are four key steps to be taken now to make the female condom more acceptable, accessible, and available.

### 1. Develop greater political and social support for the female condom at local, national, and international levels.

All stakeholders—donors, clients, service providers, policymakers, researchers, and product developers—need to advocate for the female condom. Garnering and publicizing this support will contribute to greater public awareness of, acceptance of, and demand for the female condom.

### 2. Increase public- and private-sector investment in female condoms.

Donors and governments need to increase financial and technical support for female condom programs as one of a number of cost-effective and necessary reproductive health investments. Public-sector program managers need assistance in developing innovative female condom programs that appropriately position and market the method within their communities. International agencies, governments, and manufacturers can facilitate price reductions through joint purchasing agreements. Governments can streamline the regulatory approval and procurement and supply process for new female condom products. The private and public sectors need to invest in the development and commercialization of new female condom products, as well as develop innovative channels for marketing and distributing existing products to specific audiences.

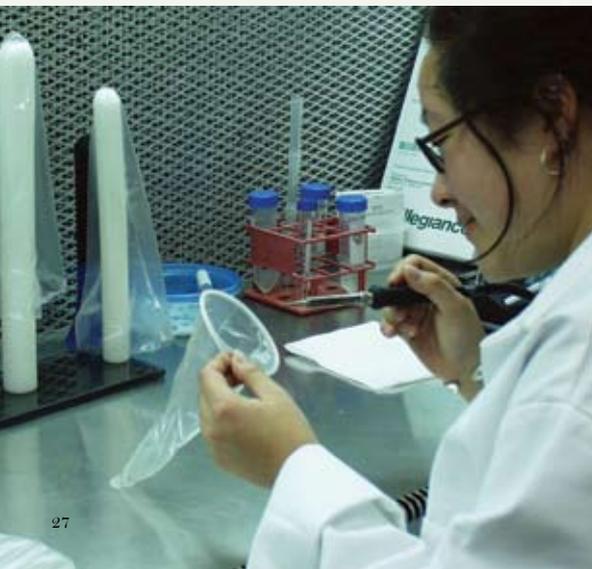
### 3. Scale up promotion of female condoms and monitor and evaluate impact.

Increasing outreach, especially through partnerships with employers and community and women's groups, can increase the demand for and supply of female condoms and reach new users. Specific outreach and education efforts are needed to foster men's acceptance of the female condom. Integrating female condom programming into existing reproductive health programs will increase the cost-effective distribution of the method, strengthen programs, and help make condoms part of mainstream reproductive health programming. With increased distribution and appropriate impact evaluation studies, it will be possible to document the impact of female condom programming on public health and justify continued program expansion. Greater

distribution and use of *The Female Condom: A Guide for Planning and Programming*<sup>38</sup> will be helpful in these efforts. Sharing information about successful female condom programs and lessons learned, especially related to key elements such as developing effective condom negotiation skills and involving men, will facilitate acceptance and diffusion of the female condom.

### 4. Conduct research to improve programming.

Rigorous studies that test ways to introduce and promote female condoms to specific audiences and evaluate the long-term impact of these efforts on public health can strengthen the case for the female condom. Operational research is needed to identify effective behavior change strategies, educate about risk, create demand for female condoms, and evaluate the impact of male involvement.



“Male and female condoms should be readily available in all health care settings ... funding should substantially increase for research into other prevention technologies, such as female condoms ...”<sup>47</sup>

— Global HIV Prevention Working Group, 2004

# A final word

Universal access to prevention, treatment, and care for those affected by HIV/AIDS is a necessary investment in the health of our communities. HIV prevention and treatment are interlinked, and the only way to make treatment affordable and sustainable is to intensify prevention efforts. Women and men whose lives are at risk need access to a range of prevention options to make the choices that best fit their circumstances. Given that the female condom effectively protects against pregnancy and STIs and is the only female-initiated STI prevention method currently available, access to this method is a public health right that needs to be ensured for all couples. The female condom is not just a promise, but an important, complementary technology that must be given a more prominent place in reproductive health programs to save the lives of millions of women and men now.



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# Selected resources

## United Nations agencies

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The Global Coalition on Women and AIDS  
[www.womenandaids.unaids.org](http://www.womenandaids.unaids.org)

The Joint United Nations Programme on HIV/AIDS  
[www.unaids.org](http://www.unaids.org)

UNFPA  
[www.unfpa.org](http://www.unfpa.org)

World Health Organization  
[www.who.int](http://www.who.int)

## Program and research resources

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AVERT  
[www.avert.org](http://www.avert.org)

Brazil Ministry of Health, STD/AIDS Program  
[www.aids.gov.br](http://www.aids.gov.br)

DKT International  
[www.dktinternational.org](http://www.dktinternational.org)

Eldis  
[www.eldis.org](http://www.eldis.org)

Family Health International  
[www.fhi.org](http://www.fhi.org)

The Global Consultation on the Female Condom  
(PDF files containing conference presentations)  
[www.path.org/projects/womans\\_condom\\_gcfc2005.php](http://www.path.org/projects/womans_condom_gcfc2005.php)

International Planned Parenthood Federation  
[www.ippf.org](http://www.ippf.org)

KfW Development Bank  
[www.kfw.de](http://www.kfw.de)

Marie Stopes International  
[www.mariestopes.org.uk](http://www.mariestopes.org.uk)

PATH  
[www.path.org](http://www.path.org)

Popline  
[www.popline.org](http://www.popline.org)

Population Council  
[www.popcouncil.org](http://www.popcouncil.org)

Population Services International  
[www.psi.org](http://www.psi.org)

Reproductive Health and HIV Research Unit of the  
University of Witwatersrand, South Africa  
[www.rhru.co.za](http://www.rhru.co.za)

Resources for Family Planning and HIV/AIDS  
Integration  
[www.fpandhiv.org](http://www.fpandhiv.org)

Reuse of the Female Condom  
[www.reusefemalecondom.org](http://www.reusefemalecondom.org)

UK Department for International Development  
[www.dfid.gov.uk](http://www.dfid.gov.uk)

US Agency for International Development  
[www.usaid.gov](http://www.usaid.gov)

## Manufacturers

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Female Health Company  
[www.femalehealth.com](http://www.femalehealth.com)

Hindustan Latex Limited  
[www.hindlates.com](http://www.hindlates.com)

Medtech Health Products  
[www.medtechproductst.org](http://www.medtechproductst.org)

Natural Sensation Company  
[www.natural-sensation.com.co](http://www.natural-sensation.com.co)

Silk Parasol Corporation  
[www.silkparasol.com](http://www.silkparasol.com)

## Other resources

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Center for Health and Gender Equity  
[www.genderhealth.org](http://www.genderhealth.org)

Cervical Barriers Advancement Society  
[www.cervicalbarriers.org](http://www.cervicalbarriers.org)

Global Campaign for Microbicides  
[www.global-campaign.org/femalecondom.html](http://www.global-campaign.org/femalecondom.html)

Implementing Best Practices in Reproductive Health  
[www.ibpinitiative.org](http://www.ibpinitiative.org)

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