

A review of the effectiveness and acceptability of the female condom for dual protection

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Abstract. The female condom remains the sole female-initiated method of dual protection against unintended pregnancy and sexually transmissible infections (STIs), including HIV. We reviewed published data on the effectiveness and acceptability of the female condom for protection against pregnancy and infection. Overall, use of the female condom is low and several barriers hinder the wider adoption of the use of the method. Research on effectiveness has focussed on pregnancy, STIs and biological markers of semen exposure. Although the data available suggest that female condoms (or a mixture of female and male condoms) may provide similar degrees of protection against pregnancy and STIs as do latex male condoms alone, this conclusion has not been demonstrated and thus comparative research is urgently needed.

Additional keywords: FC1, FC2, Femidom, Reddy Condom, Woman's Condom.

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Three decades into the HIV epidemic and despite ongoing research on vaccines and microbicides, the female condom is the sole female-initiated method of dual protection against unintended pregnancy and sexually transmissible infections (STIs) including HIV. Dual protection methods are clearly needed. Although the HIV epidemic initially affected mainly males, today, women comprise about half of all cases globally and nearly 60% of all cases in sub-Saharan Africa.¹ In some areas in Africa and the Caribbean, the prevalence of HIV in young women is up to six times higher than that in young men.¹ Women are at higher risk for infection for a range of reasons, including biological, sociocultural, economic and political factors. The risk of male-to-female transmission of HIV in high-income countries has been estimated to be twice as high as in the other direction.² At the same time, >100 million women in developing countries are estimated to have an unmet need for contraception, further compounding the reproductive health issues women face.³

Because women may lack control over sexual and reproductive decisions as a result of gender inequities, risk reduction strategies focussing on abstinence, partner reduction and male condom use can be challenging, if not impossible, for many women, especially those in married or partnered relationships. For example, 60–80% of HIV-positive women in sub-Saharan Africa are estimated to have contracted the virus from their husbands.⁴ Many issues contribute to low use of the male condom, but a key factor is men's unwillingness to use a product that interferes with their sexual pleasure. When faced with male partner resistance, few women are able to negotiate

use of this front-line prevention technology. The present review describes the types of female condoms available, reports on the studies performed on the effectiveness of the female condom against pregnancy and STIs, and gives an overview of the acceptability of the device and barriers to its use.

Types of female condoms

The United States Food and Drug Administration (USFDA) approved the first female condom, FC1 (Female Health Co., Chicago, IL, USA), for use as a contraceptive in the US in 1993. The product label also includes indications for HIV/STI protection in cases where the latex male condom will not be used. The FC1 is a loose polyurethane sheath about the same length as the male condom with a flexible ring at both ends. The ring at the closed end is used for insertion and for holding the condom in place in the vagina. The ring at the open end remains outside the vagina, where it covers part of the external genitals and anchors it in place. Because the FC1 was the first female condom approved for use by a regulatory body, most research conducted to date (and most research cited in this article) involves this type of female condom.

The Female Health Co. launched a second-generation female condom in 2005. The FC2 is similar to the FC1 in effectiveness and acceptability, but is made from synthetic latex, which reduces manufacturing cost and the crinkling noise that consumers complained about with the FC1. Since approval of the FC2 by the USFDA in 2009, production of the FC1 has stopped. The FC2 holds a CE mark, approving it for

distribution in the European Union, and has been recommended for procurement by United Nations (UN) agencies based on review by the World Health Organisation (WHO) Female Condom Technical Review Committee of its safety and effectiveness data.⁵ Today, the FC2 is sold commercially in ~20 middle- and high-income countries, and is available in the public sector in over 100 countries.

Two additional female condoms were developed in India. Both have CE approval and are distributed in several countries. The Reddy Condom (Medtech Products, Chennai, India), introduced on the market in 2002, is made of latex rubber and has a soft polyurethane sponge at the end of the pouch to aid insertion and to stabilise the pouch during sex. A firm, flexible outer ring at the open end of the pouch holds the Reddy Condom against the labia. The Cupid female condom (Cupid Ltd, Mumbai, India) is a scented, natural rubber latex device with an octagonal outer frame, and a sponge for insertion and maintaining the device in place. Neither the Reddy nor the Cupid condoms have been approved by the WHO Technical Review Committee and thus are not recommended for public sector procurement by donors.⁶

The Program for Appropriate Technology in Health (PATH) (Seattle, WA, USA) developed the Woman's Condom with input from user groups in four countries.^{7,8} Made of a thin, soft polyurethane film, the device consists of a pouch, which is packaged inside a film capsule that the woman inserts into the vagina. Once inserted, the cap dissolves and the pouch unfolds inside the vagina. Four small hydrophilic foam shapes on the outside of the pouch gently adhere to the vaginal wall and hold the condom stable during use. PATH licensed the technology for the Woman's Condom to Dahua, a manufacturer in China, in 2008. The product was approved for CE marking in late 2010 and was approved by the Shanghai FDA in early 2011. Clinical trials to secure USFDA approval for the device currently are underway.

Other female condom products have been developed that are available on a regional or country-level basis. For example, the Phoenurse female condom (Condom Bao Medical Polyurethane Corp; Tianjin, China) is available in China.⁹ Also, the Natural Sensation Compania Ltd (Bogota, Colombia) manufactures and distributes the Panty Condom, which is a woman's panty with a replaceable panty liner containing a condom made of a synthetic resin. The condom is inserted by the man's penis, and the panty can be reused with new condoms for additional coital acts. This

device is marketed in several Central and South American countries.

Effectiveness

Biologic plausibility

Data on the effectiveness of the female condom against pregnancy and disease comes from several types of sources. First, an *in vitro* study demonstrated that the FC1 is impermeable to cytomegalovirus and HIV,¹⁰ and postcoital water leak tests of used condoms from a preliminary study suggest that the FC1 has a lower rate of leaks than male condoms.¹¹ The female condom covers both internal and external genitalia, which may prove useful for preventing infections that are spread primarily by contact with skin or mucosal surfaces (e.g. herpes simplex virus, syphilis, chancroid and human papillomavirus) rather than by genital secretions. However, no studies to date have focussed on these infections.

Pregnancy outcomes

Studies also have measured pregnancy rates during female condom use. The three published clinical trials on the contraceptive effect of the female condom have documented a wide range of pregnancy rates (Table 1). The earliest trial, which was conducted among 106 women in the United Kingdom, reported a 12-month probability of pregnancy during typical use of 15%.¹² A study among 221 women in the US and 107 women in Latin America found 6-month probability of pregnancy rates during 'typical' use of 12.4% and 22.2%, respectively, and during 'perfect' (i.e. consistent and correct) use of 2.6% and 9.5%, respectively.¹³ Most recently, a study of 190 women in Japan found 6-month probability of pregnancy rates during typical use of 3.2% and during perfect use of 0.8%.¹⁴

Based on pregnancy data, the product labels for the FC1 and FC2 in the US specify 1-year typical and perfect use pregnancy rates of 21% and 5%, respectively, for the FC1 compared with 18% and 2%, respectively, for the male condom.¹⁵ No studies conducted to date permit a statistical comparison between the two devices. In the absence of a randomised controlled trial comparing the female and male condoms, their relative effectiveness is unknown.

Table 1. Studies of the effectiveness of the female condom against pregnancy

Study	Study population	Study design	Study groups	Outcomes
Bounds <i>et al.</i> (1992) ¹²	Women in the United Kingdom	Prospective, noncomparative trial	Single arm of 106 women	12-month probability of pregnancy during typical use 15%
Farr <i>et al.</i> (1994) ¹³	Women in the US and Latin America	Prospective, noncomparative trial	Single arm of 221 women in the USA and 107 women in Latin America	6-month probability of pregnancy among women in the USA and Latin America, respectively • Typical use 12.4%, 22.2% • Perfect use 2.6%, 9.5%
Trussell (1998) ¹⁴	Women in Japan	Prospective, noncomparative trial	Single arm of 190 women	6-month probability of pregnancy • Typical use 3.2% • Perfect use 0.8%

STI outcomes

A limited number of comparative studies have evaluated the effectiveness of the female condom against STI acquisition (Table 2). Two studies evaluated the female condom by assigning women into a study arm to use the method. In the first study, women with trichomoniasis attending clinics in four US cities were treated and enrolled into either a group to use the female condom ($n=54$) or a control group ($n=50$), depending on their willingness to use the female condom.¹⁶ Reinfection rates after 45 days were similar between groups. However, the interpretation of these study findings is limited by the small study size and the nonrandomised study design.

In a study conducted in an STI clinic in Philadelphia, female patients ($n=1442$) were assigned to receive counselling and provision of either the female condom or the male condom, depending on the week of their initial visit.¹⁷ Women who returned to the clinic during the 6–12 months of follow-up (depending on the timing of their enrolment) were tested for gonorrhoea (*Neisseria gonorrhoeae*), chlamydia (*Chlamydia trachomatis*), early syphilis and trichomoniasis. Women in the female condom group were less likely to have at least one of these STIs than those in the male condom group, although this difference was not statistically significant (odds ratio, 0.8; 95% confidence interval, 0.6–1.0). Study limitations include the lack of true randomisation and, because of the wide availability of male condoms outside of the research setting, the unknown frequency of male condom use among women assigned to the female condom group.

Three additional studies evaluated the STI rates among women who were given either the female and male condoms or else the male condom only. Two of these trials used a cluster randomisation design. In the first study, brothels in four cities in Thailand were randomised to receive either counselling on male condom use ($n=37$ brothels) or hierarchical counselling on the use of male condoms backed up with female condoms for times when male condoms could not be used ($n=34$ brothels).¹⁸ Sex workers in both groups were supplied with their assigned condoms and asked to return for follow-up visits every 2 weeks for 24 weeks, at which time they were tested for gonorrhoea, chlamydia, trichomoniasis and genital ulcer disease. Women in the group receiving female condoms had a nonsignificant reduction in the incidence of the combined STI outcome compared with those in the male condom only group (2.8 and 3.7 per 100 person-months, respectively; $P=0.18$).

The second cluster-randomised trial matched six pairs of plantations in Kenya to receive community-level promotion, individual counselling and supplies of either the female and male condoms, or the male condom only.¹⁹ Women located in the plantations receiving the female and male condom intervention ($n=969$) and the male condom intervention ($n=960$) were tested for gonorrhoea, chlamydia and trichomoniasis after 6 and 12 months of follow-up. No differences in the combined STI outcome were found between the two groups. Subsequent analysis, though, revealed that provider bias limited the distribution of the female condoms in the women assigned to the group with both condom types.²⁰ Finally, in a nonrandomised study, women attending an STI clinic in the US were assigned to use either male condoms (if the woman

was uninterested in the female condom) or female condoms, with male condoms as a backup method.^{21,22} Among women who reported consistent condom use, the rate of gonorrhoea and chlamydia appeared to be similar for those who mixed both female and male condoms compared with those who used only male condoms.

In summary, only two randomised controlled trials have evaluated the effectiveness of female condom use against STI acquisition.^{18,19} Both were cluster-randomised trials that compared groups assigned to female and male condom use in comparison to male condom use alone. Although neither found a statistical difference between groups, they could have been underpowered to find a difference. Furthermore, because both groups received the male condom, any differences in the effectiveness of the female condom could have been masked if the use of the female condom was low.

Participant reports of condom failure modes

Studies also evaluate the effectiveness of female condoms based on participant reports of condom failure modes. The WHO recommends the use of standardised measures of female condom functionality, which focus on breakage, slippage, misdirection (penis entering between female condom and vaginal wall) and invagination (pushing external part of female condom into the vagina).²³ Estimates of total clinical failures (i.e. malfunctions occurring during coitus or withdrawal that put women at risk of exposure to semen or pathogens) for the female condom range from 2.5% to 25.1% of acts.^{7,9,24–30} Many of these studies preceded the development of the WHO's standardised measures, making comparison across studies difficult. The wide variability in failure rates could be attributed to differences in the definitions used for clinical failure as well as differences between studies in data collection procedures, study populations (including participants' prior experience with condoms), study counselling on condom use, number of condom uses assessed and degree of study attrition. For example, study populations could differ substantially in their subjective assessment of condom failures or in their propensity to report failures.³¹

Studies of male condoms also have found wide ranges in clinical failures. Measures of condom failure might be most informative for comparing condom types within a trial with a randomised design. In randomised crossover trials of women assigned to 2²⁶ or 10 uses²⁹ of both the female and male condoms, women reported more mechanical problems with the female condom than the male condom. However, because self-reported condom problems appear to decrease as users gain experience with the device,^{27,29,30} the differences detected between the female and male condoms might have been attenuated had the trials involved more condom uses or a population with more experience with the female condom.

Biological markers of semen exposure

Because of methodological issues with other measures of condom effectiveness, researchers have developed alternative measures for testing the barrier properties of condoms. Two randomised crossover trials comparing the effectiveness of female and male condoms have tested for prostate-specific

Table 2. Studies of the effectiveness of the female condom against STIs
CI, confidence interval

Study	Study population	Study design	Study groups	Outcomes
Soper <i>et al.</i> (1993) ¹⁶	Women with trichomoniasis attending clinics in four US cities	Prospective, nonrandomised trial with group assignment by willingness to use female condom	<ul style="list-style-type: none"> Female condoms ($n = 54$) Control group ($n = 50$) 	Re-infection after 45 days
French <i>et al.</i> (2003) ¹⁷	Women attending an STI clinic in the US	Prospective, nonrandomised trial with group assignment depending on the week of their initial visit	Counselling and provision of either female condoms ($n = 855$) or male condoms ($n = 587$)	<ul style="list-style-type: none"> Female condom group 9% Control group 14% Odds ratio of ≥ 1 infection (gonorrhoea, chlamydia, early syphilis or trichomoniasis) after 6–12 months (depending on the timing of their enrolment)/for women in female condom v. male condom group
Fontanet <i>et al.</i> (1998) ¹⁸	Brothels in four cities in Thailand	Cluster randomised trial	Brothels randomised to receive condom provision and counselling on male condoms ($n = 37$ brothels) or hierarchical use of male condoms backed up with female condoms ($n = 34$ brothels)	≥ 1 infection (gonorrhoea, chlamydia, trichomoniasis or genital ulcer disease) at follow-up visits every 2 weeks for 24 weeks $P = 0.18$
Feldblum <i>et al.</i> (2001) ¹⁹	Six pairs of plantations in Kenya	Cluster randomised trial	Plantations randomised in matched pairs to receive community-level promotion, individual counselling and supplies of either female and male condoms, or male condom only. Women in the plantations receiving female and male condom intervention ($n = 969$) and male condom intervention ($n = 960$) were tested for STIs	<ul style="list-style-type: none"> Male condoms 3.7 per 100 person-months Male condoms backed up with female condoms 2.8 per 100 person-months Odds ratio of ≥ 1 infection (gonorrhoea, chlamydia or trichomoniasis) after 12 months for women in the male condom only v. female and male condom group 1.1 (95% CI, 0.8–1.6)
Macaluso <i>et al.</i> (1995) ^{21,22}	Women attending an STI clinic in the US	Prospective, nonrandomised trial with group assignment according to willingness to use female condom	Women counselled to use and provision of either female condoms backed up with male condoms, or male condoms only	Among women who reported consistent condom use, the rate of gonorrhoea and chlamydia appeared to be similar for those who mixed both female and male condoms compared with those who used only male condoms

antigen (PSA) in postcoital vaginal swabs as an objective measure of semen exposure during coitus (Table 3). The first trial, conducted among 400 women attending a family planning clinic in Brazil, randomised women to use two female condoms followed by two male condoms, or vice versa.²⁶ The rate of any PSA detection ($>1 \text{ ng mL}^{-1}$) was higher in postcoital swabs collected after female condom use than after male condom use (22% *v.* 15%; $P=0.01$). The second trial assigned low-risk women attending a clinic in the US to use 10 female condoms followed by 10 male condoms ($n=55$), or vice versa ($n=53$), and found no difference in the frequency of PSA detection between the female (17%) and male condom (14%).²⁹ When higher thresholds were used for the PSA outcome, neither study found differences between the female and male condoms in their frequency of PSA detection, which suggests that the two types of condoms are similarly effective in preventing semen exposure.

The use of a semen biomarker could provide a more efficient measure of condom failure than reliance on biological measures such as pregnancy or STIs, which are affected by factors such as fertility, timing of coitus relative to ovulation and partner infection status. The use of semen biomarkers, though, still depends on participant adherence to study procedures in terms of condom use, self-swabbing immediately after coitus and returning periodically to the clinic for specimen collection. Although the choice of the threshold for the detection of the semen biomarker has not been correlated with risk of pregnancy or STIs, the presence of semen biomarkers can be a useful measure of condom failure in studies comparing the effectiveness of different types of condoms.³²

Acceptability

Despite numerous studies demonstrating high acceptability of the female condom among various populations,^{33,34} its use remains low for a variety of reasons. It has not become a successful consumer product among general populations in key developed countries, such as the US and Great Britain. According to the 2002 National Survey of Family Growth, only 1.9% of reproductive-aged women in the US reported ever

using the female condom.³⁵ Similarly, an estimated 1% of reproductive-aged women in Great Britain in 2008–2009 reported current use of the female condom.³⁶ Recent reintroduction of the FC2 in selected developed country markets may prove more successful due to support from a wide array of reproductive health advocacy groups. In developing countries, many women live with a higher awareness of their risk of STIs and they have been more motivated to use this product when it is available. This has led to strong success stories about the uptake of the female condom in countries such as Brazil, Ghana, South Africa and Zimbabwe.^{37,38} However, high product cost, and lack of systematic introduction and programming have hampered widespread distribution and integration into existing health systems in most countries. Despite small increases in donor support for female condoms since 2005, the product still represents only 0.8% of the total condoms distributed by donor countries in 2008,³⁹ and many women remain unaware of the method.

Low use of the female condom may be attributed to limited acceptability and its relatively higher cost. For example, USAID procurement of the FC2 for developing countries is US\$0.55 compared with only US\$0.03 for the male latex condom.⁴⁰ Recognising that some women reuse female condoms because of their high cost, limited availability or perceived robustness, the WHO developed a protocol for disinfecting, washing and drying the FC1 for up to five reuses.⁴¹ However, given the lack of adequate data supporting the safety of this practice, the WHO does not recommend their reuse. Furthermore, protocols have not been developed for the reuse of other types of female condoms. Despite the higher costs of the female condom relative to the male condom, modelling suggests that the distribution of the female condom can be cost-effective in terms of the savings associated with averted HIV infections.⁴²

Low uptake of the female condom also may stem from the lack of support from international makers of public policy.^{43,44} Furthermore, uptake of an acceptable reproductive product can require time; the tampon did not become widely used until almost three decades after its first major marketing campaign.⁴⁵ In addition, the female condom is not routinely promoted by

Table 3. Studies of the effectiveness of the female condom against biological markers of semen exposure
PSA = prostate-specific antigen

Study	Study population	Study design	Study groups	Outcomes
Galvão <i>et al.</i> (2005) ²⁶	400 women attending a family planning clinic in Brazil	Randomised crossover trial	<ul style="list-style-type: none"> • Two FC1 followed by two male condoms • Two male condoms followed by two FC1 condoms 	PSA detection ($>1 \text{ ng mL}^{-1}$) in postcoital swabs after condom use <ul style="list-style-type: none"> • FC1 group 22% • Male condom group 15%
Macaluso <i>et al.</i> (2007) ²⁹	108 low-risk women attending a clinic in the US	Randomised crossover trial	<ul style="list-style-type: none"> • 10 FC1 followed by 10 male condoms • 10 male condoms followed by 10 FC1 condoms 	Rate of PSA detection ($>1 \text{ ng mL}^{-1}$) in postcoital swabs after condom use <ul style="list-style-type: none"> • FC1 group 17% • Male condom group 14%

many providers or programs. A survey of 27 antiretroviral therapy (ART) programs in Africa, Asia and South America found that although almost all provided male condoms (96%), prophylactic ART for the prevention of mother-to-child transmission (91%), and health education and social support (96%), only 32% provided the female condom.⁴⁶ The potential global demand cannot be known until barriers related to cost, access and programmatic support (including adequate counselling and training about the use of the device) are addressed.

Other factors that have limited acceptability include the large and long appearance of the FC1 and FC2, and the difficulty some women experience with inserting and removing female condoms. Experience has shown that most women learn to use the female condom after practicing its insertion and removal a few times.⁴⁷ Women also develop adaptive behaviours to address negative product attributes. For example, some women who feel that the inner ring is uncomfortable remove it after insertion. Product features incorporated into the Woman's Condom are designed to address issues that users identified as bothersome with early female condoms, such as movement of the pouch during sex, aesthetics of the device, ease of insertion and comfort during use. Whether designing a product specifically to improve acceptability will translate into increased use remains unknown; behavioural research has shown that acceptability is multifaceted and can be context-specific.

The acceptability of the female condom also is influenced by its promotion and marketing. For example, the promotion of the female condom primarily as a woman-controlled method backfired in some countries because male partners viewed female condoms as threatening to their control of their partner's sexual behaviours.^{48,49} Furthermore, the female condom often has been targeted at female sex workers, both because they constitute a core group for reducing HIV infection in communities where the epidemic is not yet generalised and because some view the female condom (and the male condom) as easier to use with clients than with emotional partners. Focussing on this narrow subset of potential users has contributed to stigma related to the method. Promoting the contraceptive benefits of the female condom to a more general population could help reposition this product relative to other methods, reduce stigma and perhaps improve acceptability.

Although some suggest that only women who already have a certain degree of 'empowerment' can successfully use the female condom, others argue that access to this method, especially when accompanied by educational activities, could strengthen women's empowerment by giving them an additional tool for negotiating their own protection against infection and improving communication between partners.⁴⁹⁻⁵¹ If a male partner refuses to use a male condom and the woman does not have access to the female condom, she has limited options to try to reduce her exposure (e.g. refuse sex and possibly risk violence, or request withdrawal before ejaculation, which would not eliminate the risk of infection). With the female condom, she potentially could suggest another method that she can initiate and that offers her partner more sensation during sex than use of a male condom,^{52,53} thereby potentially changing the dynamics of her negotiations with her partner. Given the visibility of the

external ring, which covers the vulva when the condom is in place, women often cannot use the female condom covertly or may elect not to do so, perhaps from a perceived duty to inform their partner about its use or from a fear of his response if he were to discover it.⁴⁸ Women sometimes characterise the acceptability of the female condom in terms of the male's positive reaction,⁵⁴ and the male partner's positive attitude towards the female condom has been correlated with higher adherence to the use of the device.⁵⁵ These findings underscore the decision-making role that male partners often hold regarding sexual and reproductive behaviours.

Other advantages of the female condom include the potential for increased spontaneity, given that the device can be inserted in advance of sex and does not require an erect penis for its insertion. Except for the Reddy and Cupid condoms (which are manufactured of the same material as latex male condoms), female condoms can be used with oil-based lubricants without compromising the product's integrity. Men may prefer the non-constricting sensation of the female condom in comparison to the male condom. The internal ring and the external ring may make sex more enjoyable for the male partner or for both partners, respectively, by increasing stimulation.⁵² Emphasising the positive attributes of the female condom in terms of increased sexual pleasure and freedom could be a route to increasing the use of the method.⁵⁶ Finally, some women expressed concern about their partner sabotaging male condom use by surreptitiously taking off the condom before sex ends or by tampering ahead of time with the condom (e.g. by adding pinholes).^{48,49,54,57} Women reported feeling reassured about these concerns with the female condom because they themselves initiate its use during sex.

The way forward

The female condom currently is being used off-label for anal sex⁵⁸⁻⁶¹ despite a lack of data on the safety and effectiveness of the practice.⁶² US state departments of health have given inconsistent recommendations regarding whether the female condom can be used for anal sex and the instructions for its use (e.g. whether the inner ring for the FC1 or FC2 should be removed).⁶³ Given the current use of the device rectally, efforts should be directed to determine whether the female condom used for anal sex with both men and women offers a safe and effective method for STI prevention or places individuals at an increased risk of infection.

Although the available data suggest that female condoms (or a mixture of female and male condoms) may provide similar degrees of protection against pregnancy and STIs as do latex male condoms alone, this conclusion has not been demonstrated. Data from randomised trials designed to test statistically the equivalence between the two condom types are not available. The uncertainty of this conclusion is reflected in the USFDA labelling for the FC1 and FC2, which supports their use for disease protection only in mitigating circumstances (i.e. when the latex male condom will not be used). For this reason, research on the effectiveness of female condoms compared with that of male condoms is urgently needed. Because of the methodological issues inherent in using pregnancy and STI outcomes in studies of condom effectiveness, future research

should be conducted to establish whether the female condom is comparable to the male condom in terms of protecting against the transmission of a biological marker of semen. However, whether these data would be sufficient for influencing regulatory authorities to modify the labelling for the female condom is unknown. Because the earlier effectiveness trials all involved the FC1, this research also would be important for evaluating the effectiveness of a type of female condom that is available to users.

This is an exciting time for reproductive health advocates involved in improving protection options for women through female condom promotion and programming. Product cost has been reduced with the FC2. New products that may address user needs better than with the first generation female condom have been developed and are obtaining regulatory approval. Women and men interested in the advantages of using female condoms may be able to choose from a range of products that offer different features and sensation. These accomplishments resulted from commitment and collaboration between public and private stakeholders during the past 15 years. We now need the same commitment and creativity to better understand how to market female condoms appropriately to women and their partners to realise the public health potential of female condoms to increase levels of protected sex and improve women's reproductive health.

Declaration

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or PATH.

Conflicts of interest

Coffey and Kilbourne-Brook work for PATH, an international, non-profit, non-governmental organization whose mission is to improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviours (www.path.org). PATH designed and developed the Woman's Condom with support from USAID and other donors. In 2008, PATH licensed the Woman's Condom technology for commercialization to Shanghai Dahua Medical Apparatus Corporation. PATH has no financial or royalty interest in the Woman's Condom agreement with Dahua.

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