

## TECHNICAL ISSUE BRIEF

# THE FEMALE CONDOM IS SAFE AND EFFECTIVE

### Introduction

#### The Female Condom Is Safe and Effective

On March 10, 2009, the U.S. Food and Drug Administration (FDA) approved the second generation of the female condom (FC2). Made of nitrile (synthetic latex), the design and appearance of the FC2 are essentially the same as the first generation of the female condom (FC1), which was approved in 1993 and distributed under the brand names Reality and Femidom. The World Health Organization (WHO) concluded in 2006 that the FC2 was comparable to the FC1 in both safety and effectiveness, and when used consistently and correctly, female condoms are just as effective as male condoms.

#### Female Condom Promotion Is a Cost-Effective HIV Prevention Intervention

Promoting the female condom is a cost-effective intervention, particularly given the high cost of HIV treatment and other prevention interventions, as well as when the use of male condoms is not a viable option. Two different mathematical modeling studies predicted the cost savings of promoting the female condom and concluded that an expanded effort to promote the female condom is a highly cost-effective intervention. One model predicted a cost savings if efforts targeted women with at least one casual partner and the female condom was used in 12 percent of sexual encounters.<sup>1</sup> Another predicted that expansion of female condom distribution could avert new HIV infections; this would lower the cost of treatment and make responses to both generalized and concentrated epidemics less expensive.<sup>2</sup> The use of new material for the production of the FC2 reduced the cost of the female condom by one-third, and savings will be even greater as sales increase due to economies of scale.

The high cost of the female condom relative to the male condom has been viewed as a major barrier to its widespread distribution. The reduction in cost of the FC2 has had some impact on distribution, but only when the volume of FC2 distribution markedly increases will the price drop significantly. Another way to reduce the cost of female condoms is through greater competition. Several new female condom products are currently in various stages of development and regulatory approval, some of which have already entered the market. In 2012, WHO and the United Nations Population Fund (UNFPA) released generic specifications for prequalification, which provides guidance to manufacturers on the quality assurance testing and clinical trials necessary for country regulatory and bulk procurement approval. The Cupid condom was



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**Maya Gokul of Support demonstrates the proper insertion method for the female condom at a session at the 2010 International AIDS Conference in Vienna, Austria.**

the second female condom to receive WHO/UNFPA prequalification, though it will still require an additional clinical trial for approval by the FDA, which is currently required for the U.S. Agency for International Development (USAID) procurement. The Phase III pivotal clinical trials of the Women's Condom developed by PATH, which is manufactured in China, began in 2011 with support from the National Institute of Child Health and Human Development/National Institutes of Health. The V-Amour/Protectiv, a latex female condom produced by Medtech in India, is now available in some countries. It is anticipated that these new products will be less expensive than the FC2.

#### Female Condom Can Increase Protected Sex

The female condom is the only female-initiated method available that can be worn by women for protection against both unintended pregnancy and sexually transmitted infections. Female condom use can also be initiated by men. A growing body of evidence shows that effective female condom promotion to both women and men can increase the proportion of protected sex acts.<sup>3,4,5</sup>

Qualitative studies have shown that some women are able to use the female condom in situations where they cannot negotiate male condom use,<sup>5</sup> and many users alternate between male and female condoms. Because the female condom can be inserted before sex and is not dependent on an erect penis, it may be particularly useful for women whose partners are under the influence of drugs or alcohol.

## Increased Choice Equals Increased Use

Studies conducted in a variety of contexts show that the female condom is widely acceptable and a realistic alternative to the male condom.<sup>6</sup> Lessons learned from many years of experience in the family planning field illustrate how increasing method choice can increase uptake and use of contraceptives,<sup>5,7</sup> and there are indications that this is true in the case of condoms, as well. One study found that providing a choice of condoms successfully increased acceptability.<sup>8</sup> However, given cost considerations, female condoms should be promoted as an additional option for both men and women rather than as a replacement for the male condom.

## The Female Condom Is an Untapped Resource for HIV Prevention

Despite the potential of the female condom as an effective HIV prevention intervention, efforts to promote the female condom have lagged since its development in 1993. Despite high rates of HIV infection among women globally, the number of female condoms distributed is only 1.6 percent of total condom distribution. In addition, promotion of female condoms may not only prevent new HIV infections, it could also help pave the way for future female-initiated products, such as microbicides and new multipurpose combination technologies.

## Considerations for Female Condom Programming

### Female Condom Programming within Comprehensive Condom Programming

Female condom promotion should be delivered within the context of comprehensive condom programming. In other words, programs should collaborate with country governments and other donors, such as UNFPA, to ensure that strategic plans for comprehensive condom programming are in place and guiding programmatic efforts. Whenever possible, programs should adopt a Total Market Approach to condom promotion that clearly defines the unique roles of the public, social marketing and private sectors for male and female condom distribution and that identifies the comparative advantage of each sector. In countries where stockouts or shortages of condoms are common, programs should consider strengthening supply chain management to secure the availability of male and female condoms.

### Social Marketing

Social marketing of male and female condoms can dramatically increase the number of condoms distributed in developing countries.<sup>7</sup> Scaling up mass media campaigns and branding for the female condom is needed in order to increase awareness and uptake of this method. Promoting the female condom as something that can be used to increase sexual pleasure is one approach that has been successful in increasing its use.<sup>9</sup> Acceptability and uptake of the female condom also may be increased if it is promoted as a method for dual protection against both unintended pregnancy and sexually transmitted infection, particularly in the context

of hyperendemic and generalized epidemics where the majority of infections occur within regular partnerships. Identifying a target population is an important component of social marketing. However, while it is important to make female condoms available to vulnerable groups, targeting the female condom only to highly stigmatized groups, such as sex workers, may further stigmatize the method and create additional barriers to its use. Therefore, targeting strategies should be carefully considered.

## Provide Comprehensive Sexual Risk Reduction Counseling

Female condom promotion should be delivered within the broader context of combination HIV prevention, including behavioral, biomedical and structural interventions. Programming should include sexual risk reduction counseling that incorporates a wide range of prevention messages, including messages about partner reduction and information about biomedical interventions, such as male circumcision. In order for behavior change communication interventions to achieve maximum impact, people must have access to information about all of their options for prevention, including the female condom.

### Include Men

It is essential that female condom promotion efforts also reach male partners, who are critical in the uptake and use of this method. In fact, some men may prefer female condoms over male condoms. Advantages include its larger and less restrictive size, the fact that it does not depend on a fully erect penis, that it can be inserted long before intercourse, and that it does not need to be removed immediately after ejaculation. The female condom is a method that can be initiated by both men and women and, therefore, should be promoted as such.

## Integrate Female Condom Promotion into Other Program Areas

Integrating male and female condom promotion into other services, such as family planning; HIV counseling, testing and treatment; voluntary medical male circumcision; and prevention of mother-to-child transmission can help to increase the demand for this method among potential users.

## Train and Support Providers and Peer Educators

Training for service providers focused on female condom promotion is urgently needed and currently one of the major barriers to effective promotion and/or use of this method. Programs should increase awareness about the method among service providers and also address provider attitudes that are critical to its acceptance among potential users. Counseling that includes a demonstration of how to insert the female condom as well as a discussion of effective strategies for negotiating female condom use is more likely to result in the adoption and correct use of this method. Also, providers and peer educators require the tools necessary to support successful female condom promotion, such as pelvic models and information, education and communication materials produced in local languages.



UNIVERSAL ACCESS TO FEMALE CONDOMS (UAFIC) JOINT PROGRAMME/ROBERT BODEGRAVEN

A woman demonstrates a female condom at a market in Lagos, Nigeria.

“ *The female condom is the only female-initiated method available that can be worn by women for protection against both unintended pregnancy and sexually transmitted infections.*”

### Measure Progress

Indicators that disaggregate male and female condoms are crucial to monitoring the progress of efforts to promote the female condom. Disaggregating the female condom in population-based surveys, such as the Demographic and Health Surveys (DHS), is being done in some countries. However, this practice needs to be

widespread to effectively measure the impact of female condom interventions. While the endpoint of female condom promotion and use is impact on reduction in HIV transmission and unintended pregnancy, this may prove difficult to measure. Instead outcome and process indicators should be monitored.

## Additional Readings

- "Female Condoms and U.S. Foreign Assistance: An Unfinished Imperative for Women's Health," Center for Health and Gender Equity, 2011. [PDF, 2.9MB]
- "Saving Lives Now: Female Condoms and the Role of U.S. Foreign Aid," Center for Health and Gender Equity, 2008. [PDF, 1.4MB]
- "Female Initiated HIV Prevention Methods: Joint Advocacy Statement," United Nations Population Fund and Partners, 2010. [PDF, 1.7MB]
- "Towards a Unified Approach: Inter-Agency Task Team (IATT) on Comprehensive Condom Programming," 2010. [PDF, 91KB]
- "Guidance for the Prevention of Sexually Transmitted HIV Infections," 2011. [PDF, 764KB]
- "Comprehensive Condom Programming: A Guide for Resource Mobilization and Country Programming," 2010. [PDF, 144KB]
- "Female Condom Technical Review Committee Report: Scientific and Technical Requirements to Formulate a Female Condom Generic Specification and Prequalification Scheme," 2012. [PDF, 391KB]
- "Making Female Condoms Available and Accessible," 2011. [PDF, 3.7MB]
- "Make a Move: Advocating for the Female Condom," 2011. [PDF, 1.8MB]
- Behavioral Interventions: Comprehensive Condom Use Programs
- Featured Publications, Prevention Now! Campaign Website



Woman at a rally for female condoms at the 2008 International AIDS Conference in Mexico City, Mexico.

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8. Steiner MJ, Hylton-Kong T, Figuero, P, Hobbs MM, Bhets F, Smikle M, Tweedy K, Powell S, McNeil L, Brathwaite A. "Does a Choice of Condoms Impact Sexually Transmitted Infection Incidence? A Randomized, Controlled Trial," *Sexually Transmitted Diseases*, 2006; 33(1): 31-35.
9. Philpott A, Knerr W, Maher D. "Promoting Protection and Pleasure: Amplifying the Effectiveness of Barriers against Sexually Transmitted Infections and Pregnancy," *The Lancet*, 2006; 368: 1-4.