

# The Female Condom: Tool for Women's Empowerment

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## ABSTRACT

International and US experience with the female condom has shown that the device empowers diverse populations of women, helping them negotiate protection with their partners, promoting healthy behaviors, and increasing self-efficacy and sexual confidence and autonomy. This commentary reflects on some approaches that have been taken to study empowerment and makes several observations on the political and scientific initiatives needed to capitalize on this empowerment potential.

Women's interest in the female condom indicates a need for more women's barrier methods to be made available. For some women, cultural proscriptions against touching the genitals may create initial hesitancy in trying these methods. But the disposition of regulatory agencies and the attitudes of health care providers has unfortunately exaggerated this reticence, thereby effectively reducing access to these methods. Also, lack of important detail in clinical studies restricts our capacity to introduce the female condom, or similar methods, under optimal conditions.

Future trials should prioritize community-based designs and address a range of other critical health and social issues for women. Women's need for HIV/AIDS prevention technologies remains an urgent priority. Both political and scientific efforts are needed to realize the public health potential embodied in the female condom. (*Am J Public Health*. 2000;90:1377-1381)

With the benefit of several years of research and program experience with the female condom, we may now begin to take stock of what we have learned in the field, especially as it concerns the empowerment of women in protecting their reproductive health and, more generally, making decisions and negotiating protection within their primary or other sexual relationships. In this commentary, I share my reflections—based on data from the international and national literature and on personal research and program experience—on the potential impact of the female condom on prevention of HIV and other sexually transmitted diseases (STDs) and research on family planning. Also, I suggest fruitful directions for future efforts involving this still underused technology.

After providing a brief description of available data on female condom acceptability and efficacy, I discuss 4 themes. First, the female condom has been shown to empower women to negotiate protection with male partners and to practice healthy behaviors. Second, regulatory agencies and health care providers often constitute larger obstacles to increased women's autonomy in protection than does women's own reticence to master new knowledge and skills. Third, describing the full "exposure"—that is, the nature of the intervention or approach—in female condom clinical research will enhance the potential public health impact of the device. Finally, community-level and group interventions are best suited for introduction of the female condom.

### ***The Female Condom: Efficacy and Acceptability***

The female condom was approved by the Food and Drug Administration (FDA) in 1993 as a method to protect against unplanned pregnancy as well as STDs, including HIV/AIDS. Some 2 dozen studies conducted worldwide have indicated an important public health role for this method.<sup>1</sup> A recent randomized controlled trial among Japanese family planning clients demonstrated pregnancy rates of 0.8% among consistent/correct users and 3.2% among "typical" users.<sup>2</sup> Earlier studies among couples in the United Kingdom<sup>3</sup> and couples in the United States and Latin America<sup>4</sup> had estimated much higher pregnancy rates; number of years of research and program experience with the product, training and disposition of health educators or providers, and population differences in sexual activity probably all

played a role in producing these discrepant rates.

Yet, even these earlier data on pregnancy rates allowed for an estimated 90% risk reduction potential against HIV infection.<sup>5</sup> A randomized trial conducted in Thailand brothels revealed that STD incidence was reduced by 23% among prostitutes using both female and male condoms above and beyond the reduction observed with male condoms only.<sup>6</sup> An observational trial of Zambian serodiscordant couples indicated that couples using both female and male condoms reported more than twice the level of protected sex acts as those who used only the male condom, for up to 1 year after counseling.<sup>7</sup>

Two additional observational studies have shown significant positive changes in behavior among US STD clinic clients offered the female condom and followed for 6 and 12 months.<sup>8-10</sup> The mean proportion of protected sex acts among women using the female condom at 6-month follow-up was nearly triple that at baseline in one of these studies.<sup>10</sup> The generation of additional effectiveness data on STD/HIV and contraception will continue to be important. But additional effectiveness research will be valuable only to the extent that it involves epidemiologic studies of actual use with end points of pregnancy, STD, or HIV. Surrogate outcomes—the subject, for example, of a recent abstract providing uncontrolled data on a new molecular marker for semen exposure with no concurrent pregnancy or disease data<sup>11</sup>—must now be deemed insufficient, given the quality of already-available data.

Because of the favorable clinical and laboratory results to date, many policy-making bodies and public health agencies internationally, as well as community-based groups and individual practitioners both internationally and in the United States, promote the female condom as highly effective for its intended uses. Their rationale is based on the same blend of scientific data and commonsense reasoning used for the male condom at the time of its labeling against HIV infection in the mid-1980s, when the need for HIV protection options was urgent but the quality and quantity of available data were less than ideal. Among women, the

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urgency for STD/HIV protection options remains largely unabated since the early days of the epidemic.

Small US trials of female condom use among drug-using women<sup>12,13</sup> or other women at high risk<sup>14-17</sup> and numerous international trials among varied populations<sup>1</sup> have indicated a high level of interest in the method and feasibility of use in these populations. Among the best-liked features of the female condom, both in the United States and worldwide, are (1) the fact that women can place it autonomously and can trust that it is not torn or otherwise sabotaged by the partner, (2) the high level of protection it can provide when used correctly, and (3) its soft and lifelike feel. Among the least-liked features are (1) the need to practice insertion and to use the device several times before mastering it, (2) the fact that it can be seen by the partner, and (3) for some, the inner ring.

Although some women master proper use of the device immediately, it is more common to require—as with a male condom—repeated practice and caution during early use. Some research has shown that for infrequent users, the learning period probably extends beyond 6 months.<sup>9</sup> A continuing challenge for intervention programs is helping women maintain their motivation to continue practicing until use becomes routine.

As a result of contextual variables, such as personal and partnership characteristics, preferences for the female and male condom will vary. Neither the female condom nor the male condom is effective in all instances; decades of experience in the contraceptive field have confirmed that “perfect” methods do not exist. On a research level, as noted, more data on the female condom would be helpful to specify not only levels of protection against HIV/STD but also conditions, such as enhanced counselor and client training, that favor the minimization of user error. On a program level, the cost of the device is often cited as its main drawback.<sup>18</sup>

Without minimizing the female condom’s cost, especially in relation to the male condom and especially in resource-poor communities, countless analyses have shown that in the public health domain, prophylactic efforts always outweigh in value an exclusive focus on treatment.<sup>19</sup> Development of an HIV vaccine, microbicides, and drug prophylaxis to prevent vertical transmission of HIV rests on the premise that avoiding HIV infection is a much less costly option than treatment. An oft-ignored issue here is governmental will and resource allocation. Subsidization of the female condom through international partnerships has been shown to vastly improve access to the method<sup>20</sup>; in the United States, however, this strategy is unfortunately confined to local efforts, and even those are few in number.

An additional aspect of the cost of the female condom is its reuse. Although progress has been slow in defining conditions of reuse, it appears that new guidelines should soon be available. Preliminary research indicates that simple washing with soap and water, up to 10 times, may not harm the structural integrity of the device.<sup>21,22</sup> Further data on both structural integrity and microbial retention are forthcoming.<sup>23</sup>

## Empowerment

The sum of the evidence from dozens of international trials on the female condom now demonstrates a certain “empowerment effect” among women who are counseled and trained to use the device.<sup>7-9,14,15,17,24-28</sup> When the female condom is introduced in the context of concurrent male condom availability, there is a synergistic or greater-than-additive effect. This consists of both a direct protection effect from women’s use of the female condom and an indirect effect that increases *male* condom use owing to women’s use of female condoms as a negotiation tool.<sup>6-10</sup> The outcome is greater protection overall, whether measured in behavioral change or in disease reduction, as well as greater protection from male condom use than is seen when only male condoms are provided to women.

Thus, according to a World Health Organization monograph, “The female condom has been shown to contribute to women’s sense of empowerment, especially if supported by education and informational activities.”<sup>11(p36)</sup> Authors of a 4-country female condom study conducted under the auspices of the World Health Organization and the Joint United Nations Programme on HIV/AIDS (UNAIDS) found that

the female condom may be used as a tool in the development of women’s sexual confidence and autonomy that may in a small way open up the possibility of greater equality in sexual relations between men and women. Its introduction can increase women’s sense of self-efficacy and self-worth in ways that have effects beyond the immediate issue of condom use.<sup>26(p287)</sup>

Although, at least in the United States, a fair degree of skepticism appears to exist about these potential effects, such a relationship has been seen before; gains in control over reproductive capacity and reproductive health have historically resulted in tremendous advances in social and economic status for women. Writers on women’s status and health have long made the link between seemingly separate domains of women’s lives, urging us against reductionist thinking that separates safer sex behavior from other behaviors, negotiations, and norms.<sup>18,29-32</sup> Some have attempted to illustrate graphically how increasing autonomy in one domain of a woman’s life has a potential impact

on many others.<sup>33</sup> Also, community psychology theories on empowerment articulate the various mechanisms that might have a bearing on what we have observed as a result of diverse female condom interventions.<sup>34,35</sup> While some types of knowledge do not necessarily lead to significant changes in empowerment (i.e., it is often noted that simply knowing more about HIV does not necessarily lead to behavior change), an increase in knowledge and skills in certain domains (e.g., the body) may result in tremendous gains of this type.<sup>25</sup> Certainly, no technology can substitute for making real inroads in overcoming society’s sexist practices, its oppressive gender role stereotyping, and its unhealthy gender-based power differentials. Yet, women’s perception of empowerment and their ability to act on their own behalf, and with a sense of entitlement to good health, all do seem to be positively influenced by an increased sense of awareness of and connectedness to their own bodies.

The development of a theoretic framework for this phenomenon will surely be part of the work of the new decade. Empirical studies have clearly shown that rather than adding to the burdens of what women normally need to negotiate with their partners and raising the risk of emotional or physical retribution, the female condom changes the dynamics of the dyad.<sup>17,24,26</sup> Previously, in the face of partner refusal to use a male condom, women’s sole option for self-protection was to refuse sex, and some succeeded. But for others this strategy was problematic; for example, it set up frank antagonism in the couple, with the possible outcome of violence. Women now have a negotiation tool that, in many circumstances, can be used in ways that are not threatening (and may indeed be soothing) to their partner.

An in-depth qualitative study of reactions to the female condom among men and women in Kenya and Brazil showed that the female condom, introduced in group sessions, “allowed them to talk openly about issues of sexuality that were formerly cultural taboos outside the bedroom and except with partners. The women observed that they became more open about enjoyment of sex, claiming that with the female condom it was more pleasurable.” The female condom “increased their sense of ownership over their bodies and their sexuality.”<sup>27(p35)</sup> Other evidence points to the special freedom women feel when they hold “their own” condom. A study subject put this feeling bluntly: “Once I put this in me, what can he do?”<sup>28</sup>

In a community study (n=93) conducted in southern France, female subjects (30% of whom were from northern African and 9% from western and southern Africa) reported the ability to finally “master” their own protection.<sup>36</sup> Gollub et al.<sup>9</sup> found that as a result of using the female condom, 32% of subjects

drawn from an STD clinic felt more at ease about their bodies (68% reported no difference), and 14% felt more comfortable about undergoing a Papanicolaou test.

The female condom, in exposing women's lack of knowledge about their bodies, is slowly bringing about a new awareness among both women and policymakers that women's vulnerability to infection and poor health is one outcome of our society's neglect of systematic provision of frank, detailed, practical, and positive information and education about the body and about sex. In the resulting information void, women have been distanced from their bodies. In group intervention sessions, women commonly report feelings of shame, embarrassment, and lack of control over their body, yet this is the same body that we are asking women to be proactive about protecting. We must instill in girls a knowledge of and pride in their body—and the pleasure and joy it can give—and create a sense of entitlement: to choice, to good health, and to respect. HIV/STD infection rates are expected to be reduced as one of many positive outcomes of such a "body empowerment" approach.<sup>28</sup>

## Obstacles

Women often show tremendous initial interest in the female condom, but this interest is not necessarily sustained over time.<sup>8,14,36,37</sup> A common interpretation is that the device has a certain "novelty effect" that fades. Less attention is directed toward the existence of such interest in the first place. Long-term use of the female condom seems to be more likely among women who perceive that they are at risk of HIV and other STDs, but women of quite varied profiles have enrolled in female condom studies or asked to try the device in community programs.<sup>1</sup> These include women who have previously used barrier methods and women who have not, women early in their sexual careers and women who are not, and women from various diverse cultures around the world. If there is any message here, it is the need for a great many more choices in barrier methods for women.

Much has been made in the media and in the policy and research literatures of the disagreeable "look" of the female condom (e.g., that it is "bulky" or "ugly"). Some have cited women's "dislike" of touching themselves as a formidable disincentive to trying the device. These arguments paint a rather bleak picture of the potential impact of the method, or any like it. In some settings, "hypothetical acceptability" studies (i.e., involving no actual use of the method) have dominated the dialogue about the female condom, even though research on contraceptive methods has shown that most methods are unacceptable when described or

shown in initial surveys,<sup>38</sup> and even though substantial actual use data are now available. In practice, it is a common finding that when introduced to the female condom, women across all cultures overcome whatever reticence they may have, if any, to touch their own genitals. This reticence appears to be overwhelmed in many cases by women's need for more information about their own bodies, along with their drive to find more acceptable contraception or effective disease prevention. In an Indian trial of the diaphragm, women reported that having to insert the device around coitus (and remove it soon afterward) was among its best-liked features.<sup>39</sup>

Health care providers and policymakers all too often exaggerate cultural taboos around the body and erect additional obstacles to women's access to protection; I have been told on numerous occasions that US women of particular racial/ethnic backgrounds (e.g., African American, Hispanic) "will not use the female condom." National and international field experience has shown otherwise. In fact, experience suggests that, for some women, the "draw" in a method such as the female condom is actually the opportunity to become comfortable with and learn more about their bodies, even though these personal goals may not be explicitly articulated as such in a trial (or articulated retrospectively after the trial).

We have underestimated, as a society, the value of contraceptive and disease control methods that are user dependent, require an understanding of the genitals and reproductive tract, and, importantly, have no systemic side effects.<sup>39-41</sup> Work among injection drug users and other women in situations of extreme dependence and oppression tends to suggest a dramatic shift in perceptions—a newfound sense of autonomy—when women handle the female condom for the first time.<sup>14,17</sup> The female condom becomes, then, an instrument to enhance self-knowledge of reproductive anatomy. The message sent by the enthusiastic reception of the female condom in many settings is that women welcome the opportunity to be proactive about their own bodily welfare and to reverse lifelong ignorance about the body.

The high level of initial interest in the female condom also implies the need for a greater variety of barrier methods. Out of step with women's demonstrated enthusiasm for their own barrier methods, the FDA has not kept pace in terms of supply. There have been no barrier methods approved since the female condom, even though the FDA has supposedly "streamlined" its regulatory process so that such devices would be spared the usual plodding bureaucratic pace.<sup>42</sup> Several new methods have been proposed for approval in the interval; some even predate the female

condom. The "Femcap," for example, a cervical cap that began the regulatory process on the heels of the female condom 7 years ago (and that operates in much the same manner as the Prentif cervical cap, approved since 1988), was still not approved at the time of this writing (A. Shihata, oral communication, July 2000).

Part of the problem is that in 1976 the FDA, in response to demands of women's health advocates and in an attempt to shield women from harm following the Dalkon shield disaster, tightened device regulations.<sup>43</sup> But the new regulations made no distinction between internal devices with a real risk of posing harm, such as an intrauterine device placed inside the uterus by a physician or nurse practitioner, and other devices, such as barrier devices used in the vagina that carry the same risk level as the well-known contraceptive diaphragm. The amendments classified new barrier methods submitted for approval, such as cervical caps, as "significant risk devices." In addition to a generous serving of paternalistic concern about women's "fragility," this lack of critical distinction between internal contraceptive devices and vaginal devices that can protect against STDs has paradoxically caused more difficulty in the obtaining of FDA approval of these simple vaginal devices. Literally, the FDA is "protecting" women to the point of denying them protection.<sup>44</sup>

Women's advocates' gains during the 1970s and 1980s, in demanding greater safety controls on new medical technologies with serious potential side effects, have thus turned into losses when it comes to simple but potentially lifesaving devices, such as new contraceptive diaphragms (which also block the cervix and reduce the risk of some common STDs), that are now held up in a regulatory mire. The expediting mechanism of a decade ago<sup>42</sup> was intended to correct for this possibility, yet it is clearly not being applied. Increasing the diversity of available barrier methods is crucial to improving women's reproductive health, even as we make progress on an HIV microbicide. The FDA should be held accountable by the public health community for not playing a more active role in helping to abate the HIV/STD epidemic among women.

A sense of urgency also seems to escape the US Centers for Disease Control and Prevention (CDC) in regard to the issue of the female condom. Unfortunately, the CDC lags considerably behind other international public health bodies in promoting this vital protection method. The CDC has so far not included the female condom in any of its reviews of barrier protection against HIV and other STDs. This has contributed to the undermining of confidence in this method and to its slow uptake by local health agencies, the consequences of which are restricted gains in women's HIV

prevention at a time when the proportion of women's AIDS cases continues to grow annually and incidence rates are dropping at a much-reduced pace relative to rates among men.<sup>44</sup>

## Exposure

Another lesson that can be drawn from work already accomplished is that because of the potential public health impact of the female condom, investigators and program managers have a duty to describe in detail the nature of the educational intervention or approach used to introduce it. Such information would include (1) length and context of counseling (couples, individual, group); (2) training of counselors (How long were they trained? What kinds of experience or other qualities were required? What processes and components of training were used? Did on-site staff not involved in the study undergo training?); (3) information, education, and counseling materials developed and used (video, audio, brochures, charts, anatomic models); (4) number of educational sessions; and (5) involvement of community groups.

Studies of the female condom (or other women's barrier methods) appear to have distributed themselves into "simple" acceptability or effectiveness research vs "intervention" research. In such a classification system, only the "intervention" studies are expected to describe their training and counseling methods and the educational materials used. The fallacy of this notion is that the conditions of introduction of any such device are just as much to be considered the "exposure" as the device itself. We have long known, from the women's health, contraceptive, and "quality-of-care" literature, that details involving care and education and the provider-patient (or provider-client) relationship can have a tremendous impact on the overall client experience and user preferences.<sup>38,40,41,45,46</sup>

Studies of women's barrier methods can no longer afford to follow the bare style of the classical randomized clinical trial model; we lose valuable and urgently needed opportunities to learn from each other about what works and what does not and to make progress in integrating these lifesaving tools into safer sex practices. Indeed, in the 4-country female condom study cited earlier,<sup>26</sup> the investigators attributed the "empowerment" effect in large part to the *intervention* created around the device rather than to the device itself: a vision of the female condom as a "pretext" for inducing discourse and interaction.

## Interventions

From work conducted to date, it appears crucial for research efforts to involve women's

and other community groups from the start, benefiting the study (better follow-up, more valid data), the female subjects (involvement of groups constitutes a continuing resource after study termination), and the community (establishment of new models of care for women, along with new sex and health norms).<sup>44</sup> Models of community-based HIV research are slowly becoming available.<sup>47</sup> Also, we must recognize the particular value for women of group counseling, which has been used in most of the recent successful HIV/STD behavioral interventions for women.<sup>48-51</sup> This approach to education and skill building is cost-effective, may provide more creative ways of problem solving, and may more efficiently advance the goals of peer support. Also, it may represent a more powerful (yet natural) mechanism for changing group norms than classical individual counseling, especially in instances in which a client or patient has reason to feel stigmatized in facing a health professional alone. Female condom counseling, because of the knowledge, skills, and insights it can impart, lends itself naturally to group counseling and community-based interventions.

Critical reviewers of women's health interventions and researchers themselves have noted that conventional cognitive-behavioral theories often do not "fit" well for women,<sup>52,53</sup> perhaps because they often ignore the underlying dynamics of women's risk. For women, improving "perceived control" will not increase safer sex behaviors if the real control continues to reside in the partner, fueled by societal norms. These types of behavior models, like "biomedical models" of public health issues, have been criticized more generally for being too individualistic and not relating sufficiently to society's structural barriers to good health.<sup>43,54-56</sup> Models based on concepts of "community empowerment" or community organizing, and designed at a community level, have greater relevance in work with women around the world.<sup>18,34,35,56</sup> This is particularly true for women at high risk of HIV infection, who are often isolated and without resources and who may benefit greatly from a sense of group identity and collective strength.<sup>17,57</sup> Of course, communitywide work implies the involvement of both men and women; this is critical to changing society's structural causes of poor health for women. But men's involvement need not—and, indeed, should not—negate the deliberate creation of circumstances and spaces in which women can share collectively with each other. Abundant anecdotal evidence testifies to the fact that women enrolled in group interventions prefer that work with both sexes occur as a *supplement* to and not a *replacement* for women sharing with each other.

Finally, international work demonstrates that the best female condom interventions have

addressed a range of other crucial issues: women's reproductive anatomy and overall health, sexuality, pleasure, violence, communication and family issues, and so forth. These interventions can have positive effects on multiple areas of a woman's life, as well as on the family and the community (and thus such interventions are successful beyond the narrow indices of female condom use and acceptability). They are also the most responsive to women's needs in intervention settings.<sup>1</sup>

## Conclusions

Evaluations of research projects and community interventions with the female condom, taken as a whole, have described unexpected changes in sex dynamics, women's self-esteem, and the ability to negotiate safer sex. A consistent and welcome finding is that women at highest risk of HIV infection appear to show the greatest initial interest in the method. Nevertheless, women with other risk profiles and backgrounds also demonstrate much initial interest, and the device should be made available (as is the male condom) to these women as well. We can enhance the salutary effects that have been demonstrated to occur with female condom introduction, and expand their reach to a larger public, by designing and documenting quality counseling/educational approaches and materials in all future trials of this or other women's barrier methods, developing cross-disciplinary measures of women's empowerment to use in these trials, and providing greater choice and diversity in women's barrier methods.

Bringing about greater choice in women's barrier methods will mean militating for regulatory changes. The potential public health impact of integrating the female condom and other such methods into national reproductive health programs is substantial and represents an opportunity for diminishing the present HIV/STD burden, one that was completely unanticipated 10 years ago. Few HIV/STD prevention approaches for women have reported news this good. Considering women's dire need for HIV/STD prevention strategies, we must now move without delay in applying what we know. □

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