

An Illustrative Communication Strategy for Female Condoms

Step 1: Analyze the Situation

Health and Commodity Context

**The majority of the information in this section is a global-level analysis for purposes of illustration. The country-specific situation analysis should be focused on the local context.*

The situation analysis should give programmers and stakeholders a clear, detailed understanding of (a) the current status of female condom use in the country and (b) the factors most likely to influence demand for female condoms within each audience of target users or target influencers. These may include perceived need for the product, product-related knowledge, skills, and perceptions, and social and cultural norms that may encourage or discourage trial and adoption.

Health Context

The need to improve women's reproductive health has been at the heart of global health and development discourse over the past quarter century, and the successes and weaknesses of efforts to improve women's reproductive health have impacted progress towards MDGs 3, 4, 5, and 6. As post-2015 frameworks for global health take shape, improving women's reproductive health status remains imperative: STI/HIV prevention and family planning programs at all levels must still overcome deep-seated challenges relating to gender inequality; and increasing women's control of fertility and sexual health will be critical to empowering the world's most vulnerable women and improving their quality of life.

Need for Woman-Initiated Method of HIV Prevention

Biologically, women are more vulnerable to HIV infection than men, and in most parts of the world women are less able than men to decide how and/or with whom they have sex. Wealth inequality, economic dependence on male partners, educational disadvantage, and

norms about decision-making in relationships all increase women's vulnerability, with younger and poorer women worse affected. Globally, approximately half of the 35.3 million people living with HIV are women, but in the generalized epidemics of sub-Saharan Africa, women account for 57% of people living with HIV (UNAIDS 2013).

Traditional gender roles and male-female power dynamics are barriers to negotiating safe sex for most women in the world. Unprotected sex within relationships is driven by conflicting norms relating to fidelity and trust: concurrent sexual partnerships are common, but unprotected sex denotes trust between partners. In the generalized epidemics of Eastern and Southern Africa, between 60% and 95% of new HIV infections are estimated to occur in the general heterosexual population, among people with multiple sex partners, their regular partners, and those in stable, mutually faithful but discordant partnerships (Gouws 2012), and married and co-habiting women are considered a priority, high risk population by many national HIV programs. Millions of women in transactional partnerships that leave them dependent on men for survival have even less power to insist on protection. In most concentrated HIV epidemics, female sex workers are a key population affected by HIV, despite two decades of targeted programming, while in many generalized epidemics HIV prevalence is also higher among female sex workers than in the general female population. Studies around the world have shown that even female sex workers who consistently use condoms with new, paying clients are less likely to do so with regular partners, including their non-commercial partners as well as regular clients (*inter alia*: Deering 2011; Ulibarri 2012; Yam 2013).

Unmet Need for Contraceptive Access and Choice

While global contraceptive use has increased, there are an estimated 132 million women of reproductive age (aged 15-49) worldwide who are married or in a union but have an unmet need for contraception; 56% of all such women use modern contraceptive methods while 7% use traditional methods and 37% use no method. In sub-Saharan Africa only 16% of women who want to avoid pregnancy use a modern contraceptive method, and unmet need for contraception is highest in this region (25%), followed by the Caribbean (20%) (UN, 2011). Lack of contraceptive access leads to approximately 75 million unintended pregnancies in developing countries every year, over 18 million of which result in unsafe abortions. 86% of all unsafe abortions occur in developing countries, where they are responsible for an estimated 13% of all maternal deaths (WHO 2011). Globally, it is recognized that expanding method choice is an effective strategy for increasing contraceptive prevalence: when women and couples have access to a wide range of family planning methods, they are more likely to find a method they like and can use over a period of time, to switch methods when their circumstances change, and to realize their intentions regarding lifetime fertility.

Commodity Context

The female condom was hailed by some as a game-changing innovation in reproductive health, HIV prevention and women's empowerment. With protective microbicides for women possibly still decades away, the female condom remains the only woman-initiated method of STI/HIV prevention in existence; it is also the only woman-initiated contraceptive method that offers dual protection against both pregnancy and STI/HIV infection, an essential consideration in generalized HIV epidemics and for most-at-risk women in concentrated epidemics. However, nearly twenty years after the first female condom became commercially available, female condoms have not been well-integrated into family planning or HIV prevention programs. Although it has yet to be seen whether female condom programming has the potential to challenge societal norms and shift sexual power dynamics, the female condom can undoubtedly play a unique role in the Global Plan towards the elimination of new infections among children by 2015 and keeping their mothers alive by: (1) preventing new HIV infections among women of reproductive age; and (2) helping women living with HIV avoid unintended pregnancies. Approaches that optimize the female condom's contribution to global and national health objectives must be fully explored, and more empirically driven promotion and evaluation carried out to maximize impact and cost efficiency.

Products Available

Although there are now multiple female condom products under development, only two are WHO approved: the FC2 and Cupid. The main female condom that has been distributed to date is the Female Health Company's FC1/FC2. Several new products are now in early stage introduction.



Most female condoms share fundamental design features. A female condom is a soft sheath with an insertion device at one end (e.g. a ring, sponge, or dissolving capsule) and a ring or frame at the other to secure the condom during sex. It is inserted in the vagina before sex and provides a physical barrier to sperm and infections. An advantage of all female condoms is that men do not need an erection to use it; therefore the female condom can be inserted by the woman during foreplay, and the man does not need to withdraw immediately after ejaculation.





The first commercially available female condom (FC1 or 'Femidom'), launched by the Female Health Company in 1992 and approved by the US Food and Drug Administration (USFDA) in 1993, was made of polyurethane. 90 million female condoms were distributed worldwide between 1996 and 2005. From 2002-2005 global distribution plateaued at 12-14 million units annually, but between 2005 and 2009 female condom distribution more than tripled. In 2009 combined sales of the FC1 and FC2 reached 50 million units (Female Health Company sales data, reported in Frost & Reich, 2009; UNFPA 2011^a).


The high production cost of the FC1 was a barrier to large-scale donor support. At the same time, significant cultural taboos in many target countries, coupled with the product's unfamiliar attributes, hindered trial and adoption of the FC1 and, critically, its promotion by health providers. In 2006 the Female Health Company launched the lower-cost FC2 to address these barriers. In the last five years a number of other female condom products have entered the market, enhancing product choice for programmers but also necessitating more nuanced advocacy and demand generation approaches (Beksinska 2012³).

The two female condom products currently prequalified by WHO and available for bulk procurement are the FC2 and the Cupid female condom. Other condoms such as the Woman's Condom, the Phoenurse, the HLL Female Condom, the Origami female condom and the VA worn-of-women (VA w.o.w.) condom are still under development or undergoing clinical trial.

These products are described briefly below (information correct as of September 2013; source: Universal Access to Female Condoms (UAFC) Joint Programme: *Female Condom Product Brief*, September 2013).

Product		Design & Features	Manufacture & Distribution	Regulatory Status
FC2		<p>Identical to FC1, but made of nitrile (synthetic latex)</p> <p>Flexible circular inner ring to insert the device and keep it in place during use, and a flexible circular outer ring to protect the genital area.</p> <p>Nitrile material conducts heat</p>	<p>Manufactured by the Female Health Company, Malaysia</p> <p>Distributed in 130 countries worldwide</p>	<p>Contraceptive eligibility (CE) marking</p> <p>WHO pre-qualified 2007, renewed 2012</p> <p>USFDA 2009</p>
Cupid		<p>Made of natural rubber latex</p> <p>Has an octagonal outer frame and is inserted using a medical-grade sponge which also holds the condom in place during use</p> <p>Pre-lubricated with silicone oil</p> <p>Comes in transparent or pink color, and is the only scented female condom</p>	<p>Manufactured by Cupid Ltd, India</p> <p>Distributed in India, Brazil, Indonesia, Netherlands, South Africa, Mozambique and Kyrgyz Republic</p>	<p>CE marking</p> <p>WHO pre-qualified 2012</p> <p>USFDA approval process initiated 2012</p>

Woman's Condom		<p>Made of polyurethane</p> <p>Has a soft, rounded insertion capsule which dissolves quickly after insertion in the vagina</p> <p>Four foam shapes on the outside of the condom ensure internal stability</p> <p>A flexible circular ring covers and protects the genital area.</p> <p>Not pre-lubricated: separate water-based lubricant is supplied in a sachet to be applied at point of use</p>	<p>Manufactured by Shanghai Dahua Medical Apparatus Company, China</p> <p>Limited distribution in China and South Africa</p>	<p>CE marking</p> <p>Under review for WHO pre-qualification</p> <p>Currently undergoing contraceptive effectiveness study needed for USFDA approval</p>
Phoenurse		<p>Made of polyurethane, which conducts heat.</p> <p>The body is dumbbell-shaped, with a flexible circular inner and outer ring</p> <p>Marketed with an insertion stick which attaches to the inner ring for optional use during insertion into the vagina</p> <p>Pre-lubricated with a silicone lubricant</p>	<p>Manufactured by Tianjin Condobao Medical Polyurethane Tech. Co. Ltd, Tianjin, China.</p>	<p>CE marking</p>
HLL Female Condom		<p>Made of natural rubber latex</p> <p>Has an outer flexible circular ring and is inserted with an inner flexible circular copolymer ring, to aid retention during sexual intercourse</p>	<p>Manufactured by Hindustan Lifecare Ltd (HLL), India.</p>	<p>Currently undergoing functionality study. The results of the study will be part of the product dossier to be submitted for WHO pre-qualification</p>
Origami Female Condom		<p>Made of transparent, moulded silicone</p> <p>Anatomical, ridged design.</p> <p>Fluid lining mimics the vaginal environment for the penis, creating a more natural sensation.</p>	<p>ORIGAMI Condoms Ltd, California, USA</p>	<p>Large scale clinical trials set for 2014, with the product expected to reach the market in late 2015, subject to approvals.</p>

VA w.o.w (worn of women)		<p>Made of natural rubber latex Has a rounded triangular frame for outer retention and a polyurethane sponge to secure it inside the vagina Pre-lubricated with a silicone lubricant</p>	<p>Manufactured by Hindustan Lifecare Ltd (HLL), India.</p>	<p>HLL acquired the technology and marketing rights for production and marketing of VA w.o.w® brand of female condoms in 2013.</p>
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Product Efficacy

Used correctly, female condoms are approximately 95% effective in preventing semen exposure that could lead to STI/HIV infection or unintended pregnancy; this is comparable to the efficacy of male condoms (UNFPA / WHO 2006). In a 6-month US clinical trial, 12% of women became pregnant with typical use of the female condom, while under 3% became pregnant with perfect female condom use (Trussel 2011). A WHO-mandated, multi-center study comparing female and male condoms determined effectiveness rates in Panama, China, and Nigeria of 94–98% for the FC1 and 92–96% for the male condom (UNFPA, 2006).

A study in South Africa found comparable rates of total clinical failure for the FC1 (5.4%) and FC2 (4.3%) (Beksinska, 2006). Aspects of clinical failure are defined in the table below. This finding is consistent with 95.5% efficacy in a study in Alabama, USA that compared male and female condom (FC1) efficacy (Valappil, 2005). Although mechanical problems were reported more frequently by female condom users than by male condom users in this study (34% and 9% respectively), total failure rates among those users reporting mechanical problems were the same for female and male condoms (9.4% and 9.6% respectively). The Alabama, USA study underscored the importance of practicing with the female condom until one becomes comfortable using it: comparing first use to fifteen or more uses, the rate of self-reported failure (breakage or slippage) for female condoms fell from 20% to 1.2% (Valappil, 2005).

Female condoms are less likely to break than male condoms: 0.85% of FC2s tested in the South Africa trial broke. The same trial also found that the FC2 halved incorrect penetration (i.e. the penis entering between the condom and the vaginal wall) from 1.26% (FC1) to 0.6%, whereas the outer ring of both FC1 and FC2 displaced in 3% of uses (Beksinska, 2006).

In 2011-12 UAFC supported a comparative functionality study of four female condoms at sites in China and South Africa: FC2, Cupid, the

Woman's Condom (WC), and the VA w.o.w. Total failure ranged from 3%-4.5% (see table below, Beksinska 2013).

Functionality (%)	FC2	Cupid	WC	VA w.o.w
Clinical breakage (during intercourse or withdrawal of condom from vagina)	0.25	0.10	0.00	0.08
Non-clinical breakage (before intercourse or after withdrawal of condom)	0.62	0.66	0.74	0.53
Invagination (condom pushed into vagina)	1.18	1.21	0.47	0.99
Slippage of condom out of vagina	0.98	1.48	1.28	0.43
Misdirection (penis did not enter condom)	0.60	1.22	1.13	1.19

Programmatically, a vitally important dimension of female condom efficacy is the extent to which adding female condoms to the method mix increases the total number of protected sex acts; evaluations of female condom promotion to family planning clinic clients in California (Choi, 2008) and sex workers in China (Liao, 2011) both highlighted the importance of targeted, skills-based female condom promotion in increasing the overall percentage of sex acts protected by either female or male condoms as a result of female condom interventions. A study in Madagascar showed peer education to be as effective as clinic-based promotion of female condoms in increasing overall condom usage when female condoms were introduced to an existing male condom promotion intervention targeting female sex workers (Hoke, 2007).

There is some anecdotal evidence from both developed and developing countries that female condoms are used by men who have sex with men for STI/HIV prevention during anal intercourse. However, no published, peer reviewed evidence yet exists on their safety and efficacy for this purpose. Female condoms are not WHO prequalified for use in anal intercourse and, therefore, there is currently no international recommendation that either men or women should use female condoms for STI/HIV prevention during anal sex. Female condoms should never be promoted for anal intercourse, because they were not designed to be inserted in the rectum. Removing the insertion device (i.e. the sponge, ring or capsule) distorts the female condom and affects its efficacy. **For this reason, men who have sex with men are not included as a target audience in this demand generation strategy.**

Audience and Communication Analysis

Over the last twenty years, government and non-governmental organization (NGO) distribution and demand creation initiatives for female condoms have generated evidence on the social and behavioral factors affecting acceptability and use of female condoms. In most studies, female condom use has been low and has generally declined after introductory campaigns due to lack of sustained availability (Thomsen, 2006; Liao, 2013).

A study in Brazil (Kalckmann, 2009) found that women with more frequent sexual relations (more than 3 sexual contacts per month) were significantly more likely to become long-term female condom users, whereas women who had 1-3 sexual contacts per month were more likely to drop out of female condom programs within the first month. This suggests that targeting demand generation efforts to women with higher coital frequency may be an effective approach to increasing uptake.

Relationship norms that govern trust, communication, and decision-making are a key barrier to use of both male condoms and female condoms. Asking a regular partner to use a condom, or (re-)introducing condoms into a regular partnership, is seen as a sign of cheating or an accusation that one's partner is being unfaithful. Even where women understand the risks associated with their partners', and their own, sexual behaviors, they are often powerless to protect themselves due to prevailing gender roles, sexual norms, and inequalities in wealth and decision-making power (UNFPA, 2006). In some cultures, taboos about touching or placing anything in the vagina are a barrier to female condom acceptability and use (Frost & Reich, 2009).

A female condom acceptability study among young South African men identified convenience of use for men, curiosity (to see how female condoms compared to male condoms), enhanced sexual sensation, and perceptions of better safety and comfort as facilitators of female condom use by men. Key barriers were unfamiliarity with female condoms, partner's insertion difficulties, and concern about losing control over sexual encounters (Masvawure, 2013).

When promoting the female condom as a women's empowerment tool, it is important to remember that there is no universal interpretation of empowerment. Some target users and program stakeholders may understand empowerment in terms of practical gender-specific interests (e.g. giving women a tool for preventing unintended pregnancy and STI/HIV acquisition), whereas others may think in terms of 'strategic' transformation in gender relations. Because making the female condom acceptable to men is an essential strategy for

increasing uptake, programmers should take care not to create negative perceptions of a product that is designed to empower women by *taking power away from men* (Kaler, 2001).

At the individual level, availability of female condoms, product attributes, perceived effect on male sexual pleasure (and, to a lesser extent, female pleasure), male partner and health provider attitudes, and self-efficacy to negotiate female condom use and insert the product are the factors most likely to determine whether women use female condoms:

- **Product attributes:** The female condom's image is a persistent barrier to uptake. In the absence of positive promotion of product benefits, non-users are likely to consider the female condom large, bulky, aesthetically unappealing and awkward / difficult to use (Telles Dias 2006^a, Okunlola 2006).
- **Pleasure:** The belief that male partners do not or would not like to use the female condom because a condom reduces male sexual pleasure is often a barrier to use for women. Conversely, women are more likely to accept and use the female condom if they believe that it can enhance pleasure for men (e.g. compared to male condoms because they do not feel constrained by the female condom during sex). In the South African male acceptability study (Masvuware, 2013), the main source of dissatisfaction with female condoms was insertion difficulties during trial. However, some men reported increased sexual pleasure due to the convenience of not having to wear a male condom, increased sensation due to the texture of the polyurethane FC1, and the more comfortable fit of the female condom compared to male condoms. In a study among female condom users in Brazil (Telles Dias, 2006^b), some women reported that the female condom's outer ring that stimulates the clitoris enhanced their sexual pleasure.
- **Social support for use of female condoms:** Women's uptake of female condoms is influenced by the attitudes of their male partners and the healthcare workers / health educators from whom they can obtain and learn about the method. Despite evolving gender norms in target countries, men are usually the main decision-makers in matters relating to sex, and proposing a product that her male partner has never seen or used before can be daunting (or even risky) for a woman in any type of sexual partnership. Service providers can play a key role in influencing target users to try and maintain use of female condoms - equipping providers with product-related training and knowledge has the potential to influence users' attitudes and uptake (Mantell, 2011). Health educators in public sector and NGO programs (e.g. social marketing and community mobilization interventions) may also play this role. Sufficient, balanced information about the benefits of female condoms and how to use them drives uptake (see 'difficulty or ease of insertion', below). It is important that efforts to create demand among women are complemented by awareness-raising and distribution targeted to men, as well as by tailored sensitization and skills training for healthcare workers and health educators. The association of (male) condoms with disease prevention and promiscuity by target users creates attitudinal barriers to use in marital / co-habiting and other primary or long-term partnerships. The female condom's status as a newer, lesser-known product can represent an opportunity in such settings: for

example, a three-country study in Zimbabwe, Nigeria and Cameroon (AIID, 2011) found high acceptability of female condoms among men for use in marital relationships for family planning only, and in other stable relationships for dual protection.

- **Difficulty or ease of insertion:** Total female condom failure rates have been shown to decrease markedly after the first few uses. Regular or experienced female condom users report higher self-efficacy to use the product and lower rates of failure, underlining the importance of sensitization, demonstration, trial and practice in efforts to create new female condom users. A 2008 South Africa study (Beksinska, 2012) showed how practice with female condoms effectively reduces failure rates: for example, slippage rates declined from 2.4% with condoms 1-5 to 0.9% with condoms 6-10, and no slippage was reported at last use (condom 15).
- **Negotiation skills:** Although the female condom is a woman-initiated method, to negotiate female condom use women need similar skills to those required to negotiate use of male condoms. Women with higher self-reported negotiation skills are typically more likely to have tried or regularly used female condoms, and it seems likely that there is a causal effect between negotiation skills and use. Critically for programmers, studies show that women who receive coaching and counseling in how to talk about female condoms and negotiate their use are more likely to use female condoms than women who receive only information and written instructions (*inter alia*, Choi 2008, Liao 2011, Mack 2010, Population Council 2009, Telles Dias 2006^a). These findings emphasize the importance of incorporating training in sexual negotiation skills into demand generation efforts for the female condom.

Example of Table to Organize Key Information

Target Audience	Current Behaviors	Primary Barriers to Desired Behavior	Primary Benefits of Desired Behavior
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Women in relationships and their primary partners	In most studies, female condom use has been low and has generally declined after introductory campaigns due to lack of sustained availability.	Product attributes Decreased pleasure Poor social support Difficulty to insert Negotiation Association with disease prevention and promiscuity	Increased pleasure Female-initiated Dual protection Perceived safety and comfort
Providers	Unlikely to recommend female condom or may only recommend for certain groups of women	Lack of training Provider biases Limited availability of product	Dual protection from unintended pregnancy and HIV