

## The Future of the Female Condom

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More than 10 years have elapsed since the female condom became widely available, and it remains the only female-initiated means of preventing both pregnancy and sexually transmitted diseases (STDs), including HIV infection. The female condom was developed as an alternative to the male condom, and it was hailed as a method that would enable women to have greater control over their own protection from disease. With the support of the Joint United Nations Programme on HIV/AIDS (UNAIDS), public and private funders, and the manufacturer, more than 90 developing countries have introduced the method through public distribution, social marketing campaigns or commercial outlets. In several countries that have actively promoted its use, such as South Africa, Brazil, Ghana and Zimbabwe, steadily increasing female condom sales to the government suggest that effective programs can generate demand.

At the same time, there have been disappointments. Uptake in the West and in some developing countries has been lower than was initially anticipated, demonstrating that successful introduction will not be as straightforward as was hoped.<sup>1</sup> The study by Kulczycki and colleagues<sup>2</sup> in this issue of *Perspectives on Sexual and Reproductive Health* shows that the method is not popular among some women. Indeed, there are still gaps in knowledge about how acceptable the female condom is for long-term use and whether promoting it can help reduce STD rates.

Despite both successes and disappointments, the female condom remains important to promote, especially in the face of heterosexually acquired HIV infection rates that are soaring globally. It is unfortunate, therefore, that a discourse has emerged recently that marginalizes the female condom as a viable prevention option, out of concerns about its high cost and the need for women to obtain their partner's cooperation in order to use it.<sup>3</sup> Such a conclusion is premature, as the picture is far more complex. In this viewpoint, we review what has been learned about the female condom over the past decade, and argue for a renewed commitment to behavioral intervention research and the implementation and evaluation of large-scale female condom programs.

### THE NEED FOR THE FEMALE CONDOM

Advocacy for the female condom emerged in the context of growing evidence that heterosexual intercourse—rather than women's intravenous drug use—was placing women at increased risk of HIV infection,<sup>4</sup> and that the nature of women's intimate relationships often rendered it difficult for them to request, much less insist on, male condom use.<sup>5</sup>

With the recognition that gender-based inequalities are a major force driving the epidemic, the development of prevention methods over which women have some control became an imperative. Women's health advocates called for the development of female-controlled barrier methods and microbicides beginning in the early 1990s, and following a vigorous campaign, the Food and Drug Administration approved the use of the female condom in 1993.

A decade later, gender inequalities have not abated, and together with inequalities based on race, caste and class, they continue to fuel the spread of HIV among both men and women, especially in resource-poor countries.<sup>6</sup> As a result, the proportion of HIV-positive people worldwide who are women has increased steadily. Women represent half of the 40 million people currently living with HIV or AIDS; in Sub-Saharan Africa, nearly 60% of those newly infected are women.<sup>7</sup> The majority of women with HIV are married or are in established partnerships, and likely contracted the virus from their primary male partner.<sup>8</sup> Therefore, increasing the rates of condom use remains an important prevention strategy, as demonstrated by the contribution of increased use of male condoms to the decline in HIV prevalence in several countries, including Cambodia and Thailand.<sup>9</sup>

The need for protective methods over which women have some control is even greater, now that we have definitive evidence that nonoxynol-9 spermicide offers no protection against HIV or other STDs.<sup>10</sup> The most optimistic estimates suggest that it could be close to 2010 before a first-generation microbicide is on the market, given that phase III efficacy trials are starting only this year.<sup>11</sup> The development of a vaccine against HIV will likely take even longer. At present, the female condom is the only alternative to the male condom as a means of protection against both pregnancy and STDs. This crucial fact underscores the urgency to continue conducting relevant behavioral intervention research, as well as implementing and evaluating large-scale national female condom programs.

### EFFECTIVENESS

Reliable evidence shows that the polyurethane female condom is highly efficacious in preventing both pregnancy and STDs. Estimates of its contraceptive efficacy are in the same range as those of other barrier methods: Six-month failure rates for the female condom range from 0.8% (among 190 women in Japan who used it correctly and consistently)<sup>12</sup> to 9.5% (among 115 women in three Latin American locations).<sup>13</sup> A study sponsored by the World Health Organi-

zation that is specifically designed to compare the contraceptive efficacy of female and male condoms is under way.<sup>14</sup>

Laboratory and in vitro studies have established that polyurethane is impermeable to small viruses, such as cytomegalovirus, herpes virus, hepatitis B virus and HIV.<sup>15</sup> Furthermore, by measuring levels of prostate-specific antigen (a component of semen) in the vagina, researchers demonstrated that female condom use during intercourse conferred high levels of protection against semen exposure (79–93%).<sup>16</sup>

Three well-designed use-effectiveness studies conducted in various field settings—an STD clinic in the United States,<sup>17</sup> brothels in Thailand<sup>18</sup> and agricultural communities in Kenya<sup>19</sup>—found that the female condom was at least as effective as the male condom in preventing STDs: Disease rates among women who were randomized to a female condom promotional campaign (and also had access to male condoms) were as low as, if not lower than, those among women exposed to a male condom promotional campaign. These findings lend strength to the conclusion that adding the female condom to the method mix does not cause an increase in STD incidence.

The critical public health question that remains, however, is whether promotion of both female and male condoms results in a higher level of protection than does promotion of the male condom alone, and hence in a decline in STD incidence. To offer this “added benefit,” the female condom has to contribute to a reduction in the total number of unprotected acts of sexual intercourse, especially among people at high risk. In countries and communities with a high STD prevalence, this group includes all sexually active people. Intervention programs would need to aim at increasing the proportion of episodes of sex that are protected among women and men who use male condoms inconsistently, or to target those who use protection rarely, if at all. We do not yet know whether promoting female condom use can increase levels of protected intercourse, or under what circumstances this might happen. The answers to these questions are inextricably linked to acceptability of the female condom, patterns of use and, importantly, the effectiveness of promotional strategies.

#### **ACCEPTABILITY AND USE**

Early studies of female condom acceptability reported high rates, ranging from 37% to 96%.<sup>20</sup> These studies, however, examined only short-term acceptability: Women were shown the condom and asked to try it and report one or two months later on their willingness to use it in the future. Two randomized intervention studies also demonstrated short-term uptake,<sup>21</sup> and one observational study<sup>22</sup> showed that introduction of the female condom led to an increase in the proportion of episodes of sex that were protected at three months, without decreasing the level of male condom use. Although these findings highlight the short-term demand for a barrier method that women can use, they do not necessarily indicate widespread acceptance.

Only a few intervention studies have tracked patterns

of female condom use over a substantial period—between six months and one year—while also examining overall levels of protection. These studies were conducted among populations at relatively high risk: female sex workers in Thailand,<sup>23</sup> STD clinic attendees in the United States<sup>24</sup> and Zambia,<sup>25</sup> and family planning clients in an HIV epicenter in the United States.<sup>26</sup> Interventions included individual counseling,<sup>27</sup> couples counseling,<sup>28</sup> group sessions<sup>29</sup> and structural changes.<sup>30</sup> Of these five studies, four showed an increase, albeit small, in the level of protected sex among participants who were offered female condoms.<sup>31</sup>

In one well-conducted study,<sup>32</sup> 1,159 STD clinic clients in Alabama received a female condom promotional message, were given the opportunity to practice insertion under the guidance of a nurse and were given take-home materials, including a promotional video to show their partner. After six months, the overall proportion of episodes of sex that were condom-protected (adjusted for women who had dropped out) was significantly higher, at 50%, than the 40% reported at baseline. Approximately 25% of episodes were female condom-protected. Male condom use did not decline, and most female condom users also used the male condom; those who reported 100% protection were most likely to be users of both methods. Although this study did not include a control group that received an intervention without the female condom, the approach used to account for the loss to follow-up makes it one of the strongest studies to show an added benefit of female condom promotion, at least over a six-month period.

The findings from “actual-use” studies are encouraging in that they offer evidence that effective female condom interventions will yield increased levels of protected intercourse. Yet the modest increases, as well as indicators of low uptake in the general U.S. population,<sup>33</sup> are disappointing to those, including ourselves, who believed that if women were offered a method over which they had greater control, they would adopt it readily. Hence, to identify approaches that will enhance long-term uptake, we need studies to evaluate a range of interventions, using randomized designs and long-term follow-up. Future interventions should include the two components that are now emerging as being critical to success: giving women ample practice in inserting the condom in themselves and helping them develop effective strategies to negotiate use with their partner.

Actual-use studies also demonstrate that the female condom is not going to be acceptable to all women. This point emerges in Kulczycki and colleagues’ short-term crossover trial, in which the majority of users rated the female condom as much less acceptable than the male condom on a wide range of features.<sup>34</sup> However, the study was conducted among a population of women who were already using highly effective contraceptives, and most of the women were in long-term relationships; therefore, the sample was unlikely to perceive the need for a woman-initiated barrier method. We agree with the researchers that means of protection against both pregnancy and STDs should be integrated into existing family planning programs to avoid stigmatizing

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the methods as disease prophylactics. Although efforts to make such methods appeal to a wide range of women are important, the potential of the female condom to increase protection does not depend on its being the method of choice for the majority of women, or on its being more popular than the male condom. Decades of contraceptive research show that expanding the range of options increases the likelihood that each woman will find an acceptable method.<sup>35</sup>

#### CHALLENGES TO ACCEPTABILITY

Short-term acceptability studies consistently reveal insertion difficulties for some users.<sup>36</sup> Proportions of users finding the female condom difficult to insert are as large as 33–50% in some studies.<sup>37</sup> Difficult insertion has been associated with less consistent use.<sup>38</sup> However, with practice and increased use, many of the insertion problems disappear.<sup>39</sup> In the Alabama study, the proportion of female STD clients reporting insertion difficulty decreased from 25% to 3% after women practiced inserting the condom in an anatomic model and then in themselves under nurse guidance.<sup>40</sup> To date, no study has assessed whether offering instruction, practice and problem-solving increases long-term use.

Another challenge relates to negotiation with male partners. The female condom was designed to give women greater control over their own protection, without having to rely on their partners to use a condom. Nevertheless, many studies confirm that partner cooperation is necessary for women to use the female condom successfully. Attitudes of men toward the female condom—obtained indirectly from women’s reports<sup>41</sup> or directly from men<sup>42</sup>—are generally positive. Men’s positive attitudes and willingness to use the method may even enhance its acceptability to women.<sup>43</sup>

At the same time, some women have cited their partner’s lack of acceptance of the female condom as a reason for discontinuing the method.<sup>44</sup> And some men may believe that the female condom and other female-controlled methods give women too much control over sex.<sup>45</sup> Therefore, the female condom is now usually referred to as “female-initiated,” rather than “female-controlled,” to reflect that its use is not fully in the hands of women.

The necessity to negotiate with men has led some public health proponents to conclude that the female condom does not resolve the basic inequality inherent in male condom use. Microbicide gels, on the other hand, are positioned as superior to the female condom, on the basis of the belief that women will be able to use these gels covertly. However, the difference between the two methods may not be as great as presumed: In microbicide acceptability studies, some women have reported that their partners would be aware of the gel or that they themselves would not want to conceal its use.<sup>46</sup>

Although the female condom alone cannot alter women’s control of their sexuality in the way that the pill or access to safe abortion did, female-initiated methods give women greater control than male-initiated methods. Qualitative

studies consistently show that women view female condom use as a means of enhancing their safer-sex bargaining power within the relationship, particularly when they obtain it in the context of an intervention focused on women’s sexuality and empowerment.<sup>47</sup> Men, however, need to be included in female condom interventions. To date, only one study has reported on men’s responses to various approaches that women used to introduce the female condom.<sup>48</sup> More studies are needed to identify the most effective negotiation strategies in different contexts. Interventions that target men directly are urgently needed as well, and may be especially effective in settings where men believe that they are responsible for introducing new protection methods.<sup>49</sup>

#### RESPONDING TO THE CHALLENGES

##### Role of National Promotional Campaigns

When evaluating estimates of method acceptability, it is important to also evaluate the social context—the infrastructure that supports and creates demand. Widespread promotion of the female condom has faced numerous social and political barriers—an important backdrop for the individual choices that women make. In the United States, these barriers include ridicule of the female condom in the press,<sup>50</sup> limited advertising and promotion, higher prices than those of the male condom, inadequate training of health care providers<sup>51</sup> and limited distribution within the public health system.

In contrast, governments in several developing countries and UNAIDS have attempted to design and implement comprehensive programs to strategically introduce the method into public health systems. The growth of programs in South Africa, Ghana, Brazil and Zimbabwe, as evidenced by increasing numbers of distribution outlets and increasing distribution volume,<sup>52</sup> reminds us that responses to the method elsewhere in the world may not mirror those in the West. These national promotional campaigns can help us to identify successful approaches that, by altering the social environment, may support female condom uptake. A major lesson is that introduction does not mean simply putting the female condom on the pharmacy shelf. Rather, it requires proactive, well-planned strategies to integrate the female condom into a country’s contraceptive method mix, ongoing monitoring systems and well-designed impact studies. Additionally, it is critical that governments and aid organizations ensure a sustainable supply of female condoms.

The experiences of 17 countries in which female condoms were provided by UNAIDS and the manufacturer, and where strategic introduction programs were developed, also provide useful lessons: Important elements of a successful program include training of health care providers, delivery of carefully crafted messages to an identified target audience, distribution within the public and private sectors, and assessment of the method’s impact beyond the “novelty phase,” which characterizes the introduction of any product.<sup>53</sup>

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### **Role of Advocates and Health Care Providers**

Strong grassroots advocacy and interpersonal communications have emerged as key elements of successful national programs. Experience from Zimbabwe illustrates the powerful advocacy role that women's organizations can play as catalysts in promoting the female condom. By mounting an intensive campaign that resulted in the collection of more than 30,000 signatures, these groups pressured the government to allow the importation of the female condom.<sup>54</sup>

Findings from a postmarketing survey in Zimbabwe also underscore the key role of health care providers and lay educators in increasing women's access to the female condom: More than half of women using this method had heard about it from a clinic, hospital or doctor's office.<sup>55</sup> Similarly, a Tanzanian study found that communication with a peer educator or provider had a direct positive impact on female condom uptake.<sup>56</sup>

Growing evidence points not only to the positive role that health care providers can play, but also to the possibility that they undermine promotional efforts and marginalize the female condom. Studies conducted in several national settings demonstrate that health care providers often have negative views of the method and lack information on how to promote it.<sup>57</sup> Because factors affecting female condom adoption emerged only after the method was demonstrated efficacious, medical providers and educators were inadequately prepared to counsel women about the challenges of female condom initiation and how to overcome them.<sup>58</sup> Without such preparation, clinicians and educators may contribute to frustration and abandonment of the method by women who have been inadequately instructed in its use. That, in turn, may reinforce providers' beliefs that the method is one of last resort or one for high-risk groups, such as sex workers.<sup>59</sup> Fortunately, training programs can change health care provider behavior around barrier methods, sexuality and, in particular, female condoms.<sup>60</sup>

### **Cost, Redesign and Reuse**

The higher price of the female condom, compared with that of the male condom, was identified as a barrier to sustained use of the method in some of the earliest acceptability studies both in the United States and overseas;<sup>61</sup> it continues to plague large-scale national female condom programs. Despite popular views that female condom acceptability is low mainly because of interpersonal factors, the method's high cost may underpin many challenges in female condom promotion.

In the West, the over-the-counter price of the female condom is approximately \$3.00, making it far more expensive than the male condom. Large numbers of male condoms are distributed free by public health agencies. Even when these agencies distribute free female condoms, funds allow for the supply of many more male than female condoms.

In the developing world, UNAIDS and the condom manufacturer collaboratively set a public-sector price of \$0.57, but the method remains more expensive than the male con-

dom. Without a continuous supply of free or affordable female condoms, which can be purchased and distributed by national and international organizations or which can be purchased directly by consumers, uptake is unlikely to increase.

Female condoms made of latex, which is cheaper than polyurethane, are currently in development and testing.<sup>62</sup> The potential for reusing the female condom also may address in part the challenge of affordability, at least in places where reuse is acceptable.<sup>63</sup> The condom can be washed with a bleach solution, dried and reused up to seven times without compromise to its structural integrity.<sup>64</sup> Still, the World Health Organization recommends single use,<sup>65</sup> thereby leaving the decision about reuse to individual governments, providers or users.

### **RECOMMENDATIONS**

There is reliable evidence from many sources that effective promotion of the female condom is possible. To realize the potential for the female condom to contribute to increased levels of protection, consistent efforts to identify the most effective individual and structural interventions are needed. We encourage researchers to continue conducting behavioral intervention studies to identify the most effective promotional strategies. We also urge national and international public health agencies to commit to supporting the design, implementation and thorough evaluation of programs to integrate the female condom into existing prevention initiatives.

#### **Intervention Development and Testing**

When designing interventions, program planners should consider the following aspects:

- selection and characterization of target populations of varying risk—within a country as well as cross-nationally—to provide information about the added benefits of the female condom in reducing rates of unprotected sex;
- identification of effective intervention features—how a program is promoted and delivered, and its format, intensity and duration—that lead to adoption of the method, alone or in conjunction with male condoms; and
- use of biological outcome measures when possible, as well as follow-up periods that are sufficiently long to allow an exploration of patterns of initial use, adoption, continuation and discontinuation.

#### **Support for Large-Scale Programs**

Widespread promotion of the female condom will help to destigmatize the method and normalize it as a potential method for all sexually active women and men, not just those who engage in high-risk behaviors or are living with HIV or AIDS. To develop large-scale female condom programs and ensure an adequate supply, we urgently need support from the public and private sectors and from international donor organizations. These programs should include the following elements:

- identification, through focus groups, interviews or mar-

ket surveys, of the best ways to position the female condom in the target population;

- development and dissemination of educational materials through public service announcements and direct distribution to women and men; and
- training and ongoing technical support for health care providers and prevention counselors and educators, so that they can address preconceived biases, technical aspects of use, partner negotiation and problems in obtaining the method.

### Program Evaluation

Large-scale female condom programs should include a well-designed postimplementation evaluation, with components that assess the following:

- how well the program was implemented by health care providers and other personnel, and what factors influenced its effectiveness;
- the “reach” of the program—how many people were exposed to public service announcements or one-to-one promotion; and
- over time (at least one year), proportions of exposed people who accepted and adopted the method, and user and program factors that predict uptake.

### CONCLUSION

The female condom represents an important addition to the method mix, but awaits adequate empirically driven promotion and evaluation. Efforts to resolve the challenges posed by the female condom will offer the best chance to realize its potential as a female-initiated barrier method and lay the groundwork for the promotion of other female-initiated barrier methods for HIV prevention, such as microbicides and the diaphragm, once they are demonstrated efficacious. In the meantime, we need every tool we have, however imperfect each may seem individually.

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