

October 2008

Smarter Programming of the Female Condom:

Increasing Its Impact on HIV Prevention in the Developing World

Prepared by

**FSG Social Impact Advisors and
Elliot Marseille and James G. Kahn**

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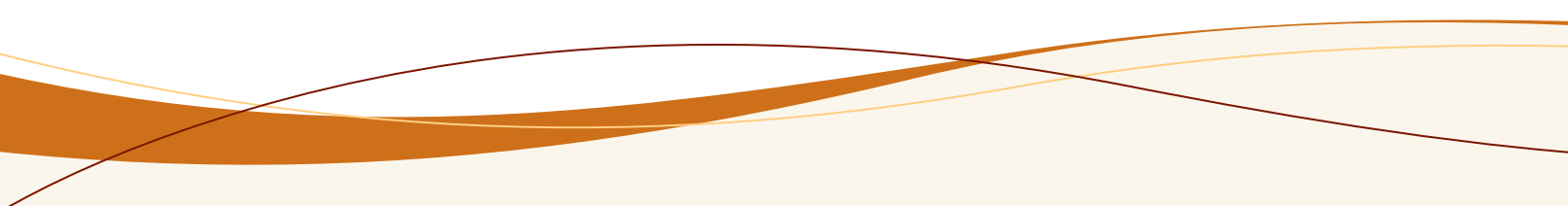
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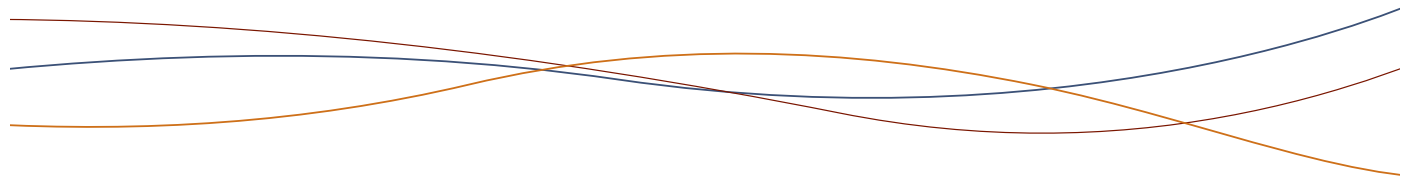
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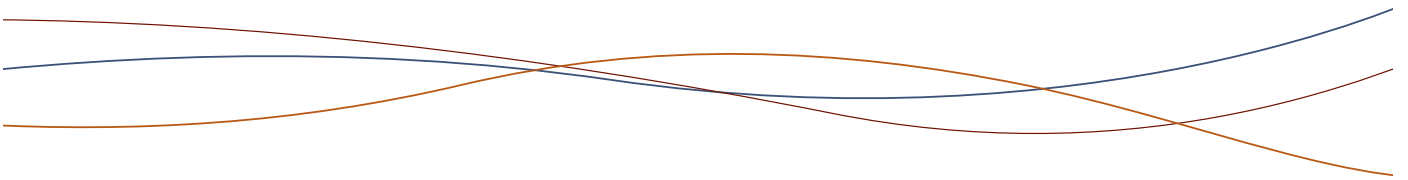
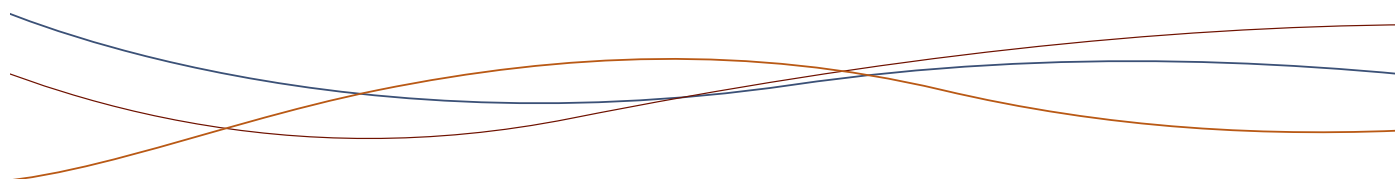
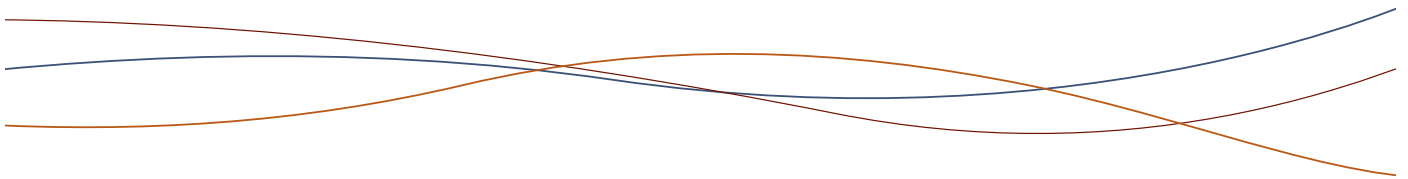


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EXECUTIVE SUMMARY



Executive Summary

The purpose of this study is to investigate the relative value of the female condom for HIV prevention within heterosexual relationships in the developing world. In the last ten years, the world has witnessed both historic financial commitments to HIV/AIDS and new prevention options, including biomedical prevention research, male circumcision, and a dramatic scale-up of voluntary counseling and testing. At the same time, where HIV remains at epidemic levels in many countries, there has been a growing commitment to treatment access alongside prevention programs. However, portions of populations, particularly youth and women, remain highly vulnerable to HIV infection. Accordingly, the global health community can benefit from a better understanding of how existing prevention options should be effectively and efficiently delivered to reduce HIV in the developing world. This report provides guidance for the global health community for considering how the female condom fits within the set of prevention interventions currently available.

The nonprofit consulting firm FSG Social Impact Advisors and academic researchers Elliot Marseille (Health Strategies International) and James G. Kahn (University of California, San Francisco) conducted this study on behalf of the Bill & Melinda Gates Foundation. The authors undertook four modules of research: a landscape analysis (literature review of the major articles, reports, evaluations, and conference agendas on the female condom during the last 15 years); programmatic analysis (comparative review of 14 female condom programs across 10 different countries in the developing world); stakeholder analysis (conversations with more than 50 implementers, donors, manufacturers, and experts); and a cost-effectiveness analysis (technical modeling of the cost-effectiveness of the female condom compared with the male condom and other prevention strategies). The research team conducted these analyses in 2007. Study methods, interim findings, and conclusions were reviewed with health economists, the foundation, and female condom stakeholders.

The female condom was launched in the developing world in the mid-1990s and is now an important prevention tool for dozens of countries' HIV prevention programs. A great deal of research was conducted prior to launch to test its efficacy and acceptability with particular groups. Initial feedback about the female condom by users in the developing world was mixed, with some hailing it as a boon to women's empowerment and others finding it challenging to use. Distribution of the female condom has varied throughout the developing world, with high volumes in Brazil, South Africa, and Zimbabwe. Interpersonal communication and provider training are hallmarks of female condom programming. The female condom has benefited from innovation with a new product already on the market, and others on the way. To date, more than 140 million units have been distributed, with a large proportion of delivered in the developing world for HIV prevention.

This is the widely known and accepted story about the female condom since its initial launch in the developing world. But this story has also been marked by a great deal of debate — a remarkable number of official dialogues dot the female condom timeline. Some stakeholders question the high commodity cost of the female condom compared with the male condom and point to the cost gap as a key reason for varied political support by developing country governments. But there are women and men who will not use the male condom, and offering protection, albeit at a higher cost, may be an appropriate investment aimed at decreasing risky sex acts. The female condom is considered an important empowerment tool for women in its own right, allowing individual women to better negotiate safer sex and societies to discuss the imbalance in sexual power between men and women. The perspective that the female condom is the only female-initiated prevention tool for women has created a strong advocacy base for promoting the product as a right for women in developing countries. Health impacts, costs, and human rights are intertwined at the core of the female condom debate.

There is no better time to enter this dialogue, as new momentum for the female condom builds with increased distribution, new female condom products, and new advocacy efforts, all seen in the last two years. Other prevention technologies, such as an AIDS vaccine or a microbicide, are on the horizon, but recent trials suggest that any evidence of success for either technology will not be seen for at least five years. This study offers new findings and recommendations for helping the female condom community move with renewed urgency toward more concerted action as existing HIV prevention efforts are reinforced.

The study provides three key findings. **First**, the female condom field lacks a consistent definition of success. Current definitions variously include number of units distributed, new cases of HIV averted, and strengthened sexual rights for women. Without agreement on success for this product, there is a tremendous risk that the debates about the female condom will only continue and more urgent action may be delayed. **Second**, the female condom is much less cost-effective than the male condom and other HIV prevention options based on analytical modeling. Reducing high commodity costs has been the focus of the field to date. In addition to commodity costs, the study's cost-effectiveness analysis identifies male and female condom marginal costs (the cost of adding one more male or female condom to a program), substitution rates, and targeting to discordant couples as the key factors to reduce costs. Disciplined attention to these levers may bring about improved cost-effectiveness. **Third**, female empowerment, which may be engendered through the use of the female condom, is central to effective HIV prevention, but such benefits are difficult to quantify.

The authors conclude that the female condom is a necessary tool for HIV prevention, specifically for those who cannot or will not use the male condom. A more sophisticated, program-centered approach is recommended to increase the impact of the female condom for HIV prevention. The cornerstone of this approach is a new definition of success for the female condom:

A New Definition for Female Condom Success in the Developing World

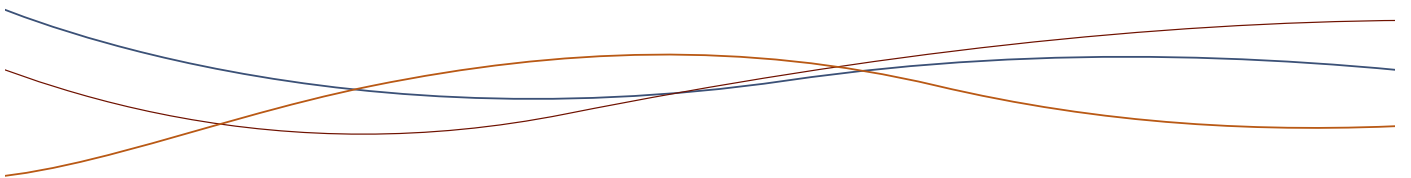
The female condom should result in averted cases of HIV/AIDS and unwanted pregnancies that could not be more readily achieved through alternative approaches, notably additional promotion of male condoms, and be distributed in a manner that is as cost-effective as possible. Additional benefits, such as improved relationships with marginal groups or expanded women's rights, should be no more costly than when achieved by other interventions that bring about similar results.

Targeting has always been prioritized for the female condom, but an even more sophisticated approach, termed "smarter programming" in this study, is needed. Smarter programming attempts to target groups and put in place interventions that optimize the levers mentioned earlier: reduced commodity and marginal costs of the female condom, reduced substitution rates with the male condom, and focus on discordant couples, where they can be identified. The report provides one scenario example for how these levers might work together, but programmers are encouraged to think creatively and act in a highly disciplined fashion with regard to their own local circumstances. A female condom Success Fund is recommended to motivate country programs to identify target audiences where the levers can be maximized.

A consequence of such smarter programming is a move away from blanket approaches to female condom delivery. Smarter programming should replace calls to normalize or mainstream the female condom in the developing world. Well-intentioned efforts to measure the success of the female condom through distribution numbers or mainstream awareness may expand the product's relevance from a sexual rights perspective, but they could also diminish impact, in terms of directing the product to those who need it most. Further, based on the cost-effectiveness analysis conducted in this study, programs that do not pursue the tenets of smarter programming will misuse valuable resources.

The findings and recommendations of this study point to a new trajectory for the female condom — specifically, an approach in which "more is better" to "smarter programming" for more cost-effective impact. This shift reflects an improved understanding of where the female condom can most likely prevent new cases of HIV and produce a higher return on investment for donors and program managers alike.

I. INTRODUCTION



I. Introduction

Nearly 20 years into the HIV/AIDS crisis in the developing world, the global health community now has a broad set of tools for helping prevent new HIV infections. With such a range of prevention interventions, there is a need for analysis to understand when to employ each tool given various factors such as transmission dynamics, cultural factors, and cost-effectiveness. In February 2007, the Bill & Melinda Gates Foundation engaged FSG Social Impact Advisors¹ to conduct an investment case analysis on the female condom in the developing world.

The purpose of this paper is to shed light on the relative value of the female condom for averting HIV/AIDS and unwanted pregnancies in the context of other interventions that are in use, such as the male condom. FSG conducted a multifaceted analysis of the female condom for the foundation, including assessments of issues of supply and demand in the developing world, stakeholder perceptions, viability of new product designs, and cost-effectiveness modeling. This particular paper focuses on four questions from the larger body of FSG's work:

1. What is the current status of female condom distribution and uptake as an HIV prevention intervention?
2. How is success defined for the female condom?
3. Under what scenarios, if any, can the female condom be cost-effective, compared with the male condom and other HIV prevention interventions?
4. What are the recommendations for donors and implementers based on this analysis?

Research Methodology

Research activities informing this work include:

- **Landscape analysis:** Literature review of the major articles, reports, evaluations, and conference agendas
- **Stakeholder analysis:** Conversations with more than 50 implementers, donors, manufacturers, and experts
- **Programmatic analysis:** Comparative review of 14 female condom programs across 10 different countries
- **Marginal cost-effectiveness analysis:** Technical modeling of the marginal cost-effectiveness of the female condom compared with the male condom

¹ FSG Social Impact Advisors is a nonprofit consulting firm that provides advice and ideas in the areas of strategy and evaluation for the social sector.

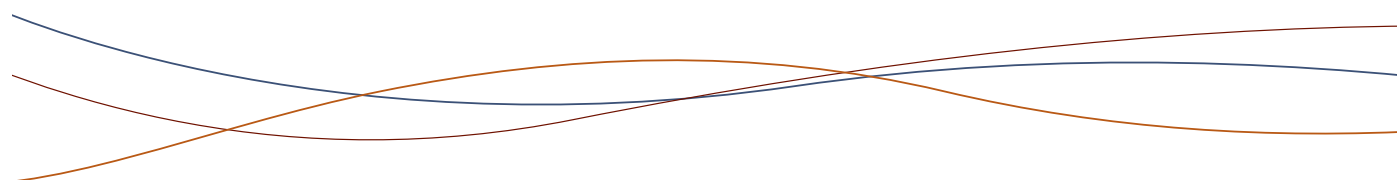
This paper uses evidence from actual programs and cost-effectiveness modeling to answer these questions and develop recommendations for donors, program managers, and researchers to effectively deploy the female condom as part of comprehensive HIV prevention strategies. To supplement a team of consultants well-versed in global health strategies, FSG partnered with Elliot Marseille² of Health Strategies International and James G. Kahn from the University of California, San Francisco (UCSF), to develop a comprehensive model for assessing the cost-effectiveness of the female condom relative to the most widespread barrier method available, the male condom. The cost-effectiveness study acknowledges that the male condom and the female condom are different and not always substitutable products, and that they are at different phases in their life cycles and serve different markets.

For donors, governments, and program managers who consider cost-effectiveness an important criterion in the allocation of resources, this study offers specific recommendations about how to best deploy the female condom. However, the study also recognizes that cost-effectiveness in preventing HIV/AIDS or averting pregnancies is only part of the picture. For example, HIV prevention depends on greater women's empowerment, an outcome that some attribute to the education and negotiation skills that are part of successful female condom

programs. Other goals may be furthered by introducing the female condom through relationship-building with marginalized groups or by studying its introduction to inform a future microbicide launch. These benefits were not quantified in this cost-effectiveness analysis because of the dearth of available data.

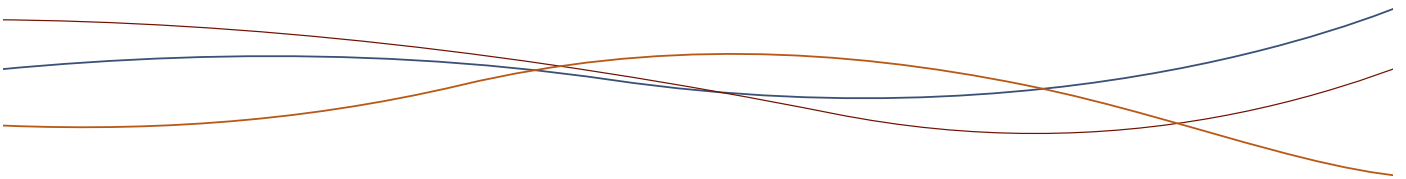
This report is not meant to be a definitive or exhaustive analysis of the female condom. FSG has limited its research scope to the developing world. Also, while FSG has reviewed dozens of articles on the female condom, the literature on this product continues to expand.

FSG Social Impact Advisors is a strategy consulting firm that helps funders make the best use of resources for the greatest possible social impact. The analyses offered here are intended to help guide funding decisions and programmatic approaches. FSG does not implement programs, fund them, or conduct advocacy; this neutral position can bring new clarity to the future of the female condom. In the interest of full disclosure, FSG Managing Director Kyle Peterson, a primary author of this study, launched the female condom as Population Services International's (PSI) country director in Zimbabwe in 1997/1998. While stating that caveat, we hope that FSG's understanding of the dynamics on the ground and all the players involved with this product makes this study a more pragmatic and provocative product in the end.



² Elliot Marseille authored a 2001 study titled "Cost-effectiveness of the Female Condom in Preventing HIV and STDs in Commercial Sex Workers in Rural South Africa."

II. SITUATION ANALYSIS



II. Situation Analysis

The global disease burden of HIV/AIDS is staggering, accounting for 39.5 million infections and 2.8 million deaths worldwide in 2006.³ Despite promising efforts to increase access to treatment and prevention programs, the number of people living with HIV and deaths attributable to AIDS continues to grow. During the past two decades, the number of people living with HIV has increased in every region of the world. However, the burden of HIV/AIDS remains highest in sub-Saharan Africa, a region that accounts for only 10% of the world's population but over 60% of HIV/AIDS infections. Seventy-two percent of deaths in sub-Saharan Africa are due to AIDS.⁴

Women in particular suffer a disproportionate impact of the HIV/AIDS disease burden, especially women in highly afflicted sub-Saharan Africa. In this region, three women are infected with HIV for every two men. Among young people ages 15 to 24, the magnitude of this disparity is even greater, with three young women infected for every young man.⁵ A number of factors place women at heightened risk for contracting HIV, including the threat of violence (both in relationships and in conflict situations), lack of economic independence, cultural norms and expectations, biological differences, and work in the sex trade.⁶

In the face of this crisis, a number of prevention interventions are available to developing world health leaders, multilateral institutions, donors, and implementers. The ABCs of prevention — abstinence, fidelity (be faithful or reduce the number of partners), and male condom use — have served as the cornerstone of prevention efforts for the last quarter century. Other prevention interventions include voluntary counseling and testing (VCT), blood safety, prevention of mother-to-child transmission (PMTCT), school-based HIV education programs, outreach to sex workers, mass media programs, screening and treatment of sexually transmitted infections, and, most recently, adult male circumcision. Most governments and donors offer a package of these services, emphasizing some more than others, with varied approaches that include the public and private sectors, community representatives, medical practitioners, the media, religious organizations, and policy influence, just to name a few.

Given women's increased risk of contracting HIV and the known difficulties of negotiating male condom use in cultures in which requests for protected sex are often interpreted as signs of infidelity or mistrust, there is great need for a safe and effective alternative to the male condom. To date, the female condom

is the only technology available that women can turn to as an alternative to the male condom. A number of organizations, including the International Partnership for Microbicides, the Contraceptive Research and Development Program (CONRAD), and the Population Council, have partnered with pharmaceutical firms to develop a microbicide that can be inserted by women in gel or perhaps ring form; however, two Phase III trials have not shown efficacy and the trials have been halted. Newer microbicides in development are based on different scientific approaches, but trials of these products are a few years away and their development and commercialization could take a decade or more.

State of the Male Condom

The male condom has become a ubiquitous and important method in the prevention of HIV/AIDS. According to the United Nations Population Fund (UNFPA), approximately 11 billion condoms were distributed in 2007. However, there are still significant obstacles to using male condoms and demand is far from satisfied in the developing world.

UNFPA further states, "Many people at risk of HIV/STIs do not use condoms. Some do not realize that they are at risk of infection or understand how to protect themselves. Some worry about how their partners will react if they suggest using condoms, or they believe condoms will make sex less enjoyable. Some are discouraged by the social stigma associated with condoms. Some have difficulty finding a convenient and affordable source of supply. Effective condom programs must overcome all of these potential barriers by:

- Creating a reliable supply of quality condoms by improving stock management and storage conditions;
- Making condoms readily available even for spontaneous users;
- Promoting demand for condoms by raising awareness of HIV/STI risks and teaching people how to use condoms correctly and consistently;
- Working to eradicate the social stigma associated with condoms; and
- Promoting a supportive environment by advocating for HIV prevention and condom use in the broader community.'

(UNFPA/WHO/PATH, 2005, "Condom Programming for HIV Prevention, a Manual for Service Providers.")

³ UNAIDS "AIDS Epidemic Update," December 2006.

⁴ UNAIDS "AIDS Epidemic Update," December 2006.

⁵ UNAIDS "AIDS Epidemic Update," December 2006.

⁶ UNAIDS "AIDS Epidemic Update," December 2006.

The female condom was introduced in the United States in 1992, and the decision by the government of South Africa in 1995 to include the female condom as part of its early prevention activities effectively launched the female condom in the developing world.⁷ Public and private sector distribution in Zimbabwe followed in 1997. Over the past decade, the female condom has experienced modest growth in distribution in the developing world, with the majority of female condoms distributed by large-scale public sector programs. To date, more than 140 million units have been sold.⁸

The Female Health Company (FHC), the primary manufacturer of the female condom, introduced its first product, the FC1, in 1993. Consisting of a welded, prelubricated polyurethane sheath with flexible rings at each end, the FC1 has been marketed under a variety of brand names in more than 130 countries around the world. The FC1 was sold to governments and donors based on an agreement with the Joint United Nations Programme on HIV/AIDS (UNAIDS) at approximately \$0.80 per unit,⁹ depending on the volume purchased. The FC1 was the only female condom on the market until 2002, when the Dr. Reddy's company launched an additional product, constructed of a prelubricated latex pouch with a polyurethane sponge insertion and flexible outer ring. Unlike the FC1, the Dr. Reddy's female condom has not received US FDA approval, nor has it been procured by any public sector agency. In 2005, the Female Health Company introduced the FC2, the replacement for the FC1, made of a synthetic rubber (nitrile) material and manufactured at lower costs. The FC2 is sold through similar government and multilateral arrangements at approximately \$0.57 per unit.¹⁰ (Male condoms, by comparison, are purchased by the same institutions for approximately \$0.03 per unit.) The FC2 has been approved and recommended by the WHO and is currently under review for approval by the US FDA. A number of other female protection products are available, such as the Natural Sensations panty condom, but they have not gained prominence among large private or public procurers.

Several additional female condom products are currently in development. The Program for Appropriate Technology in Health (PATH) has developed a new female condom that is inserted like a tampon. Made of polyurethane, PATH's Woman's Condom consists of a flexible outside ring that includes a dissolvable insertion capsule with stabilizing foam shapes, plus separate lubricant. The Belgium Female Condom, developed by MEDITEAM, is made of natural latex and is designed to cover the entire vulva and base of the penis. The Silk Parasol panty condom, developed by the Silk Parasol Corporation (U.S.), is a reusable panty with refill condoms. These products are in various stages of development and regulatory approval, and their ultimate availability is dependent upon more funding. It will be several years before any of them are on the market.¹¹

Several organizations are involved in supporting, researching, and implementing the female condom including donors, researchers, product developers, social marketers, and various public sector health systems. Key donors and multilateral organizations that have been instrumental in providing female condom funding include UNFPA, US Agency for International Development (USAID), UK Department for International Development (DFID), and the Netherlands Development Cooperation.¹² Organizations such as the World Population Foundation (WPF), Family Health International (FHI), and the Reproductive Health Research Unit (RHRU) play a significant role in advocacy and research related to the female condom. Key implementers include Population Services International (PSI), Marie Stopes International (MSI), and DKT International. These three organizations apply social marketing or community distribution techniques in the private sector and currently support female condom distribution programs in twenty, four, and two countries, respectively. Organizations such as Ghana's Society for Women and AIDS in Africa (SWAA) and the Hindustan Latex Family Planning Promotion Trust in India are also working to promote the female condom. Implementation

⁷ Mantell, JE, Scheepers, E, Karim, QA. 2000. "Introducing the Female Condom through the Public Health Sector: Experiences from South Africa," *AIDS Care*. 12(5): 589-601.

⁸ Female Health Company.

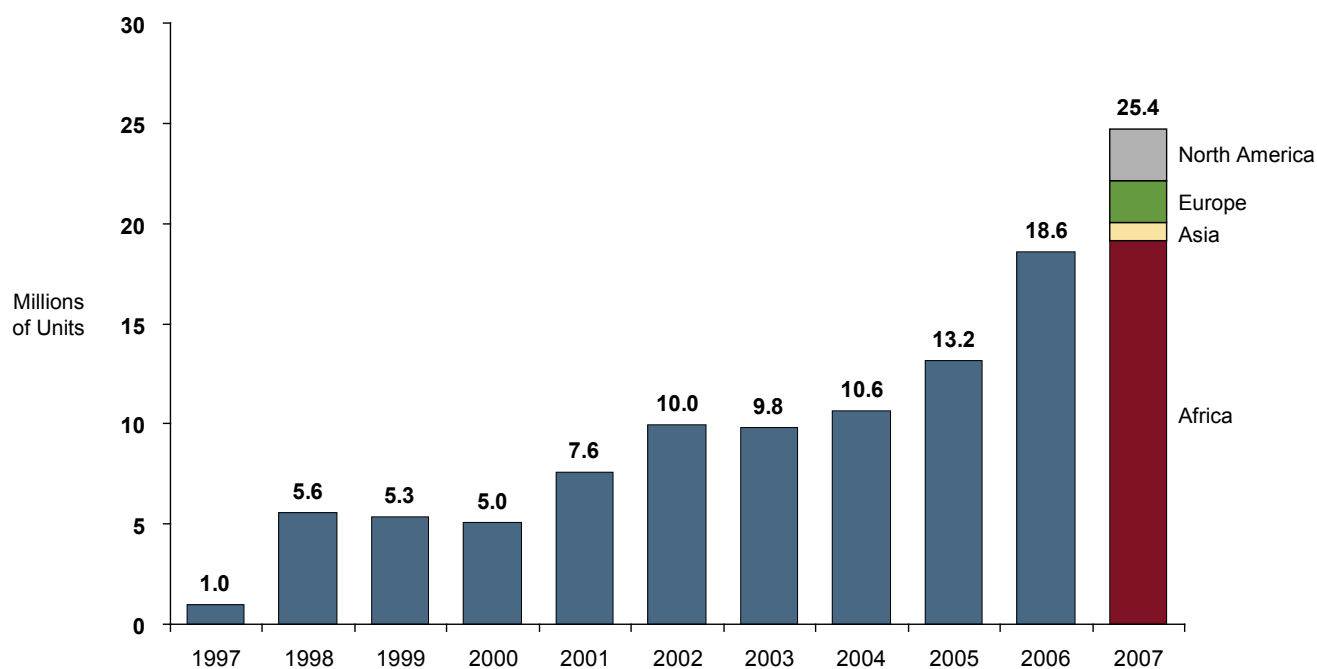
⁹ At current USD - UK Sterling exchange rates.

¹⁰ Female Health Company. FHC estimates that at distribution levels of 180 million units, the cost of the FC2 could drop to \$0.30 per unit.

¹¹ Bekinska, M. 2005. "The Female Condom: Reviewing the Past and Exploring Future Potential." Priorities Conference in Reproductive Health and HIV, Stellenbosch, South Africa. (PowerPoint presentation.)

¹² Other donors include WHO; CONRAD; The Global Fund Against AIDS, TB and Malaria; DANIDA; the Hewlett Foundation; and the Lemelson Foundation, among others.

Exhibit 1: Estimated Total Distribution of Female Condoms (1997-2007)



Source: Female Health Company (FHC)

in the public sector is largely supported by ministries of health, with the largest programs in Brazil, South Africa, and India, and smaller programs in Zimbabwe, Ghana, and Namibia. Important advocates of the female condom include the UNFPA Global Female Condom Initiative, the Dutch Universal Access Campaign, and the Center for Health and Gender Equity's Prevention Now! campaign.

During the last ten years, studies have shown that introduction of the female condom can increase the total number of protected sex acts,¹³ increase consistency of condom use among female sex workers (FSWs),¹⁴ and decrease unprotected sex acts.¹⁵ Ten studies evaluating the health impact of the female condom were reviewed for this report, including Theresa Hoke's Madagascar study,¹⁶ the Thailand sex worker study,¹⁷ and the Zambia study of couples in STI clinics.¹⁸

¹³Hoke, TH, Feldblum, PJ, Vandamme, K, et al. 2007. "Temporal Trends in Sexually Transmitted Infection Prevalence and Condom Use Following Introduction of the Female Condom to Madagascar Sex Workers." *International Journal of STI and AIDS*. 18(7): 461-6.

¹⁴Feldblum, PJ, Kuyoh, MA, Bwayo, JJ, et al. 2001. "Female Condom Introduction and Sexually Transmitted Infection Prevalence: Results of a Community Intervention Trial in Kenya." *AIDS*. 15(8): 1037-44.

¹⁵Musaba, E, Morrison, CS, Sunkutu, MR, Spruyt, A, Chomba, AB. "Long-term Use and Acceptability of the Female Condom among Couples at High Risk of HIV in Zambia." *Int Conf AIDS*. 1996 Jul 7-12; 11:238 (abstract no. Th.C.430).

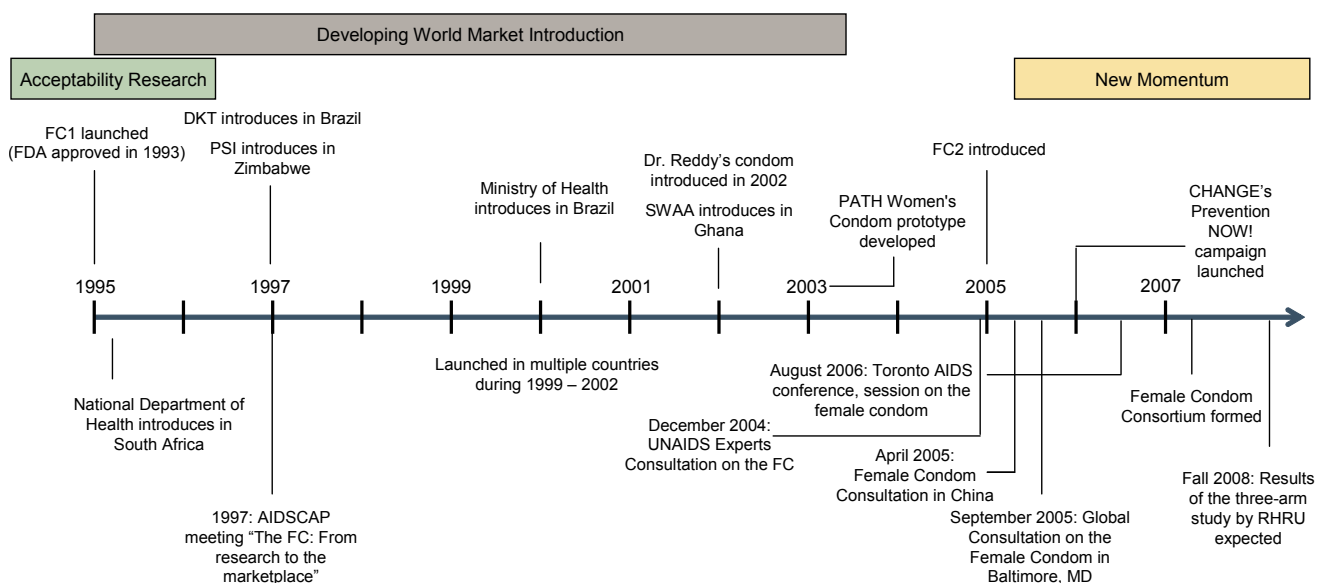
¹⁶Hoke, TH, Feldblum, PJ, Vandamme, K, et al. 2007. "Temporal Trends in Sexually Transmitted Infection Prevalence and Condom Use Following Introduction of the Female Condom to Madagascar Sex Workers." *International Journal of STI and AIDS*. 18(7): 461-6.

¹⁷Fontanet, A, Saba, J, Chandelying, V, et al. "Protection against STDs by granting sex workers in Thailand the choice of using the male or female condom."

¹⁸Musaba, E, Morrison, CS, Sunkutu, MR, Spruyt, A, and Chomba, AB. "Long-term Use and Acceptability of the Female Condom among Couples at High Risk of HIV in Zambia." *Int Conf AIDS*. 1996 Jul 7-12; 11:238 (abstract no. Th.C.430).

Exhibit 2: Timeline of female condom activity

Signs of New Momentum for the Female Condom

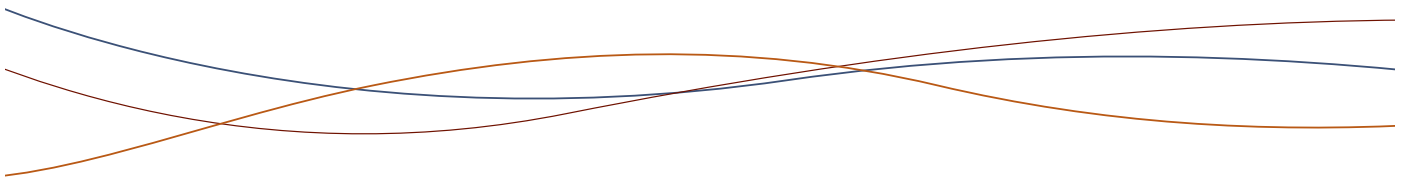


Source: "The female condom: Reviewing the past and exploring future potential," RHRU, 2005; FSG analysis

The female condom is at an inflection point after roughly 15 years of existence in the developing world. Moving from an early acceptability stage in the early 1990s, to market introduction in the mid-1990s, to a period of unmet or questioned expectations at the beginning of this decade, the female condom is receiving increased attention through new products, increased distribution, and additional funding, as seen in Exhibit 2. The global health community continues to invest funds in the effort to develop new technologies to prevent HIV/AIDS, such as vaccines and

microbicides. While male circumcision gains interest, funding, and momentum, there is also discussion about re-emphasizing attention to women's methods and needs. This is an opportune time to review what has been learned about the female condom to date and to reflect upon how these lessons can inform future decision-making in order to ensure that female condoms are provided as cost-effectively as possible, while providing maximum protection against new HIV cases.

III. PROGRAMMATIC AND STAKEHOLDER ANALYSIS



III. Programmatic and Stakeholder Analysis

FSG conducted programmatic analysis to assess country-level distribution and promotion and stakeholder analysis to capture perceived barriers to female condom support as reported by donors, implementers, and advocates. The programmatic analysis validated a set of best practices known to the female condom community and reemphasized the importance of targeting. The stakeholder analysis identified a key issue missing in the decade-long dialogue about the female condom: a clear and shared definition of success that incorporates the issues of health impact, cost-effectiveness, and sexual rights. Without such agreement on a definition of success, opportunities to implement the female condom may be missed and donors may maintain a wait-and-see attitude about its use.

A. Programmatic Analysis

FSG collected data from 14 female condom programs across 10 different countries and seven different organizations, and conducted interviews with implementers, both at their headquarters and in the field. FSG focused on understanding what drives successful, sustained female condom uptake. The programs selected for analysis represent both high-profile, established programs and newer, emerging ones, and they were chosen to provide a mixed sample with regard to geography, organization, delivery approach, and types of lessons learned. Programs were evaluated based on their own stated goals, as indicated by the population groups defined as their targets.

The programs analyzed were:

- DKT: Brazil, Mexico
- Government (Ministry of Health): South Africa, Brazil
- Hindustan Latex Family Planning Promotion Trust: India
- MSI: Uganda, Namibia, Mongolia
- Society for Women and AIDS in Africa (SWAA): Ghana
- PSI: Myanmar, South Africa, Tanzania, Zambia, Zimbabwe

Above all else, FSG's analysis confirms the importance of targeting the female condom. Other findings include the importance of interpersonal communication and peer education for female condom promotion and the observation that program managers make do with highly constrained budgets.

- **FSG's analysis of the 14 country programs underlines the importance of identifying specific audiences and designing programs to reach them.** Five of the assessed programs emerged as doing a particularly effective job of identifying target audiences and designing appropriate programs to meet their needs. Such customized programs for targeted audiences can result in strong “penetration” (number of units distributed per person within a designated population). PSI Myanmar, for example, had relatively low annual distribution, but its penetration of the stated target audiences — men who have sex with men (MSMs) and female sex workers (FSWs) — was dramatically better than in the MSI Uganda program, where target groups were not as well-defined.
- As mentioned in the literature and confirmed in this analysis, **specific target audiences require specific distribution outlets for penetration to occur.** Use of nontraditional outlets – such as hair salons, truck stops, universities, workplaces, female sex worker locations, and HIV/AIDS networks and support groups — is often necessary for effective distribution to hard-to-reach target groups. For instance, the goal of PSI's program in Zimbabwe has not been national coverage or expansion, but rather a concentration on well-researched target groups, including FSWs, women who know they are HIV-positive, university women, and low-income women in steady relationships. An estimated 80% of the program's female condom distribution comes through such channels, with over half of sales coming from beauty salon programs in which stylists provide the product, along with education and training, to their clients. Similarly, in addition to utilizing beauty salons, PSI Zambia also conducts outreach to high-risk groups such as truck drivers at truck stops and miners at copper mines.

- **The programs that were the most adept at targeting adopted product positioning appropriate for their selected target groups.** For instance, the PSI Zambia and MSI Namibia programs have adopted dual positioning, emphasizing HIV/AIDS prevention for FSWs and pregnancy prevention for married couples. To avoid stigmatization within the general population, PSI Zimbabwe has positioned the female condom for pregnancy prevention despite focusing its distribution strategy on high-risk groups, such as FSWs and HIV-positive women.

The following tables summarize high-level data from the analysis of female condom programs. Five programs are featured with the highest penetration based on stated target populations (average annual distribution/1,000 total population).

Table 1: Quantitative summary of five female condom programs with highest penetration based on stated target populations

Quantitative Data	PSI Myanmar	PSI Zambia	PSI Zimbabwe	MSI Namibia	MOH Brazil
Program Launch	2003	1995	1997	2001	2000
Stated Target Groups	FSWs, MSM	FSWs; Young, married, urban couples	FSWs; HIV-positive women; University women; Low-income women in relationships	FSWs; MSM; Working class men and women	FSWs; HIV-positive women; Drug users; Partners of drug users
Estimated Size of Target Population	359K	410K	2.2M	374K	2.9M
Price to the Consumer	\$0.02-0.05	\$0.12	\$0.01-0.24**	\$0.27	Free
Cumulative FC Distribution	356,220	1,309,496	5,907,034	532,872	10,300,000
Average Annual Distribution	89,055	109,125	590,703	88,812	1,471,429
Growth in Annual Distribution (CAGR)	0.89	0.53	0.31	0.39	0.13
Total Population Penetration (Average Annual Distribution / 1,000 Total Population)	2	9	45	42	8
Target Population Penetration (Average Annual Distribution / 1,000 Target Population)	248	266	270	238	506
Cumulative Program Spend	\$457,871	\$1,062,434	\$3,698,959	-	-
Average Annual Program Spend	\$152,624	\$132,804	\$410,995	\$227,679*	\$8,000,000*
Average Program Spend Per FC Distributed	\$1.29	\$0.81	\$0.63	-	-
Cumulative Spend on Advertising/Promotion	\$25,196	\$112,660	\$478,621	\$252,000	-
Average Annual Advertising/Promotion Spend	\$8,399	\$14,082	\$53,180	\$42,000	\$2,000,000*
Cumulative Spend on Interpersonal Communication	\$12,639	\$64,133	\$306,902	\$150,000	-
Average Annual Interpersonal Communication Spend	\$4,231	\$8,017	\$34,100	\$25,000	\$3,000,000*

Notes: Spending on provider training is not broken out for PSI programs; these expenses are captured under other categories (e.g., local salaries, interpersonal communication). One year of program spending data missing for Zambia (1998). Only one year of total program spend data available for Namibia.

* Based on 2006 data only.

** Price was originally set at \$0.24 but has fallen to the equivalent of \$0.01 more than once due to economic instability and inflation.

Source: PSI data, MSI data, MOH Brazil data, FSG interviews and analysis

Table 2: Qualitative summary of selected female condom programs analyzed

	DKT Brazil	MOH Brazil	MOH / NGOs Ghana	PSI Myanmar	MSI Namibia	MOH South Africa	PSI Tanzania	MSI Uganda**	PSI Zambia	PSI Zimbabwe
Program launch	1998	2000	2000	2003	2001	1997	1998	2001	1995	1997
Product positioning	Dual positioning	HIV/AIDS prevention	Dual positioning	HIV/AIDS prevention	Dual positioning	Dual positioning	Dual positioning	HIV/AIDS prevention	Dual positioning	Pregnancy prevention
Sector	Private	Public	Both	Private	Both	Public	Private	Private	Private	Private
Stated target groups	●	●●●●	●	●●	●●●	●	●●	●	●●	●●●●
Distribution outlets	●	●●	●●●●	●●	●●●●	●	●●	●	●●●●	●●●●
Use of mass media?	Not since 2000	No	Yes	No	Not since 2001	No	Formerly*	No	No	Not since 1997
Focus on interpersonal communication?	No	Yes	Yes	Yes	Yes	No	Formerly*	No	Yes	Yes
Dedicated FC staff?	No	Yes	Yes	No	No	Yes	Formerly*	No	No	Yes
Active targeting of men?	No	Yes	Yes	MSM only	Yes	Recently	No	No	No	No
Level of in - country Advocacy	High	High	High	Low	High	High	Low	Medium	Medium	High
Other FC programs	MOH	DKT	Other NGOs	NGOs	MOH	PSI	T-MARC (AED)	None	MOH	MOH, Women and AIDS Support Network

Stated Target Groups

- FSWs
- Women in relationships
- HIV - positive women
- Drug users
- Sexually active women
- MSM
- Other

Distribution Outlets

- Peer networks
- Beauty salons
- Mainstream shops
- VCT centers
- Other health clinics
- Other

Notes: *PSI Tanzania no longer has funding to support programmatic efforts (only commodities); ** MSI 's FC program in Uganda was shut down after 2004

Sources: DKT, PSI, MSI, MOH South Africa, MOH Brazil, MOH Ghana, UNFPA, FSG analysis

B. Stakeholder Analysis

Conversations conducted by FSG with more than 50 stakeholders with knowledge of and program experience with the female condom (donors, researchers, program managers) revealed support for the female condom but also the key fault lines in the debate about the product. Interviewed stakeholders focus on the issue of the female condom’s high commodity cost and low political support.

Most interviewees identified the female condom as a product with long-term potential, claiming its unique value as the only effective, female-initiated method of preventing HIV, STIs, and pregnancy. A number of interviewees also highlighted the potential for the female condom to aid the introduction of other vaginally inserted products, including microbicides. As stated by one participant, “The female condom is absolutely crucial for the introduction of the microbicide. It’s critical that the female condom is

training people who can talk about their sexual organs comfortably. I would really like to see some of the microbicide groups fund the female condom to learn from its lessons.”¹⁹

While interviewed stakeholders were generally positive about the female condom, they also articulated important notes of skepticism. Specifically, some interviewees questioned whether the female condom could be viable commercially and whether it is truly female controlled. According to one interviewee, “The female condom is a product that is unlikely to ever reach mass appeal. It is even more difficult to use than the male condom, which is sufficiently difficult to use. The female condom needs a higher level of education and typically requires training to see continued use, which is often difficult to implement when resources are limited. Customer consultation is also culturally awkward in many countries. I don’t see it having sufficient volume to be commercially attractive as a product.”²⁰

¹⁹ FSG interviews.

²⁰ FSG interviews.

The interviewees, like the literature and meeting notes from the major consultations held over the last ten years, tended to focus on the challenges facing the female condom. Hurdles include inconsistent supply, product attribute challenges (such as noise and difficulty in use, loose fit, unsightliness), absence of provider support, the need for additional operational research, cultural barriers, and women's lack of empowerment. Opinions have evolved with respect to these barriers. Where product attribute challenges were initially perceived as constraining adoption of the female condom, more recent discussions seem to prioritize the **high commodity cost of the female condom with the corresponding low political and financial support that follows from it**. To a lesser extent, interviewees also mentioned that limited education and training act as a significant barrier to increased uptake.

- **High commodity costs:** The female condom's current commodity costs are more than 15 to 20 times higher than those for the male condom (\$0.80 for the FC1 and \$0.57 for the FC2 as compared with \$0.03 or less for the male condom). This difference exists in part because female condoms require more complicated manufacturing processes and more expensive raw materials.²¹ A 2004 consultation organized in London by the Global Campaign for Microbicides (GCM) on behalf of the Global Coalition on Women and AIDS described a vicious cycle in which high commodity costs breed low donor interest and limit procurement volumes, which limits the ability to meet demand, which in turn discourages additional interest, so that high commodity costs persist. Recommendations for breaking this cycle included catalyzing or subsidizing other product developers, re-engaging on female condom re-use, and supporting large-scale commodity purchase in a number of countries to increase demand and ensure supply at lower unit costs.
- **Low political and financial support:** Laura Frost describes a lack of global political and financial commitment to the female condom. According to Frost and others, many of the recommendations from the earliest consultations on the female condom have not been implemented or have only been partially implemented because of the lack of a coordinating hub for the female condom. In addition, family planning

groups, with the exception of UNFPA, have not pushed the female condom as a contraceptive device, preferring more affordable hormonal methods.²² A new report by the Center for Health and Gender Equity reports that low U.S. political support for the female condom and simple bureaucratic blockages have created serious barriers to increased access to this product.²³

C. A Decade of Experience and Dialogue without a Consistent Definition of Success

Amidst the programmatic lessons learned and the series of consultations undertaken since the female condom's launch in the developing world, there has been limited discussion about what constitutes success for the female condom. Some stakeholders, such as PSI, view the female condom as a complement to the male condom and consider its benefits in terms of incremental cases of HIV prevented. In this view, success is less about pure numbers distributed than about the quality of the targeting. Others describe success as "widespread, sustainable uptake and use of female condoms."²⁴ In this version of success, the goal is to "normalize [the female condom] 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."²⁵ Finally, some advocates of the female condom promote its ability to empower women to negotiate protection and open dialogue about sex in male-dominated societies.

What purpose should the female condom serve today, against a backdrop of other prevention interventions such as the male condom, voluntary counseling and testing, and male circumcision? Three issues, presented below, must be examined in order to articulate a definition of success for the female condom:

1. The incremental benefits of the female condom compared with the male condom
2. The cost-effectiveness of the female condom compared with other interventions
3. Women's empowerment benefits from female condom use

²¹ Current commodity costs of the FC2 are an estimated \$0.57, making the product 19 times as expensive as the male condom.

²² Frost, L. and Pratt, B. 2006. "A Technology for Dual Protection against Sexually Transmitted Infections and Pregnancy." Access Book, Chapter 8-Draft.

²³ Center for Health and Gender Equity. 2008. "Saving Lives Now: Female Condoms and the Role of U.S. Foreign Aid." Takoma Park, MD: Center for Health and Gender Equity. Note: While USAID headquarters queries missions globally on an annual basis on country needs for female condoms, requests from in-country missions for female condom procurement are dependent on USAID or PEPFAR officials having experience with and knowledge about the acceptability and efficacy of female condoms. Unless a Health, Nutrition and Population Officer (representing USAID) or the Ambassador requests the female condom, there will be no push from Washington, DC, to make procurement and programmatic funding available for the female condom. Further, female condoms are not mentioned in the OGAC's program guidance. In several of the US governments' centrally funded HIV/AIDS programs such as AIDSTAR (AIDS Support, Technical Assistance Resources), female condoms are not part of an institutional set of services; rather, female condom program dollars must be requested through individual country champions.

²⁴ Global Campaign for Microbicides and the UNAIDS Global Coalition for Woman and AIDS. 2004. "Observations and Outcomes from the Experts' Meeting on Female Condoms." London, 10 December.

²⁵ Hoffman, S, Mantell, J, Exner, T, Stein, Z. 2004. "The Future of the Female Condom," *International Family Planning Perspectives*, 30(3) 139-145.

First, a definition of success must consider the comparative benefits of the female condom vis-à-vis other products that have broad reach and similar efficacy, such as the male condom. While upwards of 140 million female condoms have been distributed, approximately 11 billion male condoms were distributed worldwide in 2007 alone — and the current market for male condoms is still growing in many developing countries. For example, PSI's male condom sales have increased from an estimated 340 million units in 1997 to 1 billion units in 2006. Furthermore, PSI has achieved significant male condom sales in countries with high HIV prevalence, such as Mozambique, Lesotho, Zimbabwe, Botswana, South Africa, and Zambia, as seen in Table 3.²⁶

It is within this context that one needs to understand the incremental benefits provided by the female condom, measured by additional cases of HIV/AIDS averted. Studies mentioned in this paper suggest that introduction of the female condom can create incremental benefits, particularly by preventing infections among vulnerable groups that cannot use male condoms. If incremental benefits are to be pursued, the female condom's role could be regarded as more of a specialized product in the fight against HIV/AIDS, rather than a widely distributed one.

Skeptics of the female condom tend to compare distribution figures or usage rates unfavorably with those of the male condom. Typically those programs that have achieved higher

unit distribution of the female condom are regarded as the most successful, irrespective of any greater use among particular audiences who might be most vulnerable (such as female sex workers or women in stable relationships in high-prevalence countries) or the cost-effectiveness of female condoms versus other interventions. However, even relatively low distribution can be compelling if the target audience is identified and effort is focused on those women whose partners are unable or unwilling to use the male condom.

But even when targeting is strong and incremental benefits are gained, the male condom may still garner a higher return on investment because of the female condom's high commodity and programmatic costs. Therefore, a second dimension of success should consider the cost-effectiveness of the female condom compared with the male condom and other prevention interventions. A few studies have been conducted on the cost-effectiveness of the female condom, but they have not examined the critical issue of cost-effectiveness compared with other HIV prevention alternatives, such as the male condom. David Dowdy and Michael Sweat modeled the expansion of the FC2 in Brazil and South Africa and found that distribution of the female condom to 10% of current male condom users would avert an

Table 3: PSI male condom distribution in selected high HIV prevalence countries — 1999, 2006, and compound annual growth rate (CAGR) from 1999-2006

	1999	2006	CAGR
Mozambique	9,858,401	22,732,196	0.13
Lesotho	347,998	3,167,929	0.37
Zimbabwe	8,961,442	49,122,000	0.28
Botswana	2,744,568	4,107,377	0.06
South Africa	3,920,479	22,428,888	0.28
Zambia	6,724,646	13,208,310	0.10

Source: PSI, FSG analysis

²⁶ www.psi.org.

estimated 604 HIV infections at \$20,683 per infection in Brazil, and 9,577 infections at \$985 per infection in South Africa.²⁷ Other work in this area, a study by PATH/UNFPA, identified cost savings to the health care system based on a modeled number of new infections averted.²⁸

The female condom may at first seem cost-effective because it increases the total number of protected sexual acts, but this finding does not necessarily mean that the female condom is more cost-effective than the male condom. Such cost-effectiveness assessments without such a comparison are incomplete: female condoms may increase the number of averted cases of HIV/AIDS, but we do not know whether the same number of cases could have been averted through the less costly support of the male condom or other prevention interventions.

Third, it is necessary to better understand the important benefits of women's empowerment conferred by the female condom. Research has shown an "empowerment effect" from the female condom, which can be conferred to the individual woman or the health system overall. The benefits include women's enhanced ability to negotiate safe sex, increased openness to discussing sex, and sexual pleasure and pride in their bodies.²⁹ Female empowerment benefits also include the female condom's ability to act as an important catalyst for more general empowerment and self-efficacy. Programs that distribute the female condom throughout the developing world strengthen programmatic relationships with marginalized groups, such as female sex workers. Kaler suggests that even if female condom uptake is slow or modest, the programmatic value of interpersonal or mass media communication that features women using this device is a profound boon for public health.³⁰

There is a need to better understand these additional benefits, since women's empowerment and HIV prevention are linked. Women who cannot negotiate barrier protection with a partner who may be infected cannot reap the benefits of such protection. Erica Gollub canvassed the literature on the "empowerment effect" of the female condom and found multiple studies that demonstrate the female condom's ability to increase sexual

confidence that may "in a small way open up the possibility of greater equality in sexual relations between men and women."³¹ Further, international consultations, such as the International Conference on Population and Development (Cairo, 1994), have articulated the connection between women's empowerment and sexual health and declared that women's empowerment is an important end in itself: "*The Programme of Action, adopted by 179 governments, marked a new understanding among world bodies that population and development are inextricably linked, and that women's empowerment is the key to both. And, for the first time, the reproductive and sexual health and rights of women became a central element in an international agreement on population and development.*"³²

These views — about the size of the intended audience, the costs of the product itself and associated distribution costs, and the fact that the female condom is used by women who often do not share the same sexual rights as men — are tied up in the often emotional, complicated, and inconsistent definition of success of the female condom. An inconsistent definition of success for the female condom exposes two risks. First, at the global level, advocates and donors could end up talking past each other. Efforts to bolster the female condom (through mainstreaming and scale-up or through subsidization of new developers or manufacturers) should be reviewed to determine whether they are the best ways to support a relatively expensive product that has profound value but target-specific application. Second, at the country level, female condom programs may not avert significant numbers of HIV/AIDS cases or create desired empowerment benefits for the people who need them the most. In other words, without a consistent view of success and the funding and programming to support clear objectives, stakeholders may miss opportunities to save lives through the use of this important commodity.

In order to shed further light on the female condom's role in prevention programs, its cost-effectiveness compared to other prevention interventions, and the value of female empowerment, we undertook the first-ever marginal cost-effectiveness modeling exercise comparing the female condom with the male condom.

²⁷ Dowdy, DW, Sweat, MD, and Holgrave, DR. 2006. "Country-wide Distribution of the Nitrile Female Condom (FC2) in Brazil and South Africa: A Cost-Effectiveness Analysis." *AIDS*. 20:2091-98.

²⁸ PATH, UNFPA. 2006. "Female Condom: A Powerful Tool for Protection." Seattle: UNFPA, PATH.

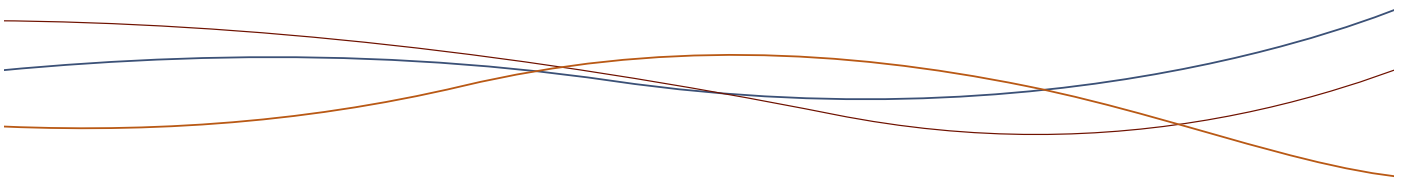
²⁹ Gollub, EL. 2000. "The Female Condom: Tool for Women's Empowerment," *American Journal of Public Health*, 90(9): 1377-1381.

³⁰ Kaler, A. "The Future of Female-Controlled Barrier Methods for HIV Prevention: Female Condoms and Lessons Learned." *Culture, Health & Sexuality*, 6(6): 501-6.

³¹ Gollub, EL. 2000. "The Female Condom: Tool for Women's Empowerment." *American Journal of Public Health*. 90(9): 1377-1381.

³² www.iwhc.org.

IV. COST-EFFECTIVENESS ANALYSIS



IV. Cost-Effectiveness Analysis

The cost-effectiveness analysis was conducted to understand under what conditions the female condom could be cost-effective when compared to the male condom. Because the commodity cost of the female condom is many multiples greater than that of the male condom, it might seem that the female condom would never be comparatively cost-effective. However, there may be circumstances in which the male condom cannot be used or where the cost of promoting additional use becomes excessive. The modeling exercise sought to identify the conditions under which the female condom could be cost-effective.

The analysis was carried out with a computer-based simulation incorporating key features of female condom use, male condom use, and program implementation. The analysis pays particular attention to assessing the effect of male condom use levels on the cost of distributing the *next* additional male condom (that is, the marginal cost) allowing us to compare the costs of more male condoms to the cost of more female condoms. Other important parameters include substitution effects (the rate at which couples use female condoms in sex episodes where male condoms would have been used instead), different types of marketing and promotion programs, male condom waste rates, and different types of sexual partnerships.

Review of Past Female Condom Cost-Effectiveness Analyses

As HIV prevention efforts expand, the urgency of understanding the cost-effectiveness of available prevention options will increase. This urgency is driven by the imperative to make the best use of available resources. Because HIV cases that would have occurred without prevention programs typically cannot be observed directly, computer-based epidemiologic and cost-effectiveness models are needed to project the consequences of new spending on prevention. Two previously published analyses of female condom cost-effectiveness suggested more favorable results than those advanced in the current study. Critiques of these studies follow:

Dowdy, DW, Sweat, MD, Holtgrave, DR. 2006. "Country-wide distribution of the Nitrile Female Condom (FC2) in Brazil and South Africa: A Cost-Effectiveness Analysis." AIDS. 20(16):2091-8.

Dowdy et al. found that the FC2 could be cost-effective in both South Africa and Brazil, where the modeled cost per HIV infection averted is compared with the cost of antiretroviral therapy (ART). The appropriate comparison is with other prevention options such as male condoms, not with treatment. The analysis also assumes that the FC2 would be distributed at volumes approximating 10% of male condom volumes. At higher volumes, costs decrease substantially and cost-effectiveness rises. These favorable results depend on the comparison of female condoms with relatively expensive ART (\$208 and \$2,500 per person per year in South Africa and Brazil, respectively) rather than with other prevention options, especially the male condom. The study's favorable results also stem from low female condom costs, unrealistically low substitution rates, and decreasing marginal costs over very large increases in distribution (i.e., not allowing for potential increasing need for marketing and its attendant costs).

Marseille, E, Kahn, JG, Billingshurst, K, Saba, J. 2001. "Cost-Effectiveness of the Female Condom in Preventing HIV and STIs in Commercial Sex Workers in Rural South Africa." Social Sciences & Medicine. 52(1):135-48.

Marseille et al. estimated the cost-effectiveness of the female condom in the context of a hypothetical sex worker peer outreach program in a very high-prevalence district of South Africa. The favorable cost-effectiveness estimates of this study stem from an unrealistically low estimate of substitution rates, low program costs, and an estimate of the per-episode risk of HIV transmission that was higher than estimates published later based on more sophisticated methods.

Average Costs and Marginal Costs

The term “fully-loaded cost” refers to all of the costs entailed in delivering condoms to their users. In addition to the commodity itself, these costs include packaging, shipping, and storage; transportation to the point of sale; and marketing, promotion training, and overhead costs.

The “average fully-loaded cost” consists of the sum of these costs divided by the number of condoms sold. The term “marginal cost” refers to the cost of distributing just one more condom package. Marginal cost may be either higher or lower than average costs. Because many of the components of a condom program are fixed in the short run, (e.g., rent, administrative overhead, capital equipment), marginal costs may be lower than average costs. For example, rent does not increase if one more package of condoms is sold. However, as the market for condoms is satisfied, it requires more resources to identify and reach the next potential condom user. This tends to make marginal costs higher than average costs.

We modeled and report on five types of cost and cost-effectiveness outcomes:

- 1. Health outcomes.** Cases of HIV averted by the female condom program.
- 2. Fully-loaded female condom program costs.** These costs equal the bulk purchase price of the female condoms themselves (the “commodity cost”) plus packaging, distribution, education, and promotion costs.
- 3. Cost per incremental episode protected (IEP).** In evaluating the female condom versus the male condom for each risk group of interest, it is sufficient to establish the relative cost of protecting the episodes that otherwise would have gone unprotected.
- 4. Cost per HIV infection averted.** This consists of net program costs divided by the number of HIV cases averted. From program costs, we deduct the saved medical care costs from unwanted pregnancies and lifetime antiretroviral costs that would have occurred had the female condom not prevented pregnancies that resulted in the birth of an HIV-infected child.
- 5. Cost per disability-adjusted life-years (DALYs) averted.** We repeat the above comparisons using the DALY, which includes HIV and contraceptive benefits in the same metric and allows comparisons between female condom initiatives and other HIV or non-HIV-related public health interventions. We also include DALYs gained because of reduced maternal mortality associated with newly contracepted episodes through use of the female condom.

The analysis incorporates setting-specific cost, price, condom market, and epidemiological data, and model parameter estimates drawn from peer-reviewed scientific literature wherever possible. Program costs in this model were based on the social marketing programs of Population Services International (PSI). PSI is one of the largest implementers of female condom programs in the world, with active programs in 20 countries. We used PSI's female condom cost data because of the quality and availability of the information and the consistency of its reporting formats across countries and years. However, we also explore the implications for the cost-effectiveness of providing free female condoms in the context of public sector programs. Results were subjected to extensive sensitivity analyses, including univariate, scenario, and threshold analyses. We analyzed the costs and benefits of the earlier version of the female condom, the FC1. The most recent version of the female condom is the FC2, made of

synthetic latex. The FC2 costs about \$0.30 less to manufacture than the FC1 and appears to have similar benefits and possibly higher levels of acceptability. Should the FC2 prove successful, it is likely to have a more favorable cost-effectiveness profile. However, the lower cost of the FC2 would not change the major direction of our findings.

Please note: For those interested in more detail on the cost-effectiveness analysis, a separate article describing the technical specifics is forthcoming.

Finally, we did not include the female condom's benefits in reducing other STIs, such as syphilis and gonorrhea. The male condom has equivalent benefits in this regard; therefore, STI-related benefits would be neutralized in that key comparison. Furthermore, compared with combined HIV and contraceptive benefits, the STI-related benefits are modest.³³

Cost-effective Compared with What?

Cost-effectiveness is relative, and nothing is intrinsically cost-effective. Rather, cost-effectiveness analyses indicate whether one use of funds is likely to generate more benefit than the same funds directed to some other use. Thus, all cost-effectiveness analyses should be explicit about what options are being compared.

The current analysis focuses on female condom cost-effectiveness compared with that of the male condom. It then expands the set of comparators to consider a broader set of HIV prevention options. The male condom is the most appropriate initial comparator to the female condom because both products are barrier protection methods and agencies that are organized to promote one type of condom are well positioned to promote the other; and indeed many promote both.

However, we recognize that the male condom has an advantage over the female condom in that it has been marketed aggressively and has been ubiquitous in the developing world for the last 30 years, whereas the female condom is still an immature product in many developing countries. A generation of men and women has grown up aware of the male condom as a tool to avert pregnancies or STIs. Women are only beginning to learn about the female condom and many do so without the attendant sexual freedom enjoyed by men. If female condom uptake increases, unit costs could decline. We explore the implications of lower female condom costs on cost-effectiveness results.

³³ Marseille, E, Kahn, JG, Billingham, K, Saba, J. 2001. "Cost-effectiveness of the Female Condom in Preventing HIV and STDs in Commercial Sex Workers in Rural South Africa." *Social Science & Medicine*. 52(1): 135-48.

A. Model Input Parameters

The model assumes equal effectiveness in male and female condoms.^{34, 35, 36} Six key inputs underpin the model:

- **HIV transmission rates.** The model incorporates the best available estimates on the risk of transmission per episode of unprotected sex.
- **Female condom and male condom costs.** Fully loaded unit costs for 12 PSI male and female condom programs are shown in Table 4. The non-commodity portion of female condom distribution tends to be about the same as for male condom distribution, or 60 to 65%. The fully loaded cost of the male condom declines as volume increases and fixed costs are spread over more units and levels off. It then rises as it becomes more expensive to reach the last portion of potential male condom users and episodes. The marginal cost of the female condom also changes with coverage levels. However, lacking sufficient data to fully quantify this effect, we used average female condom costs as calculated by PSI. We have also documented results based on country-specific data gathered as part of this study from Tanzania, Zambia, Zimbabwe, and Myanmar that better reflect marginal costs than the unit costs presented in Table 4.
- **Substitution of female condoms for male condoms.** A certain portion of female condoms will actually displace male condoms. As the proportion of episodes covered by male condoms rises, more are susceptible to this “substitution” effect. This effect is supported by data from six studies, from which we were able to

derive estimates of female-condom-to-male-condom substitution rates. These estimates are included in the model.^{37, 38, 39, 40, 41, 42} In all of these studies the female condom was distributed free of cost. Basic economic theory suggests that if they were priced, and especially if they had a higher price than the male condom, substitution rates would decline. Female condom purchase and use levels would also decline.

- **Male condom and female condom waste rates.** The model incorporates the best available data on the portion of male condoms that are distributed but never used.^{43, 44} While the waste rate for female condoms must be greater than zero, in the absence of pertinent data, we assume that there is no female condom waste, thus biasing results somewhat in favor of the female condom.
- **Female condom re-use.** It is possible to wash and re-use the female condom, although studies indicate that this rarely occurs in practice. The model assumes no re-use of the female condom. Re-use for newer versions of the female condom (FC2 or the Dr. Reddy’s female condom) may be even less likely or not recommended.⁴⁵
- **Perinatal and infant HIV medical cost savings.** The female condom is as effective as the male condom in preventing pregnancy. Perinatal cost savings are thus immaterial in a comparison of the effectiveness or cost-effectiveness of these two barrier methods. However, when comparing the female condom with other HIV prevention interventions that have a lower contraceptive benefit, the excess benefit of the female condom in reducing perinatal and infant HIV medical costs must be taken into account. Our estimate accounts for the

³⁴ Pinkerton, SD, Abramson, PR. 1997. “Effectiveness of Condoms in Preventing HIV Transmission.” *Social Science & Medicine*. 44(9):1303-12.

³⁵ Trussell, J, Sturgen, K, Strickler, J, Dominik, R. 1994. “Comparative Contraceptive Efficacy of the Female Condom and Other Barrier Methods.” *Family Planning Perspectives*. 26(2):66-72.

³⁶ Elias, CJ, Coggins, C. 1996. “Female-controlled Methods to Prevent Sexual Transmission of HIV.” *AIDS*. 10 Suppl 3:S43-51.

³⁷ Fontanet, AL, Saba, J, Chandelying, V, et al. 1998. “Protection Against Sexually Transmitted Diseases by Granting Sex Workers in Thailand the Choice of Using Male or Female Condoms: Results from a Randomized Controlled Trial.” *AIDS*. 12(14), 1851-9.

³⁸ Thomsen, SC, Ombidi, W, Toroitich-Ruto, C, et al. 2006. “A Prospective Study Assessing the Effects of Introducing the Female Condom in a Sex Worker Population in Mombasa, Kenya.” *Sexually Transmitted Infections*. 82(5):397-402.

³⁹ Musaba, E, Morrison, CS, Sunkutu, MR, Wong, EL. 1998. “Long-term Use of the Female Condom among Couples at High risk of Human Immunodeficiency Virus Infection in Zambia.” *Sexually Transmitted Diseases*. 25(5):260-4.

⁴⁰ Hoke, TH, et al. “Temporal Trends in STI Prevalence and Condom Use Following Introduction of the Female Condom to Madagascar Sex Workers”

⁴¹ Ministry of Health, Brazil. 2000. “Acceptability of FC in Different Social Contexts,” *Brasilia*.

⁴² Choi, KH, Gregorich, SE, Anderson, K, Grinstead, O, Gomez, CA. 2003. “Patterns and Predictors of Female Condom Use among Ethnically Diverse Women Attending Family Planning Clinics.” *Sexually Transmitted Diseases*. 30(1):91-8.

⁴³ Myer, L, Mathews, C, Little, F (2001). “Tracing Condom Fates: Design and Pilot Results of a Study Investigating the Use and Wastage of Public Sector Condoms.” *African Journal of Reproductive Health / La Revue Africaine de la Santé Reproductive*. 5:66-74.

⁴⁴ Myer, L, Mathews, C, Little, F, Karim, SS. 2001. “The Fate of Free Male Condoms Distributed to the Public in South Africa.” *AIDS*. 15(6):789-93.

⁴⁵ Because access to female condoms is often limited and re-use has been reported, WHO commissioned two consultations to study the evidence on the issue. Based on the findings, WHO does not recommend or promote re-use of female condoms. Sources: Laura Frost. 2002. “WHO Information Update: Considerations regarding Re-use of the Female Condom, July 2002.”

Table 4: Country-specific averages for fully-loaded male condom and female condom costs

	① ② Loaded Unit Costs		③ Percent CPG of Total Program Cost		Non-COG Program Costs	
	MC	FC	MC	FC	MC	FC
Cameroon	\$0.10	\$1.37	38.2%	52.9%	61.8%	47.1%
Congo	\$0.11	\$1.74	54.5%	36.3%	45.5%	63.7%
Mozambique	\$0.23	\$3.38	16.9%	19.2%	83.1%	80.8%
South Africa	\$0.14	\$1.79	32.0%	36.4%	68.0%	63.6%
Tanzania	\$0.10	\$2.00	31.4%	37.1%	68.6%	62.9%
Togo	\$0.21	\$2.34	56.2%	31.5%	43.8%	68.5%
Zambia	\$0.21	\$1.81	33.4%	41.4%	66.6%	58.6%
Zimbabwe	\$0.09	\$1.47	59.3%	46.7%	40.7%	53.3%
India	\$0.11	\$2.35	39.5%	29.8%	60.5%	70.2%
Myanmar	\$0.08	\$3.12	54.3%	22.8%	45.7%	77.2%
Thailand	\$0.13	N/A	36.6%	N/A	63.4%	N/A
Haiti	\$0.10	\$1.38	33.1%	46.3%	66.9%	53.7%
Average over countries	\$0.13	\$2.07	40.4%	36.4%	59.6%	63.6%

① Averaged over up to 9 years of PSI program; at PSI program level of coverage; usually > 50% of episodes.

② Total program costs divided by sales.

③ “Cost of goods” is commodity and packaging costs.

Source: Population Services International (PSI) data

probability of pregnancy, the portion of pregnancies that go to term, the proportion of births that are unwanted as opposed to mis-timed, the cost of perinatal care including postnatal family planning services, and the portion of the population that has access to PMTCT services and ongoing antiretroviral drug therapy. The average cost of a pregnancy is based on the relevant portions of the WHO-recommended mother-baby package. Because contraception reduces the incidence of mother-to-child HIV transmission, in places where there is access to antiretroviral therapy this means saving a lifetime of treatment costs, which thereby enhances the cost-effectiveness of the female condom. Pregnancy-related costs averted are about \$0.10 per newly protected episode and averted HIV costs are an additional \$0.13 per newly protected episode.⁴⁶

We employed multiple sensitivity-analysis techniques to model and assess how results change with a wide range of changes in the values of key inputs. These analyses were particularly important in this study because not all of the data were available in optimal form. We conducted one-way sensitivity analyses in which the values of key variables were altered one at a time, as well as scenario sensitivity analyses in which multiple inputs were changed to simulate a different setting or implementation scenario.

⁴⁶ In addition, we estimated the life-years added through reduced maternal deaths resulting from episodes newly contracepted via the female condom, and added these to the averted DALYs resulting from female condom availability.

B. User Groups

The market for female condoms consists of users with widely varying sexual behavior and HIV prevalence and susceptibility profiles. These factors affect both the cost and the effectiveness sides of the economic assessment. In order to portray this variation and to ensure that the analysis captures the most feasible cost-effective strategies, we constructed three user or client-type scenarios for the female condom. We then applied these scenarios in a high-prevalence setting that would support a more favorable cost-effectiveness outcome than would lower prevalence settings.

The three user groups or client-type scenarios we portray are FSWs, women with regular partners, and women with casual partners.

- **Female sex workers.** FSWs and their clients are portrayed in our model as having a very high risk of HIV infection. Given typically high male condom usage rates among sex workers, the model assumes high rates of substitution of male condoms with female condoms within this population group. Because the prevalence of HIV is high in sex workers and their clients, the frequency of discordant episodes is also high.⁴⁷
- **Women with regular partners.** This scenario portrays female condom users whose sexual relationships are overwhelmingly with spouses or with other “steady” partners. Male condom use tends to be low in these partnerships, and substitution rates are also low. Although in high-prevalence settings women with steady partners

are still highly vulnerable, HIV prevalence rates tend to be relatively lower in this scenario, as are discordance rates. Since a high proportion of women are in regular partnerships, the lower annual risk levels in regular partnerships are consistent with recent findings that discordant regular partnerships account for a very high proportion of total incidence.⁴⁸ That is, annual risk can be lower in regular than in casual partnerships, yet still account for a larger portion of total incidence.

- **Single women.** These female condom users primarily have sex with casual partners. Male condom use levels, substitution, HIV prevalence, and discordance all assume values that are somewhat higher than in the “women with regular partners” scenario and lower than in the sex worker scenario.

C. Key Findings

Female condoms appear to be much less cost-effective than male condoms when distributed through traditional social marketing and public sector channels. Table 5 displays the central results from our study. Results are presented as the ratio of costs per newly protected episode between the female condom and the male condom. On the bottom two rows of Table 5 we show the cost of the female condom per HIV case averted and per disability-adjusted life-years averted. Since a number of viable HIV prevention options have cost-effectiveness ratios of \$100 per DALY averted or better and less than \$500 per HIV case averted, it would appear that the female condom is not cost-effective, even with this expanded range of comparators.

Table 5: Summary cost-effectiveness results with traditional condom social marketing

	SWs	Women with regular partners	Single women
MC cost per added episode protected	\$0.50	\$0.10	\$0.20
FC cost per added episode protected	\$10.90	\$2.20	\$2.40
Ratio of FC : MC cost per episode protected	21	15	13
Ratio of FC : MC cost per episode protected if ignore substitution	4	14	11
Cost per HIV infection averted	\$20,640	\$9,800	\$8,450
Cost per DALY averted	\$1,020	\$480	\$420

Source: Cost-effectiveness model

⁴⁷ “Discordance” refers to sexual episodes between an infected and an uninfected person, the only type in which HIV transmission can occur and therefore the only type in which either the female condom or the male condom can be effective. All else being equal, the higher the level of discordance, the greater the likelihood any given condom will interrupt HIV transmission.

⁴⁸ Dunkle, KL, Stephenson, R, Karita, E, et al. 2008. “New Heterosexually Transmitted HIV Infections in Married or Cohabiting Couples in Urban Zambia and Rwanda: An Analysis of Survey and Clinical Data.” *Lancet*. 371(9631): 2183-91.

Data Limitations of this Study

The precision of this analysis was constrained by absent or imperfect data on a number of important input parameters. Perhaps the most important limitation stems from a dearth of information on how the unit cost of male and female condoms varies by sales volume. As mentioned under “female condom and male condom costs” previously, we have extensive information on average unit costs. However, we have limited marginal cost data for programs that include male condom promotion and other prevention activities. Apart from Zimbabwe, we also have no information about the cost of attaining new episodes of protection within an existing male condom promotion program.

The marginal cost of the male condom could be lower than the average costs, as we found for the female condom. This is because as fixed costs are spread across a larger number of condoms, average costs decline. However, as male condom use increases, programs may need to increase their expenditures on promotion, suggesting an increase in marginal costs. We make the assumption, favorable to cost-effectiveness for the female condom, that male condom marginal costs are rising. This is “favorable” in the sense that, compared with the male condom, the female condom looks increasingly cost-effective as male condom costs increase. However, there may be situations in which male condom costs are so high that the male condoms are no longer cost-effective. At that point, the proper standard by which to measure female condom cost-effectiveness would no longer be the male condom, but other types of readily available prevention strategies.

Similarly, there are no data on how the marginal costs of the female condom change with program expansion. At a certain point, those who are easiest to reach will have been reached, and the cost of distribution begins to rise, thus increasing unit costs. Our analysis does not account for these eventual rising costs and instead uses current average cost and marginal costs based on current sales volumes.

Our estimates of substitution rates are based on six published studies that document male condom coverage levels before and after the introduction of the female condom. They range in male condom coverage from 31% to 97% of episodes. Client groups include sex workers, family planning patients, and STI clinic patients. The data show a strong correlation and close fit between male condom coverage and substitution. However, because substitution affects cost-effectiveness, particularly in groups with high substitution such as sex workers, it would be useful to gather more information on substitution levels by particular user groups. Imposing a higher price on the female condom than for the male condom should also have the effect of lowering substitution, and these price effects should be quantified.

Because of an absence of data, we were also not able to analyze the marginal costs of the male condom and the female condom

by user group, such as regular partnerships, sex workers, and their clients. It is likely that marketing and distribution costs for some of these groups diverge significantly from average program unit cost. The analysis would allow for cost-effectiveness results that more accurately reflect the costs of attaining increased use levels among the various female condom users.

We also found limited usable data pertaining to the portion of male condoms that are wasted. Importantly, all of the information on condom waste pertains to free condom programs where one would expect waste levels to be higher. Based on a study of free, publicly distributed condoms in South Africa, which indicated a 13% waste rate, we adopted 20%, 10%, and 5% rates of waste by FSWs, women in casual partnerships, and women in regular partnerships, respectively. (Myer, L, et al., The fate of free male condoms distributed to the public in South Africa. *Aids*, 2001. 15(6): p. 789-93.)

The estimates derived for the contraceptive benefits of the female condom also contain parameters for which data are sparse. For example, we do not know with certainty what portion of births was truly unwanted as opposed to being mis-timed in HIV-negative versus HIV-positive mothers. Nor are good estimates available for the pregnancy reduction benefits of other HIV prevention interventions against which female condom cost-effectiveness might be compared, such as voluntary counseling and testing; information, education, and communications campaigns; and school-based interventions. These interventions can reduce unprotected episodes through partner and episode reduction and thus also reduce the risk of pregnancy.

Finally, derivations of demand curves for both male and female condoms are also excluded from our analysis. Demand curves quantify and display how condom consumption varies with price. These curves, if available, would help us predict the effect of using price as a tool for reducing the rate at which female condoms substitute for male condoms. The data available on how price variation within a country affects demand are sparse, with very limited price variation. Further, the demand data are aggregated, so we cannot separate the effect of price on the number of users from the level of use among users. This distinction may have implications for unit costs. Nevertheless, we are able to relate fully-loaded unit costs of condoms to individual use levels in each country. This information is sufficient to derive the cost-effectiveness estimates expressed as the cost per newly protected episode. Where data were absent or incomplete, we ran sensitivity analyses with a wide range of plausible inputs for key inputs and combinations of inputs. The sensitivity analyses suggest that our qualitative findings — that the female condom is substantially less economically attractive than the male condom and other HIV prevention options — are true for the majority of plausible combinations of input values.

The numerical results summarized in Table 5 suggest a fairly dramatic difference in the cost-effectiveness of the female condom as compared to the male condom — specifically, the cost of the female condom is estimated to be roughly 13 to 21 times higher than that of the male condom. Sensitivity analysis using FC2 costs rather than FC1 costs improves the cost-effectiveness, but not by much: the female condom drops to being 10 to 20 times higher in cost than the male condom.

Perhaps the most surprising result of this analysis is that traditional female condom programs are not cost-effective even for female sex workers who are at very high risk. This is because substitution rates (of female condoms for male condoms) are very high in this group, so that only a small portion of female condoms provides additional protection. For women with regular partners, female condoms are not cost-effective because of the lower cost of the male condom compared with the female condom and because HIV risk levels are generally lower in women with regular partners than in sex workers and in many women with primarily casual partners. (Relatively lower risk levels are still consistent with the fact that women in regular partnerships account for a high portion of total incidence.) For single women, cost-effectiveness of the female condom is compromised by both significant substitution and the large cost differential between female condoms and male condoms. The

factors unfavorable to female condoms overwhelm the effect of the modestly higher risks in this group compared with women who have regular partners.

It should be noted that in some settings and in some female condom user groups, particularly women with regular partners, the estimates of male condom marginal cost used in the model may be too low. Men may not use the male condom, regardless of the intensity and quality of condom marketing and information campaigns. In these situations, the correct comparison is no longer between female condoms and male condoms. Because male condoms are not an option, female condoms should be compared with other possible HIV prevention options. This reasoning can be applied to any situation in which the market for male condoms is “saturated” — that is, where every reasonable effort has been made to generate demand and to fulfill that demand. After a certain level of male condom adoption, the cost of further adoption becomes exorbitant, and male condoms are no longer a reasonable comparator. However, with a range of \$400 to \$1,000 per DALY averted, the female condom is not an attractive option when compared with the best available data on the cost-effectiveness of other underutilized HIV prevention strategies, such as male circumcision, FSW outreach and counseling programs, or prevention of mother-to-child-transmission.

Male Condom “Saturation” and Female Condom Cost-Effectiveness

In settings where there is a significant unmet demand for male condoms, it makes sense to scale up access to male condoms before large-scale introduction of the female condom. This is because it is more efficient to cover risky sex episodes with relatively inexpensive male condoms than with more costly female condoms wherever possible. However, what about settings with a long history of intensive male condom marketing? Are at least some of these markets “saturated”? That is, have some markets reached a point in which everyone who can be persuaded to use male condoms is in fact using them? Might some of the residual unprotected sex then be “topped off” with the introduction of the female condom? There are three reasons to believe that a focus on “saturated markets” is unlikely to yield a cost-effective role for the female condom:

- First, broadly speaking, the market for male condoms is far from saturated as evidenced by the rising demand for male condoms in many developing countries. As noted above, it is more efficient to address existing unmet demand with male condoms than with female condoms because of the significant cost differential.
- Second, it is not easy to know when a market is saturated. What constitutes a fully rigorous promotion campaign? Effective demand can change both because of program marketing activities and because of secular trends. The 100% *Jeune* campaign of Population Services International in Cameroon provides a good example of the role of both of these variables in affecting male condom uptake. (Plautz, A, Meekers, D. 2007. “Evaluation of the Reach and Impact of the 100% *Jeune* Youth Social Marketing Program in Cameroon: Findings from Three Cross-Sectional Surveys.” *Reproductive Health*. (4)1.)
- Third, topping off the residual unprotected episodes without any particular target audience in mind could result in many of the female condoms simply displacing male condoms.

Assuming that reducing HIV transmission is a primary program goal, the female condom may not be a cost-effective alternative, even where it is impossible to increase male condom uptake.

There are combinations of parameter values in which the female condom could be cost-effective compared with the male condom. This occurs whenever the fully loaded marginal cost of the male condom exceeds that of the female condom and substitution levels are under about 10%. However, in order for either condom to be cost-effective compared with other available HIV prevention options, the unit cost would need to be under about \$1.50, and used in discordant pairings about 25% of the time. This implies HIV prevalence of about 15% or higher. As will be described in the Conclusions and Recommendations sections, the combinations of conditions under which the female condom might be cost-effective are likely to be limited.

Lastly, the analysis attempted to calculate the opportunity costs of the female condom in terms of the empowerment benefits that have been studied and were discussed earlier. No data exists on the value of these empowerment benefits at present. We addressed this issue by a simple thought experiment of quantifying the value that would have to be placed on these benefits in order for the female condom to become cost-effective. In an exploratory scenario, to avert 100 cases of HIV, a significant amount of funds — ranging between \$400,000 to \$900,000 — would have to be spent on the female condom over what would have to be spent on the male condom. To put this another way, with a budget of \$100,000, between 90 and 120 additional cases of HIV could be averted by investing in the male condom rather than the female condom. These estimates prompt us to ask whether the non-HIV prevention goals of the female condom could be achieved more efficiently through other means.

D. Findings Discussion

The results presented in Table 5 are based on average condom cost figures and typical HIV prevalence rates in sub-Saharan African countries. However, there are scenarios where the female condom will fare much better or worse, depending on female condom costs, male condom costs, different substitution rates, and HIV prevalence. For example, in South Africa, a country with high HIV prevalence, fairly low female condom costs, and roughly average male condom costs, the cost-effectiveness of the female condom would be better than for any of the user groups shown in Table 5. Depending on the particular user group and the substitution rates, the cost-effectiveness could improve even further (or worsen).

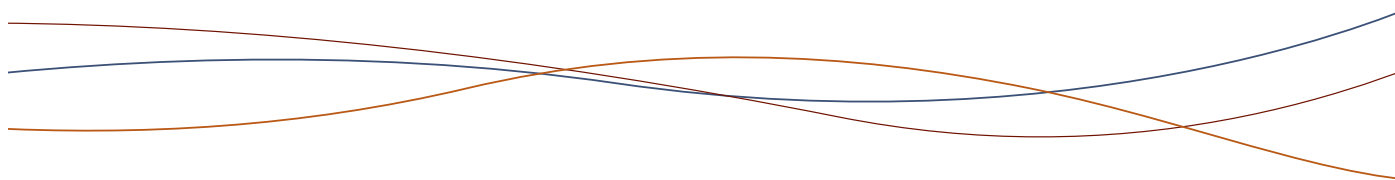
Much depends on what happens in any particular country and with any particular user group as managed within a particular program. The modeling exercise shows a vast difference in

cost-effectiveness between male and female condoms based on average costs. It may be difficult or impossible to close this gap, but it can be narrowed through attention to a number of key levers. These levers are discussed below.

- 1. Substitution rates:** Based on the cost-effectiveness modeling work conducted, substitution rates seem to be relatively low for women in long-term relationships. For FSWs, substitution is high overall, with a minority of “low substitution” sex acts where use of the male condom may not be possible. Assigning a higher price to the female condom compared with the male condom should reduce the substitution of female condoms. However, we found that shifting a program from priced female condoms to free female condoms has a very unfavorable effect on incremental cost-effectiveness, because of the high rates of substitution among those newly recruited to the female condom.
- 2. Use of the female condom by known **discordant partners**** increases both incremental cases of HIV averted and cost-effectiveness, because only in such pairings is there a risk of HIV transmission.
- 3. Marginal costs of the male condom:** Some target audiences — for example, women in long-term relationships — require high levels of investment in male condom promotion to convince them and their partners to use the male condom. Female condom cost-effectiveness is enhanced when used by these target populations.
- 4. In order to increase cost-effectiveness, the **marginal costs of the female condom**** can be reduced. Cost reduction options include more efficient program planning and capitalizing on economies of scope by integrating with and leveraging other activities, such as male condom distribution, as a primary area of focus. Female condom marginal costs may be particularly low in programs that sponsor many activities and can therefore distribute fixed costs over multiple activities (such as sharing the costs of transport between female condom programs and male condom programs).
- 5. Any reduction in the commodity cost of the female condom** may improve cost-effectiveness.

In summary, we recognize that cost-effectiveness is not the only criterion on which funding decisions for the female condom should rest. Importantly, where the female condom is the only technology that can be used by women to protect themselves, every effort must be made to ensure that women are protected as cost-effectively as possible through attention to the levers mentioned above. There are also important social goals supported by female condom promotion that are difficult to quantify. However, a very high estimate would need to be assigned to the female condom’s ability to help attain these other goals in order to justify spending on the female condom.

V. CONCLUSIONS



V. Conclusions

As this study has shown, the female condom has been introduced in dozens of developing country settings, and during the last 15 years it has:

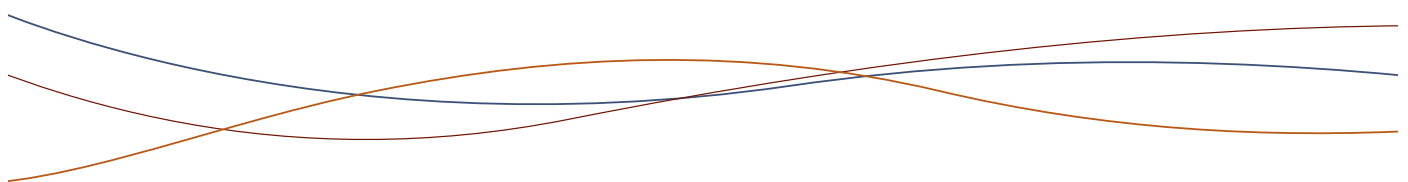
- Generated interest and use under tough budgetary constraints
- Averted cases of HIV and unwanted pregnancies
- Created strong voices of support for women's individual and societal sexual rights
- Spurred new technical improvements
- Awakened governments, donors, and implementers to the importance of multiple approaches to HIV prevention

Yet, against this impressive backdrop, the female condom is at an impasse with key funders ambivalent about its future, mostly because of concerns about commodity and programmatic costs. The result is an unhelpful stalemate of sorts, with advocates calling for a “fair run” for the female condom and researchers and skeptical donors wanting more data and proof before deliberate action and investment can take place. This report offers a number of conclusions that can help to break this impasse.

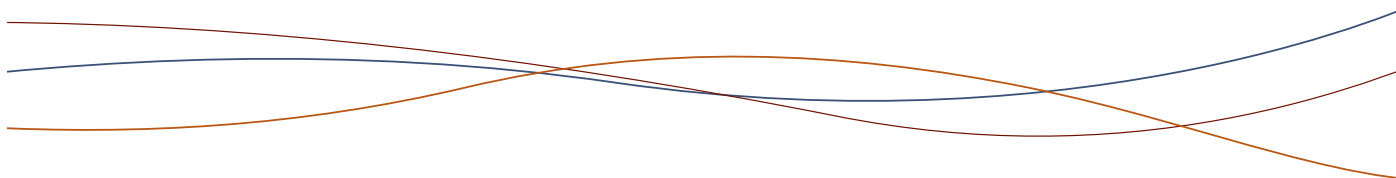
1. **The female condom deserves support as a vital technology in the toolbox of HIV prevention when it can be directed to individuals who cannot or will not use the male condom.** This analysis supports programming for the female condom that is as cost-effective as possible.
2. **The field does not have a consistent definition of success for the female condom.** Some view the female condom as a specialized product that should provide incremental HIV protection, complementing the male condom. Other interviewees felt that more units distributed represents success regardless of whether female

condoms prevent new cases of HIV, or whether the female condom is introduced in a cost-effective manner. Some advocates view distribution of the female condom as being important in conferring women's empowerment benefits both to the individual and society, and that empowering women is a key step toward stemming the epidemic. The lack of a consistent definition of success for the female condom is probably the greatest blind spot for this prevention option and the most severe obstacle to garnering additional support. A definition of success for the female condom is offered in “Recommendations”.

3. **The female condom is currently not cost-effective.** The female condom is much less cost-effective than male condoms when distributed through traditional social marketing and public sector channels. The female condom is also substantially (10- to 100-fold) less cost-effective than other available HIV prevention strategies. With the introduction of the FC2, commodity costs have come down for the female condom, but such reductions are insufficient to change the direction of our findings. While cost-effectiveness is only one consideration in the choice of different prevention strategies, we believe that this analysis should inform the design of female condom programs so that they might become more cost-effective in the future.
4. **The female condom provides crucial benefits in terms of women's empowerment, but these are difficult to quantify.** Women's empowerment is central to effective HIV prevention, and programs that confer these benefits should be supported by donors. However, this does not necessarily mean that the female condom is the most effective or most cost-effective means of delivering these benefits. Research is needed to specify these benefits, such as an individual woman's improved ability to discuss and negotiate sex.



VI. RECOMMENDATIONS



VI. Recommendations

The various analyses conducted in this study — a literature review, expert interviews, research on 14 active female condom programs in developing countries, and a cost-effectiveness modeling exercise — point to the paramount need for a consistent definition of female condom success and a framework for putting the definition into action. A new definition of success is recommended below, followed by advice on “smart programming.” Lastly, additional and more specific recommendations are offered to program managers, donors, and academics.

A. A New Definition of Success for the Female Condom

The female condom should provide benefits for HIV/AIDS prevention at a cost that compares reasonably with the incremental costs of alternative ways to prevent HIV, with due acknowledgment and understanding of the many benefits that do not readily lend themselves to quantification.

A similar definition of success was broached at a technical update held on the female condom in 2001. However, the definition was limited to incremental benefits, not cost-effectiveness relative to the male condom, and the idea of additional benefits was missing.⁴⁹ This new definition of female condom success challenges the notion that more investment should be dedicated to the female condom solely because its current distribution and investment are low compared with that of the male condom. This definition also brings up the issue of additional choice in prevention methods as an end in itself. Donors may value choice in prevention options, but program managers are faced with the practical consequences of trading off choice against other important values. As long as the female condom is supported by limited

public resources, implementers must weigh the incremental benefits that it can deliver — additional averted cases of HIV/AIDS or other benefits — against its cost. Alternatively, if donors value choice regardless of health benefits, the opportunity cost of this value should be explicitly stated.

The proposed definition of success should rebalance the debate from the current dialogue on top-down, supply-oriented efforts to increase purchases of the female condom or reduce the costs of manufacturing to a greater dialogue on the bottom-up determination of where the female condom can best deliver incremental value, given the relative advantages of the male condom. This study shows that the female condom is roughly 10 to 20 times more expensive than the male condom, depending on the target audience. This gap would be difficult to close through increased volumes of the female condom or improved manufacturing processes. Further, donor guarantee/subsidization of higher-volume purchases and program support may simply duplicate benefits derived from the male condom. A top-down perspective is not the answer; rather, a highly targeted approach is more likely to achieve success as defined in this study.

B. Smarter Programming

The female condom should be introduced strategically to specific target audiences within certain countries to manifest the new definition of success. The UNAIDS Guide for Planning and Programming serves as perhaps the best guide at present, because it suggests that the female condom should be introduced as part of an integrated package of prevention interventions, targeted at populations that cannot use the male condom consistently.

A New Definition For Female Condom Success In The Developing World

The female condom should result in averted cases of HIV/AIDS and unwanted pregnancies that could not be more readily achieved through alternative approaches, notably additional promotion of male condoms, and should be distributed in a manner that is as cost-effective as possible. Additional benefits, such as improved relationships with marginal groups or expanded women's rights, should be no more costly than when achieved by other interventions that bring about similar results.

⁴⁹ Friel, P. 2005. “Review of Past Action Plans and their Implementation.” Global Consultation on the Female Condom. Baltimore. September 26-29. (PowerPoint presentation).

But programmers can go a number of additional steps further. Smarter programming can improve both health impact and cost-effectiveness by identifying and serving target audiences where some combination of four critical conditions can be optimized: seroprevalence discordance, low substitution of female condoms for male condoms, low female condom marginal costs, and high male condom marginal costs. These conditions, or levers, while not necessarily new to the dialogue on the female condom, can be used by programmers to develop strategies with certain target audiences that are most likely to provide averted cases of HIV/AIDS not otherwise covered by the male condom, administered as cost-effectively as possible. One such strategy, which attempts to reduce the marginal costs of the female condom among those who are at high risk of infection and are not willing to use the male condom, is provided for illustration and discussion.

Illustrative Strategy: The female condom as an alternative method of protection for female sex workers who cannot use the male condom. As discussed, FSWs who cannot use the male condom with their paying partner (because a male client is unwilling or cannot use one because of inebriation) would rank as a high priority for the female condom, because the product can avert new cases of HIV/AIDS in these risky scenarios.

There are two approaches for addressing this target audience. First, female condom distribution can piggy-back on male condom campaigns — leveraging existing resources and infrastructure — and be positioned as an alternative for FSWs who cannot use the male condom. Targeting FSWs and their clients with male and female condom outreach would limit substitution. Second, the female condom can be socially marketed (sold) at affordable prices that are still markedly higher than the price of the male condom. Charging a price for the female condom reduces the likelihood that sex workers would use a female condom when a cheaper (or free) male condom is a possibility, but such a price might reduce female condom uptake.

In assessing whether this market segment meets the criteria for success, program managers should weigh two additional factors. First, it is important to reflect upon comparative program investment in sex worker clients emphasizing the importance of male condom use. Such additional investment in male condom programs may not be worthwhile in countries where male condom use has been heavily promoted for a quarter of a century (most countries with significant sexual transmission of HIV). This may suggest that the marginal cost of the male

condom in these circumstances would be extremely high. Second, program managers should consider the value of the less quantifiable benefits, such as markedly improved access to female sex worker groups (to provide other health services such as STI prevention, treatment, and education, etc.).

The above strategy attempts to optimize some of the conditions for success. Programmers can try to find a similar scenario in their country settings, or they can seek out conditions of discordance, high marginal male condom costs, low marginal female condom costs, and low substitution in a range of other scenarios. We encourage programmers to find or create these conditions through sex worker outreach programs, through prevention-for-positives programs, by working with women in stable relationships, or even by working with university students. Without careful attention to these conditions, however, female condoms may not reach women most in need of them and they will not be delivered in a cost-effective manner. Program managers should be cognizant of the potential stigma conferred by highly-targeted programs as well.

Additional recommendations follow for program managers, donors, and researchers.

C. Stakeholder-Specific Recommendations

Program Managers: Program managers have a critical role because they can make decisions about where and how the female condom is integrated into HIV/AIDS prevention campaigns. Specifically, program managers can consider the following:

- Gathering data to make more informed decisions about whether and how the female condom should be supported. The data limitations explained in this study could be partially remedied by improved data collection by program managers. Many of the 14 programs that FSG analyzed for this study had readily available data for price, staffing, and female condom distribution. Data was limited for costs of promotion, interpersonal communication, and provider training. Expenditures per target group were, in almost all cases, unavailable. Program managers could attempt to collect this information and calculate the true marginal costs for the female condom or any other intervention that uses a male condom program as a foundation.

- Evaluating their smarter programming efforts:
 - **Target audience discipline:** To ensure that the female condom is not being offered across the board, program staff can do simple market audits annually.
 - **Cost-effectiveness:** A primer to help conduct a rough but useful estimation of the marginal cost of the female condom follows. This costing exercise is likely to generate a better understanding of the female condom cost structure and identify opportunities to contain those costs.
 - **Measurement and enhancement of incremental benefits:** Estimation of incremental benefits is complex. A thorough assessment would require

estimation of the portion of condoms used in formerly risky sex acts. Assessing risk, in turn, requires data on the behavior profile of female condom users and their partners, and on the HIV prevalence level in these groups. A simpler but still useful assessment might consist of a survey of female condom users that generates information on frequency of sex episodes and prospectively assesses the portion of condom-protected episodes, before and after initiation of female condom use by the consumer. This survey may provide actionable information that program managers can use to refine the marketing and targeting of the female condom.

Female Condom Marginal Cost Analysis Primer

1. **Time frame.** Select a recent period such as the last 12 months. Estimate the number of female condoms that the program distributed during that period.
2. **Commodity costs.** Assign a current unit commodity and packaging cost and multiply the unit cost by the number of condoms sold (or distributed for free).
3. **Personnel.** For each staff member, determine what portion of work time is spent specifically on the female condom program. Include field staff who are directly involved in implementing programs, as well as administrative staff. Also estimate the female condom-related time of those who are involved in marketing, promotion, and IEC. A useful way to help people think about this is to ask, "If there were no female condom activities, how many hours per week would be freed up?" Multiply the percentage of full time devoted to female condoms by the compensation (including fringe and allowances) of each staff member. Bear in mind that the actual time spent on the female condom may be very different from what is implied in formal job descriptions or payroll records.
4. **Promotional materials.** By checking invoices or other records, estimate the cost of female condom-related promotional materials.
5. **Transport and storage.** Costs of storing and transporting female condoms to points of sale or distribution may be close to zero, as female condoms are often transported along with other items. However, over the course of a year, the absence of female condoms might mean that fewer vehicle trips would have to be made. If that is so, estimate the number of trips saved and multiply by the cost of each trip, including fuel and driver's compensation.
6. **Research.** Any research related to female condom marketing or use should be included. Since surveys often include other issues, take the proportion of questions that are specifically related to female condoms as a proportion of total questions and multiply by the cost of the research effort. Since there are fixed costs entailed in designing and implementing the research, take 50% of the cost derived from the "percent of questions" calculation described above.
7. **Generate a unit marginal cost.** Add up each of the items two to six above, and divide by the number of female condoms distributed during the corresponding time period.

Strictly speaking, the result is not truly a marginal cost. Marginal cost is the cost of providing the next one unit of output. Also, marginal costs can vary according to their intended users. Some users may require more persuasion, and thus higher marketing costs. Others may be geographically remote and require more transportation costs. The closer this exercise is tied to particular users, the more precise and useful the result will be. However, for program planning purposes, the approximation generated using this method is useful.

Donors: Donors that support the female condom do so with a range of motivations. While a common thread may be to reduce the burden of HIV/AIDS, some donors are looking for clear evidence of value for money, others are motivated by the female empowerment potential of the product, and a few consider their backing to be a form of diversification or hedging to ensure that the female condom remains one of several prevention interventions. There can be overlaps among these motivations for an individual donor. Donors will continue to pursue their own agendas, but for the sake of HIV/AIDS control, funders must ensure that the female condom is distributed and promoted to increase the number of HIV cases averted in as cost-effective a manner as possible. Several specific recommendations are offered for donors:

- To fund existing programs and potentially new ones, a **Female Condom Success Fund** could be created in order to provide incentives for program managers, advocates, and academics/researchers to implement, support, and evaluate approaches in line with the conditions of smarter programming mentioned above.
- Donors can also support important research gaps that are mentioned in this study.
- The male condom campaigns aimed at the target audiences examined in this study — female sex workers, women in long-term relationships, and single women with multiple partners — must be supported as long as the marginal costs of the male condom are not prohibitively high. While male condoms may be used less by women in longer-term relationships, creative efforts that might cost more than present campaigns should be directed toward both women and men. With more data about the marginal costs of the male condom for specific target audiences, program managers could inform donors about the best use of resources for either male condoms or female condoms to create incremental acts of HIV/AIDS averted.

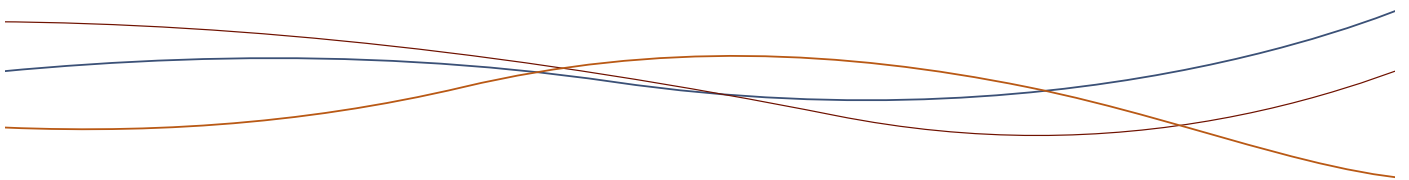
As for whether donors should invest in research and development projects to create new, more affordable female condoms that could improve cost-effectiveness, they should first consider the behavior of other funders of the female condom. If other donors are unwilling to support female condom programming in the field, R&D investments that yield lower commodity costs may offer little value to the female

condom overall. The cost-effectiveness modeling suggests that R&D improvements would have to be extraordinary to garner cost-effectiveness commensurate with the male condom.

Academics and Researchers: Researchers play an important role in the continued exploration of the female condom as a value-added tool in the fight against HIV/AIDS. There are a number of data limitations that these researchers could address:

- Most importantly, the value of the less quantifiable benefits of the female condom should be identified and inventoried.
- The marginal costs of both male and female condoms by user group were not available through this analysis because program managers currently do not collect this data. Researchers can work with program managers to design research that captures this information and then offer guidance about the best way to collect this information in the future.
- As mentioned in the data limitation section, additional research on female condom substitution is recommended, particularly among different user groups.
- Data on public sector programs is particularly weak. Information about programmatic costs from government programs is spotty or too general to be helpful.
- Various aspects of the contraceptive benefits of the female condom also require better understanding. These include the portion of pregnancies that are truly unwanted and the contraceptive benefits of competing HIV prevention options such as VCT and information, education, and communication campaigns.
- Data bearing on the demand for male condoms and female condoms and how demand varies with price would refine the estimates presented in this study, and would allow us to be more specific about the relationship between price, uptake, and substitution.
- The cost-effectiveness analysis conducted for this study used a model that incorporated data from more than a dozen female condom programs, rather than analyzing individual programs in depth. To confirm the results of this study, researchers can focus on discrete female condom programs.

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Disclaimer

Please note that the opinions expressed in this paper are those of the authors and do not represent the views of the Bill & Melinda Gates Foundation. Questions about the foundation's opinions and plans regarding the female condom should be directed to and addressed by the foundation.

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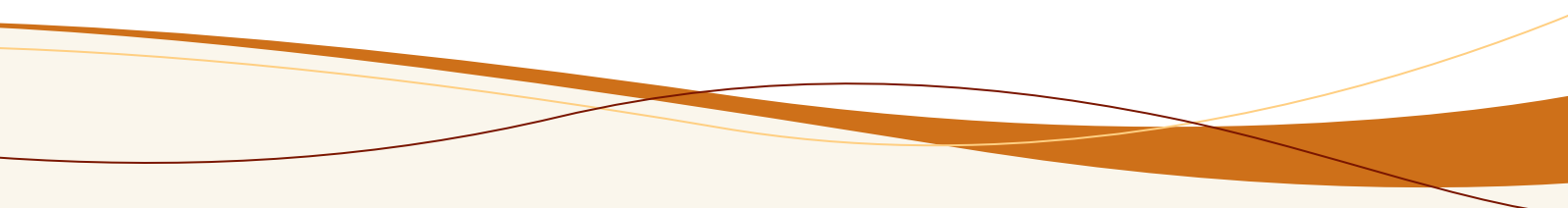
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