

THE
FEMALE
CONDOM

From

Research

to the

Marketplace



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Family Health International (FHI) is a nongovernmental organization that works to improve reproductive health around the world, with an emphasis on developing nations. Since 1991, FHI has implemented the AIDS Control and Prevention (AIDSCAP) Project, which is funded by the United States Agency for International Development (USAID). FHI/AIDSCAP has conducted HIV/AIDS prevention programs in 40 countries. The AIDSCAP Women's Initiative was established in 1994 to mainstream gender issues throughout AIDSCAP and raise awareness of the impact of HIV/AIDS on women within the international community.

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Preface

AIDSCAP's direct involvement with matters related to the female condom as an AIDS prevention method began in October 1993, when AIDSCAP hosted the first female condom conference. The meeting, which attracted 45 health professionals, policy makers, researchers and NGO leaders, generated a research agenda largely focused on acceptability and affordability. It is encouraging that today, much of that research agenda has been carried out.

Yet, in 1997, many questions about the device and its use remain unanswered and the female condom, the only woman-initiated protective method, is not widely available, particularly in the developing countries. This conference, "The Female Condom: From Research to the Marketplace," was convened to address the outstanding issues that act as barriers to those men and women who want the device. One hundred and thirty individuals from 19 countries representing 60 organizations came together in this meeting to consider current issues relating to the female condom, particularly ways to increase its accessibility. AIDSCAP is proud to have hosted a conference that met the felt need of so many diverse groups and individuals. It is also grateful for the support provided by USAID to the conference and to research on the female condom.

Out of this conference come over 40 actions for policy makers, donors and the private sector, women's advocates, program planners, scientists in research and development, researchers in the field and community organizations. These challenge all sectors interested in increasing the accessibility of the female condom for contraception and disease prevention. AIDSCAP deeply appreciates the wide participation that led to clear guidelines for those who can make a difference globally. AIDSCAP fully supports and encourages the implementation of these recommendations and believes that together we can move the female condom from research to the marketplace.

Peter R. Lamptey

FHI Senior Vice President, AIDS Programs

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Other AIDSCAP staff who played important advisory roles as members of the conference working party were William Schellstede, a senior vice president of Family Health International, Gina Dallabetta, associate director of the STD Unit, Phil Hughes of Population Services International, Jan Hogle of the Evaluation Unit, and Molly Strachan and Sara Padilla of the Latin America/ Caribbean Regional Office.

Without the support of USAID, this meeting could not have succeeded in bringing together the major organizations concerned with the female condom. Special recognition is given to contributions made by Duff Gillespie, Victor Barnes, Paul Delay, Barbara de Zalduondo, Alan Getson, John Novak, Jeff Speiler and Kirsten Vogelsong. The encouragement and support of Ward Cates, JoAnn Lewis, Paul Feldblum, Carol Joanis, Jason Smith, Markus Steiner and Eli Carter of Family Health International are greatly appreciated. The Women’s Initiative is grateful to the 18 facilitators, 12 experts and 6 moderators who helped guide the meeting. The reporters are also to be thanked for the detailed notes that contributed to the development of these proceedings.

Finally, thanks go to all of the men and women around the world who have expressed a need to use the female condom and to the conference participants who accepted the challenge of advancing knowledge and understanding about this critical issue.



Introduction

Many women around the world have made it clear that they want the female condom. In acceptability studies and other types of introductory research, women and their partners have repeatedly said they would keep using the female condom if it were available. This overriding message emerged from the two-day working conference, “The Female Condom: From Research to the Marketplace,” held May 1 and 2, 1997, in Arlington, VA.

Family Health International’s AIDS Control and Prevention (AIDSCAP) Project sponsored and coordinated the conference through its Women’s Initiative, with funding from the U.S. Agency for International Development (USAID). The more than 130 participants from 19 countries included experts from service programs, research projects, governments, women’s advocacy groups, manufacturers and product developers, marketing experts and the donor community. (See attached participant list.) The conference explored unresolved issues surrounding the female condom and ways to increase its availability, especially to women in the developing world.

The female condom offers women a way to protect themselves from sexually transmitted disease (STD) and unintended pregnancy. Research has shown it to be safe, effective if used consistently and correctly, in demand and acceptable to many women and men. While it is not yet generally available, affordable, promoted or marketed to full scale, it has been approved for sale in a growing number of countries at a public price.

Conference participants identified cost as a major barrier to widespread availability of the female condom. To bring the device to the marketplace, it was agreed, the private sector is one important option to pursue. Another critical issue is funding from donors, who must coordinate their efforts effectively, efficiently and as expeditiously as possible where HIV/AIDS prevention is concerned.

The public health community, women’s organizations, the private sector and governments need to address the individual and societal factors that put women at risk of STDs. Specifically, these groups should provide women with a method over which they have some control to prevent STDs and unintended pregnancy.

CONFERENCE OVERVIEW

Innovative Design

The conference had two specific objectives: first, to share lessons learned since 1993, when 45 representatives of health, AIDS prevention and family planning agencies discussed the potential role of the female condom in international AIDS prevention; and second, to develop strategies to increase awareness, acceptability, availability and affordability of the female condom based on the latest domestic and international research findings and experiences from the field.

To meet these objectives, each participant selected one of seven fields of inquiry on which to focus. These included science, women’s empowerment, product delivery, product introduction, price, policy, and evaluation.

The innovative design of the conference had participants initially working closely within each of the seven fields to identify critical issues. The groups then shared ideas across disciplines, in “cross-sharing” sessions. This interaction was designed as a holistic approach to exploring ways to increase accessibility of the female condom, and allowed participants to identify differences, find common ground and propose recommendations.

Redouble Our Efforts

Speakers in the opening session identified the key issues the conference would explore. In her welcoming remarks, Dr. E. Maxine Ankrah, director of AIDSCAP’s Women’s Initiative, pointed out that the 1993 conference had examined what was known about acceptability and affordability of the female condom and produced a broader research agenda. Much of that research agenda has been addressed, she explained, including more than 20 abstracts and presentations made at the 1996 international AIDS conference in Vancouver. “At this second conference, our goal is to enhance accessibility,” she said.

Dr. Peter Lamphey, FHI senior vice president for AIDS programs, put the conference in the context of the larger AIDS epidemic. Women face powerful constraints in reducing their risk of acquiring STDs, including HIV, he said. In countries with mature epidemics, HIV infection rates are increasing most rapidly among women, particularly young women. In urban areas in southern and eastern Africa, for example, HIV prevalence rates of up to 40 percent have been reported among antenatal women. “Often the greatest source of HIV or STD risk for most sexually active women is their husband or stable partners, who have multiple sexual partners,” he said.

In his opening remarks, Dr. Duff Gillespie, USAID Center for Population, Health and Nutrition deputy assistant administrator, identified the difficult questions faced by donors. “We don’t have many tools, and the female condom is definitely a potential tool,” he said. “But the context in which we have to make decisions is the budgetary situation, which is not expanding but contracting.” Any new investment in the female condom requires a subtraction from something else, he said. In 1995, USAID conducted acceptability trials in 19 countries and is currently supporting research on the possibilities of female condom re-use. This year, USAID plans to purchase 150,000 female condoms for research and familiarization purposes but has not decided whether to add the female condom to its commodity distribution program. Such a step would make the female condom far more widely available in the public sector. “We want this conference to provide us with technical advice and personal experiences to help us make an informed decision,” Dr. Gillespie said, referring to investment in the female condom.

Recent research on spermicides is disappointing, and the development of virucides or other new microbicides has been slow, said Dr. JoAnn Lewis, FHI senior vice president for reproductive health. “We must redouble our efforts, not only to continue the search for new options, but also to find ways to increase the availability, acceptability and affordability of those few options that already exist.” The female condom may be the only option in the immediate future.

Dr. Purnima Mane, Joint United Nations Programme on HIV/AIDS (UNAIDS) Office of the Executive Director, programme and planning coordinator, summarized the task for participants. “The female condom provides a technology that women have some control over,” she said. Recent UNAIDS research has shown that the device increases the number of protected sex acts and lowers STD rates when offered with the male condom, she added. “But we need to identify more action points, talk through the difficulties and find common strategies. We need to find ways to get more resources allocated.”

It is simply a question of survival, according to Priscilla Misihairabwi, director of the Women and AIDS Support Network (WASN) in Zimbabwe. “The reality for me and for the majority of African women is that prevention of HIV is impossible without something we can control,” she said. A petition campaign throughout Zimbabwe coordinated by WASN resulted in 30,000 signatures of women asking for the female condom; this effort helped persuade Zimbabwean officials to move forward this year with the first large-scale introduction of the device in the developing world. “It gives me great pleasure and excitement today to be at an international forum that seeks to discuss not only acceptability or efficacy of the female condom, but one that also seeks to celebrate the fact that almost 15 years into the epidemic, a device women lobbied for is finally a reality for some of us,” Misihairabwi said.

Over the course of the meeting, several primary streams of thinking emerged. Women’s advocates presented urgent and compelling arguments in favor of increasing accessibility of the female condom as widely as possible because it offers women at risk of HIV infection a viable way to protect themselves. Scientists and donors asked hard questions about the contribution the female condom can make to disease prevention, given its cost, the training required for acceptability, regulatory approval for single use and the competing demands on limited resources.

Reports and Recommendations

Following the opening session, the mini-groups met in their seven areas of inquiry. Because of strong interest, there were two groups each in the areas of science and women’s empowerment. In the cross-sharing sessions which followed, participants from different groups sought common direction; the policy and product delivery groups, for example, shared ideas, discussed overlapping areas of concern, and debated courses of action.

The second day opened with an experts’ fair, with six groups meeting simultaneously. Experts’ presentations informed and guided discussions on: Social Marketing; Communications and Empowerment; International and National Advocacy/Policy; FHI/AWI Kenya and Brazil research entitled “The Female Condom as a Woman-Controlled Protective Method”; Science; Products in Development and The Female Condom: Reality, Femidom, Femy. The brief presentations were repeated four times. Each participant could attend four of the six sessions, which helped to refine the issues identified during the first day. Discussions during the mini-workshops and experts’ fair led to three directional workshops covering research, policy and interventions, with each group producing recommendations. In the closing session the seven fields of inquiry reported their findings and recommendations. (See attached conference agenda.)

The purpose of the conference was to identify recommendations for action. It was not designed to include formal presentations of new scientific findings. A comprehensive review of the scientific information available on the female condom was undertaken just before the conference by the World Health Organization and UNAIDS. A draft of this document *The Female Condom: A Review* was sent to every workshop participant in order to establish a common ground of information.¹ The final published document formed part of a new WHO/UNAIDS information package on the female condom. This was available at the conference, along with various information sheets.

Section I of this report summarizes the most important information discussed through the seven focal points of inquiry. Section II synthesizes the major issues refined at the conference in the expert fair presentations and debates. Section III offers recommendations developed by the working groups in the seven focus areas and the three directional workshops. These recommendations target six audiences that can have an impact on expanding access to the female condom: policy makers; donors and the private sector; women's advocates; program planners; scientists in research and development; researchers in the field; and community organizations. In Section IV, six overall action steps are identified that can help accomplish the conference's primary goal: to expand accessibility of the female condom, advancing through the research lab to the marketplace.



¹ UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. *The Female Condom: A Review*. (Geneva: WHO), 1997.



FOCAL POINTS OF INQUIRY

The mini-workshops had seven areas of focus: science; empowerment; price; policy; product delivery; introduction strategies; and evaluation. Each of these areas addressed the issues of technology, acceptability and cost.

Technology covered effectiveness in pregnancy and disease prevention, safety, re-use and other matters related to the physical device. Acceptability covered operations research questions, including which types of users like the device and why, how and whether to target audiences, what types of training and support are needed, social marketing issues and others. And cost involved technology and acceptability issues, as well as policy concerns. In addition, because it is a woman-initiated device, the female condom frames all of the scientific issues in the context of women's empowerment, so analysis of the impact of this device on women's lives also provided underpinning for each group.

There were two working groups each for science and empowerment, and one group for each of the other five areas of focus. The summaries below synthesize the thinking in each area and highlight some of the most recent research findings. *The Female Condom: A Review* was a valuable resource for all of the working groups and can provide additional background for readers of this report.

Science—What Do the Data Tell Us?

Dr. James Shelton, USAID Office of Population senior medical scientist, who facilitated one of the science working groups, summarized the existing research by stating, “We know more about the clinical acceptability studies. The programmatic work requires more research.”

The female condom is a soft loose-fitting sheath made of polyurethane plastic with two flexible rings, one used as an anchor inside the vagina and the other remaining outside the vagina. Its contraceptive effectiveness is similar to that of other barrier methods, and appears promising as protection against STDs. In fact, in laboratory studies it is impermeable to organisms that cause STDs, including HIV. Findings from two of the three STD clinical studies on the female condom conducted to date are highly encouraging,² and the third study found that, like the male condom, the female condom is effective at preventing disease only if used correctly and consistently with every act of sexual intercourse.³ Because it is approved for one-time use, the higher cost per use and lower effectiveness of the device, compared to hormonal methods, make it less attractive as a strictly contraceptive device.

² Soper DE, et al. Prevention of vaginal trichomoniasis by compliant use of the female condom. *Sexually Transmitted Diseases*, 1993, 20:137-9; Fontanet AL, et al. Increased protection against sexually transmitted diseases by giving commercial sex workers in Thailand the choice of using male or female condoms: a randomized controlled trial. 1997. Unpublished.

³ Mason P et al. Sexually transmitted diseases and HIV in commercial sex workers supplied with female and/or male condoms. 1996. Unpublished.

While results from studies vary widely, the female condom is clearly acceptable to both women and men in many situations. “Included among the acceptors are first-time family planning users, indicating that the female condom increases method use for disease prevention and contraception, and does not merely substitute for male condom use,” according to the WHO/UNAIDS review, which summarizes 42 acceptability studies.⁴

Clearly, the female condom is a new device and requires education for all involved, from policy makers to service providers to individual users. One of the science groups included government officials from Honduras who had never seen the device. When they opened it, saw and felt it for the first time, their reaction was similar to that of most others; they were surprised by its size and did not immediately understand how it was to be used. The group discussed it as a female-initiated method rather than a female-controlled method. “The woman can choose the timing, but most of the time, she still needs her partner’s approval,” said Dr. Ward Cates, FHI senior vice president for biomedical affairs.

The experts tended to identify areas of concern that matched their current area of responsibility or field. For example, Dr. Shelton said cost benefit analysis was essential to understanding the female condom’s possible contribution to HIV/AIDS prevention. Dr. Cates, an STD specialist and epidemiologist, encouraged additional effectiveness studies. Dr. Zena Stein, co-director of the HIV Center at Columbia University in New York, said that acceptability studies that focused on sustained use were critical. And Dr. Maria Eugenia Fernandes, AID-SCAP/Brazil resident advisor, said that operations research on service delivery approaches needs attention.

The other science group closely examined the issues of re-use. Because the polyurethane material is stronger than latex it may retain structural integrity for more than one use. However, the device must be cleanable so that no potentially harmful microbes are retained. Researchers working on re-use studies at FHI have estimated that it will take about five years before approval for re-use can be expected from the U.S. Food and Drug Administration (USFDA). Exposure to pathogens in re-use is a major concern, and approval from regulatory agencies would be necessary.

The female condom, unlike the male condom, can be used with any lubricant. However, Dr. James McIntyre, co-director of the Reproductive Health Research Unit at the University of Witwatersrand, who is conducting re-use research in South Africa, cautioned that promoting oil-based lubricants with the female condom might lead people to use these same lubricants with latex condoms, to possible disastrous effect.

⁴ UNPD/UNFPA/WHO/World Bank, op. cit., Executive Summary.

Another way to address the cost/re-use issue is to attempt to create a less expensive disposable device. Currently, the Reddy Medtech Company in India and Princeton, NJ is developing such a product, and it is being tested in field studies.

Effectiveness was another area of concern. A large-scale study is underway in Birmingham, Alabama, to test STD outcomes of different barrier methods, funded by the National Institutes of Health (NIH). Dr. Robert Spirtas, chief of the NIH Contraceptive and Reproductive Evaluation Branch, said that recruitment has been slow, however. A new methodology that might be more cost effective in studying efficacy is to measure effectiveness directly, using a high-technology method of examining the vagina for microbes after use of the female condom.

Empowerment—Group Support Is Crucial

The female condom potentially gives women the power to initiate use of a method to prevent STDs and unintended pregnancy. It may also serve a broader purpose: in the process of gaining the confidence and skills needed to use the female condom, and hence gain more control over their sexual relationships, women may become more empowered in their lives in general. Both empowerment working groups began by discussing a conceptual model for the word “empowerment.” They also identified barriers to women’s increased accessibility to the female condom.

Women’s perception of personal risk of STD/HIV infection and knowledge about the female condom are cornerstones of women’s empowerment concerning their sexuality, according to one working group. Empowerment was considered as a multilevel concept, like a series of concentric circles, with the women in the middle, then the sexual partner, then the community norms, and finally institutional factors. Other issues were the freedom to buy, to use and to talk about the device.

The second empowerment group relied on the “Women’s Empowerment Framework”⁵ to guide its discussion. This strategy was used by the Zimbabwe Women and AIDS Support Network (WASN). WASN director Priscilla Misihairabwi described the framework as having five steps: welfare—the ability to be and stay healthy; access—to services and resources; conscientization—internalized awareness with the will, energy and support system leading to action; participation—mobilization of women who are ready to share; and control—being able to make choices and decisions in the home and outside the home without dominance or subordination. The system can be entered into at any of the five steps and can apply to any health issue.

⁵ The Women’s Empowerment Framework was developed by Sara Hlupekile Longwe. *Gender Equity and Women’s Empowerment*, UNICEF.

UNAIDS has recently coordinated studies in Costa Rica, Indonesia, Mexico and Senegal on sexual negotiations, women's empowerment and the female condom. The studies concluded that focus group discussions both prior to and after distribution of the female condom help women to accept it. "We used a lot of community strategies and role plays to encourage use," said Dr. Mane. "We learned about the crucial role of group support." She also pointed out the accessibility problem that has arisen with wide-spread acceptability. "They want more of it [the female condom] now," she said. The device is not yet available to meet the demand that has been created in these countries and women who want it cannot get it. This view was supported by AIDS-CAP research conducted in Kenya and in Brazil (discussed below).

In Zimbabwe the product will soon be available. Misihairabwi explained that it will be marketed in a way that will avoid association with the male condom, which has the perception of promoting promiscuity. Preliminary research indicated that men like the device; this may be one major reason why women like it. "It's female centered, but the men like having the psychological responsibility off of them," said Misihairabwi. "They don't have to worry about how it's placed, exiting quickly or putting it on. So the acceptability of men gives the women more control."

Both groups concluded that the female condom has great potential for acceptability among men and women. Important factors for successful introduction include training women how to use the device, creating support groups to help women overcome barriers to use, and involving men. Women and men reported that it feels more natural than the male condom, and women said it is easier to get men to use the female condom. Among the general barriers to use are that it appears large, is difficult to insert at first, may be noisy for some and is relatively expensive compared to the male condom. Other barriers to empowerment include the lack of female pelvic models to teach users proper use and the need for education about basic reproductive anatomy.

Increasing women's empowerment requires a multilevel process of change in individual relationships, societal values and institutional priorities. Thus, various kinds of partnerships can help to increase women's empowerment, from the mobilization of women themselves, to encouraging the private sector and policy makers to support ways to make the female condom more accessible.

Price—A Critical Barrier

The price of the female condom is a critical barrier to accessibility. A recently negotiated public sector price has enabled a few countries to buy several hundred thousand female condoms to start up national programs, but much larger supplies are needed for large-scale distribution and sustainable supply. Major donors such as USAID have procured limited supplies for research and familiarization purposes but have not yet decided whether to include the female condom as part of programs that provide commodities to developing countries at free or reduced prices.

The price structure for the female condom can be thought of as having three tiers: free in the public sector, which would require the most subsidy; low cost through social marketing projects, which would require some subsidy; and full price in the commercial market.

In the fall of 1996, UNAIDS negotiated a public-sector price of about US \$0.62 with The Female Health Company based in Chicago, IL, USA, which makes and markets the only female condom currently on the market. This price compares with the unit price of a male condom of about US \$0.05. Social marketing experts estimate that the actual cost of each female condom is about US \$1.00 to \$1.50 when the costs of delivery, education of users, advertising and other expenses are included.

Currently, the female condom sells on the commercial market for US \$2 to \$3, and it is approved only for one-time use. Studies are planned to assess the number of times it can be re-used—two, five or even ten times. Using it just twice would cut the cost in half.

The public price is only about 10 percent above the actual production cost. Economies of scale might bring the price down a little, but not significantly. “The only way to get the production price down is to break the technology barrier to create a much less expensive material,” said Dr. Michael Free, Program for Appropriate Technology in Health (PATH) vice president and senior advisor for technology.

Given its high price and the limited resources available, tradeoffs must be made regarding health supplies and commodities. For example, would spending money on large-scale distribution of the female condom result in net savings by reducing the transmission and treatment of STDs compared to the cost of the male condom? To address this question, FHI is undertaking a three-year community intervention trial in Kenya. In the study, the incidence of STDs will be measured among two groups of women. Both groups will have access to the male condom, in addition, one will have the female condom available.

However, because of its high price, the female condom should be promoted and sold at the same time efforts are made to sell the concept of a female-initiated method. This requires continuing emphasis on research in female condom product development, including design and materials, as well as other products such as microbicides. To increase access in the immediate future, advocates have to engage both the private sector and donors in subsidizing the cost. There are female condoms available and women who want to use them. The challenge is to find a combination of commercial and donor support to link the condoms with the women.

Policy—Targeting Whom?

Policy makers face difficult choices in making the female condom more accessible, particularly in terms of availability, cost, sustainability and targeting of limited supplies. The supply and cost issues were primary to the working group in this focus area. Until the cost issues can be resolved, some kind of targeting will have to take place, the study group agreed. Limited supplies lead to tough choices. Whom should be targeted and how? Should these supplies be targeted to “core STD/HIV transmitter groups,” or distributed to the general population or some other target groups? In many countries the epidemic is well established in the general population, so targeting commercial sex workers or other populations considered at the center of the epidemic will not prevent it from spreading beyond these “high risk” and often marginal groups. This strategy would deny women in the mainstream equal access to the female condom.

Policy makers addressing the AIDS epidemic have to decide how much to endorse and promote the female condom. Will it undercut other, more effective interventions, specifically the male condom, and in the end be a less effective intervention? A UNAIDS-sponsored study in Thailand found that when the female condom and the male condom are offered together, the number of protected sex acts increases. Also, the incidence of STDs was found to decline by about one-third (30%) during the study, although this cannot be attributed to the female condom alone. This suggests that adding the female condom could be an asset in preventing STDs in some circumstances. However, as several participants pointed out, the current USFDA labeling is for pregnancy prevention only.

Long-term availability depends on demand as well as cost, so UNAIDS and USAID are assessing the potential worldwide demand. UNAIDS received responses to a survey from about 58 countries, which indicated a demand in 1997 for 3 million female condoms at US \$0.66 and for 5 million in 1998 if the price were reduced by about half. Many countries returned the survey saying they were not familiar with the product and would need more information. USAID recently allocated US \$100,000 for the purchase of female condoms for operations research and to familiarize countries with the device.

One of the major questions the working group addressed was how the supply could be sustained even if advocates were to create a demand for the product and it was made available. Mitchell Warren, PSI country representative for South Africa, a facilitator of the group, said one way to think of sustainability was using the formula, $a + b + c = d$, with:

a = public distribution systems, distributed free or very low cost through government or donor subsidy

b = social marketing price, cost sharing, with lesser subsidies

c = commercial sector, sold at full price

d = a sustainable balance of supply and demand resulting from the managed interplay between a, b and c.

It was suggested that some funds from social marketing and private sector sales might be used to subsidize the public distribution. “You need to play with the numbers to find the right balance, the right percentages,” Warren said. “It’s bad planning if you don’t. You need the balance for sustainability.”

Product Delivery— How to Reach the Consumer?

In over 40 acceptability studies an encouraging proportion of women and men say they will use the female condom if they can get it at an affordable price. How will the female condom reach the consumer and who will ensure that it does? By casting this as a method *initiated* rather than *controlled* by women, it will be less threatening to men and should have broader success. Men can then become involved more easily, since many prefer this method to the male condom.

So far, the female condom has been available in developing countries primarily through short-term research studies, including social marketing studies supported by USAID and coordinated by PSI in Bolivia, Haiti, Guinea, South Africa and Zambia. Social marketing campaigns rely on advertising to sell products at reduced, subsidized prices.

“A large supply of the commodity is needed to go beyond the novelty phase,” said Mitchell Warren, who coordinated the South Africa campaign. “Or you have to take the number of female condoms that are available and target certain audiences. This is a hard decision to make and hard to live with.” An important issue underlying delivery of the female condom is sustainability. Can some of the cost of the product be covered by consumers or must it be totally subsidized? The PSI social marketing studies set the price at two to four times the cost of a male condom—a highly subsidized price—and sold it to commercial sex workers, university students and young professionals at clinics, brothels, pharmacies and through promoters.

In Bolivia, the female condom cost twice as much as the male condom; in Zambia it was four times as much. In a five-month period in 1996, more than 16,600 female condoms were sold in Bolivia and 8,500 in Zambia. In follow-up interviews with consumers in those countries, about two-thirds said it was reasonably priced, and about one-third said it was expensive. In Haiti there was a 30 to 50 percent repurchase pattern in the factory areas, explained Daun Fest, PSI country representative in Haiti. “One reason is the possibility of informal prostitution at factories,” she said. Women involved in such activity apparently had come to rely on this newly available device.

In May, the Government of Zimbabwe launched the first large-scale effort in a single developing country to make female condoms available to the general population. The government purchased several hundred thousand at about US \$0.62 cents each, the public sector price offered by The Female Health Company. Government officials said they hope to make the product available to married women, especially in rural areas where people cannot afford to buy it even at subsidized prices.

However, the shift of resources to the female condom is a problem, according to Daisy Nyamukapa, condom management coordinator for the National AIDS Coordination Program. “It is a new product and we need to establish the demand. But we don’t have the resources to differentiate the message,” she said. “We need to present it as a contraceptive sheath, as a family planning product, as well as for disease prevention. If we had more resources, we could do a more targeted introduction.”

In theory, the female condom could reach consumers through the same channels as male condoms—pharmacies, kiosks, market stalls, clinics, community-based distribution, peer educators and many other places. But working group participants pointed out many barriers to achieving such a distribution system, including the fact that providers do not perceive it as a family planning approach but as HIV/AIDS prevention, according to Milton Cordero, director of Profamilia in the Dominican Republic. Donors also need to become more involved in the distribution system. “We are pushing at the grassroots level, but the female condom needs to be a much higher priority at the donor level,” said Phil Hughes, PSI private sector officer. Other barriers discussed included the need to appeal to men as well as women, the need for training to introduce it, and the need to work out regulatory and quality assurance approaches for a new product.

Gender-Sensitive Introduction Strategies

Successful introduction of the female condom requires gender-sensitive strategies based on understanding the roles the device can play in male-female relations. This is essential in overcoming problems.

To address gender issues, the working group on product introduction outlined the need for both mass introduction approaches and interpersonal strategies. Mass strategies need to avoid presenting the female condom as a device used primarily for casual sexual encounters. Access and availability need to be maximized. Thus, messages in mass markets need to present the female condom as a means of preventing pregnancy as well as STDs. In Zimbabwe, the social marketing effort is calling the product the “Care Contraceptive Sheath,” for men and women who care. It is not marketed as a condom or solely as a woman’s device.

“Market research in Zimbabwe suggested that packaging should be gender neutral,” said Guy Stallworthy, program manager who worked with the PSI project there. “If there is too much focus on empowerment of women, then men feel threatened.”

The product needs to be marketed for AIDS prevention but without stigmatizing it, and marketed towards women while involving men. The way to do this is to stimulate an interactive process between the mass strategies and the interpersonal approaches, said Stallworthy, a facilitator of this working group. Mass market strategies use radio, television, posters and over-the-counter sales to develop general product awareness, focusing on product name recognition. In contrast, messages for small groups or more narrow audiences can focus more on AIDS prevention and women's empowerment. A person may hear about the device through a media campaign but identify with using it through a personal intervention.

Interpersonal introduction can occur in women's groups, worksite groups and various peer education support groups. All of these situations can build skills and confidence. Recently completed AIDSCAP studies in Kenya and Brazil introduced the female condom to women through peer support groups. "The women found it easier to introduce the female condom to men as a contraceptive device rather than as protection against STDs first," said Dr. Wangoi Njau, director of the Centre for the Study of Adolescence in Nairobi. As the study progressed, she said, women were able to raise the issue of STDs with their husbands. Unmarried women found it easier to introduce the female condom than did married women. Obviously, different strategies are needed for different relationships.

The product can be valuable to a wide range of women, pointed out Judith Timyan, PSI country representative in Bolivia. Couples who talk to each other about sensitive matters might agree to use the female condom. "But the female condom is also needed for those women who never talk with their partner," she said. In such situations, women's support groups can provide a forum in which women share strategies on using the device with partners.

The working group concluded that more research is needed on gender issues. How could the product be best introduced to men, and how would men introduce it to their partners? What are the best intervention strategies to promote continued use? Cross-cutting issues closely connected to gender-related introduction include price, re-use, product delivery at particular outlets, empowerment of women and evaluation of programs.

Evaluate While Implementing

The female condom is a new device, with limited research results available on a host of programmatic issues related to its use. Hence, researchers need to determine what types of evaluations need to be done on the device and what kind of indicators and instruments would be most effective in undertaking these evaluations. To be most useful in advocating to increase the accessibility of the female condom, for example, evaluations need to focus on policy decisions and service delivery issues.

Given limited resources, policy makers must assess the potential value of various levels of investment in the female condom. What added benefits are there in promoting the female condom for family planning? What about for STDs? How should the product be positioned i.e., family planning vs. STD vs. reproductive health strategy? In family planning research, it has been found that the more methods a person has to choose from, the greater the overall use of contraception. Would this be true when adding the female condom to a method mix?

Cost effectiveness studies are needed to compare the female condom to other barrier methods in terms of its impact on STD/HIV transmission. Measuring the impact of an intervention (i.e., introducing the female condom) on the incidence of HIV—the number of new cases during a given time span—is extremely difficult because of the long HIV incubation period. Among the other issues are ethical and practical concerns from informed consent and refusal rates to confidentiality and cost. The impact on the incidence of certain STDs, (chlamydia and gonorrhea, for example) can be measured as well as the change in the percentage of protected sex acts.

Evaluation of service delivery questions can assist program planners. Various product introduction strategies need to be evaluated to determine which work best under what circumstances. What combination of training support groups, community-based distribution, social marketing, clinical and other distribution systems are most effective? And what indicators can best demonstrate degrees of effectiveness?

Where the female condom is now being introduced, assessments of knowledge, awareness, attitudes and practices of acceptors and others should be undertaken. Where possible, the female condom should be included in regular data collection systems such as the Demographic and Health Surveys.

Another important evaluation issue is the impact the female condom might have on women's empowerment. Research organizations, including FHI's Women's Studies Project, have developed assessment tools to measure the impact of family planning on women's lives. Such efforts might provide models for measuring how learning about one's body and learning to negotiate and use the female condom affects gender relationships and women's empowerment in general. Dr. Barbara de Zalduondo, senior technical advisor of USAID's Division of HIV/AIDS, PHN Center, noted that, "The costs of female condom promotion should be shared across a variety of health and empowerment programs if these more general salutary effects can be demonstrated."

In one of the cross-sharing groups, Dr. Paul Feldblum, deputy director of FHI's Contraceptive Use and Epidemiology Division, pointed out that by focusing so heavily on the cost issue, progress may get bogged down in assessing the possible impact of the female condom. "We need to go ahead and make it widely available in a few limited areas, and then measure and assess that effort," he said. Sometimes, the logistics can only be figured out as the program is being implemented. The view of the group was that enough is known to begin. Information from this intermediate stage would guide the next steps toward full blown programming.





**TARGETING
AUDIENCES TO
INCREASE
ACCESSIBILITY**

To take the female condom from research to the marketplace, specific audiences need to be targeted with information and recommendations. The main audiences

addressed at this conference were policy makers, donors and the private sector, women's advocates, program planners, scientists in research and development, researchers in the field, and community organizations. These audiences have varying perspectives, responsibilities and power, but to contribute towards making the female condom more available, they all must understand several critical issues. Below is a synthesis of four primary issues that were discussed at the conference's experts' fair, where experts summarized the latest research findings and field experiences while guiding discussions among the participants. The directional workshops that followed the experts' fair sharpened the discussions still further. The four key issues are: re-use; social marketing; women's support and empowerment; and new products.

Re-Use: Urgent but Years Away

There have been anecdotal reports that because of the relatively high cost of the female condom, women are re-using it, even though it is approved for one-time use only. Regulatory approval for more than one-time use would greatly reduce its cost. For example, the cost would be cut in half if it could be marketed to be used twice; cost could even be reduced to \$0.13 per use if approved for five time use.

Re-use questions are difficult to research. Can pathogens safely be eliminated with routine washing in normal conditions? Is there a decline in effectiveness or reliability after a certain number of uses? Will the device weaken after repeated washing? Even if approved for re-use, how are women going to track the number of times they have used it? Studies have been designed to test the device for structural integrity and the retention of pathogens after multiple uses. Studies will be conducted by FHI with USAID funding.

Laboratory research sponsored by FHI has found that patting the female condom dry is scientifically the best method to use after washing, compared to air drying or no washing. In a small study of devices artificially inoculated with pathogens, less than one percent of the microorganisms were recovered from the condoms that were patted dry after being rinsed with warm tap water, said Carol Joanis, FHI Contraceptive Use and Epidemiology Division associate director for marketing research. Before testing the structural integrity of the device after human use, however, a disinfecting process has to be found that will protect laboratory workers from exposure to possible pathogens while not altering chemical and structural changes of the condom. Once these initial "single use" studies are completed, FHI plans to carry out similar tests after five and ten uses, using a caustic cleaner such as Ivory soap. Soap will be used because it is available worldwide.

FHI's research approach is designed for seeking USFDA approval for re-use. Researchers in South Africa are also conducting re-use studies. This careful, step-by-step approach may take five years. Dr. Lillian Yin, USFDA director of the Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices, said that the agency is willing to approve it for re-use but it "needs proof" it is safe and reliable following multiple uses.

Social Marketing: Needed, Full Scale

What impact would marketing the female condom have on STD infection rates? “We don’t know the impact because we haven’t taken any campaign to large enough scale,” said Judith Timyan. Female condoms can be made affordable to users through social marketing programs, she said. Social marketing is a technique that uses donor funds to subsidize a product while still selling it, thereby recovering some costs. Pilot social marketing projects in five countries have shown that men as well as women will buy the device at highly subsidized prices.

A key step in going to full scale is maintaining a large enough supply. At current prices, governments or donors can purchase about 12 times as many male condoms as female condoms for the same cost, since male condoms cost about US \$0.05 and the female condom US \$0.60 each. Do not take away funding from the male condom but add to the funding for women who have no other protection, said Timyan. But pragmatists replied, “Where’s the other pot of money?”

The other dilemma in social marketing is whether to target core transmitters or the general public. “We need to market it to the general public,” said Timyan. “The female condom will empower women who are monogamous but who have unfaithful husbands. It’s for women who cannot use the male condom.” Others felt the limited supplies should be targeted to commercial sex workers and others in high-risk situations who, in theory, have more impact on the STD/HIV epidemic.

The only way to address these questions is to scale up female condom campaigns fully in three or four countries, said Guy Stallworthy, PSI program manager. “If we don’t scale up and monitor what happens, we’ll be having this same meeting three years from now and not have any more answers,” he said.

Women’s Empowerment: Support Groups and Grass-roots Work

A women’s empowerment approach with the female condom needs to work toward building communication between men and women rather than tearing it down, said Saraswathi Sankaran, who heads an educational and AIDS NGO in Chennai, India. In a pilot study there, women would only agree to introduce the device to their husbands by talking about its importance for the family’s welfare. Similarly, an acceptability study in Senegal found that marketing it as a women’s empowerment device led to men opposing it. Marketed to men and women, men were more likely to accept it. In some cultures the woman may be better off if the man feels he made the decision to use it. In PSI’s social marketing program in Zambia, 46% of the purchasers were male.

Two recent FHI/AIDSCAP studies, conducted in Kenya and Brazil, found that peer support can help women who are vulnerable to STDs to negotiate the use of the female condom with reluctant partners. Peer support groups helped the women overcome obstacles to its use. These included the fact that it was unfamiliar and they had to learn how to use it, and they had to communicate with their partners in most cases regarding its use. The women shared their strategies in the peer support groups, helping each other to figure out ways to get men to use it. Most used pregnancy prevention as an entry point. Also, they left the condom out so that the partner could see it and ask what it was, gave men the opportunity to read the brochure and educate themselves about it, asked the partner to give it a try before making a joint decision, and used it in ways that increase sexual pleasure. In Brazil, different forms of mutual support were shared by group participants, such as strategies for stimulating use and curiosity through experiencing the female condom in different situations and positions, suggesting solutions for difficulties of insertion and manipulation, suggesting the use of additional lubricant, and

giving support to overcoming the difficulties in the negotiation of its use with the partner.

Recruiting through women's organizations, the AIDS-CAP studies examined the impact of the female condom on sexual relationships and how social, cultural and economic factors might promote or hinder its use. Each study lasted four months and included an initial interview, initial focus group, two peer support meetings, a final focus group and an exit interview. Both also involved male partners. In Brazil, 103 women and 24 men participated in the study. Almost two-thirds of the men said they wanted to continue to use the device. About 75 percent of the women said they liked it very much and another 20 percent liked it all right. The female condom was popular with men and women in Kenya as well, where 100 women and 46 men participated in the study. In both settings, women found a way to negotiate its use without appearing to challenge the status quo of the gender relationship.

Grass-roots advocacy provides women with a means of addressing broader cultural and political barriers to its use. For example, the Women and AIDS Support Network (WASN) coordinated a petition campaign throughout Zimbabwe which it delivered to the Ministry of Health on World AIDS Day, in December 1996. This influenced policy makers to launch a nationwide introduction of the female condom in 1997. "The petition was an educational tool," explained WASN's Misihairabwi. "It raised awareness. Women demanded to learn more. They wanted to know why we don't have the female condom. The petition created interest. They would ask health workers doing immunizations about it." It can also help to draw on existing local resources wherever possible, including local research organizations and the existing infrastructure.

Products: Expanded Marketing, New Development

There is currently one female condom on the market, with manufacturing and international marketing rights owned by The Female Health Company, based in Chicago, Illinois. The manufacturing facility is in England, where the product entered the market in the early 1990s. The USFDA approved it for use in the United States in 1993. Main sales have been through the commercial market in the United States, England and other European countries. "The Female Health Company does not plan on any redesign," said Dr. Mary Ann Leeper, president and chief operating officer. "Any change in the technical design would mean starting from scratch in clinical trials and regulatory approvals," she said. Instead, the company is focusing on expanding its marketing efforts through its public sector price and commercial markets.

Two other products are also in development. Jane Hunnicutt, director of the HHH Development Company, described the "Janesway" product that is beginning clinical trials. A disposable model of latex and cotton, it is attached to a female panty in a way that looks like lingerie. Men have liked it better than the male condom in initial research. The Reddy Medtech Company is developing a condom with a unique design that employs a small sponge in the pouch to keep it in place. The company plans to seek USFDA approval, said Dr. A. V. K. Reddy, founder and director of The Reddy Medtech Company. It is disposable and should cost around US \$0.32 each, he said.





SECTION
3

NEXT STEPS TO THE MARKETPLACE

Conference participants developed recommendations for action during the working group sessions and directional workshops. These recommendations are grouped according to the most appropriate target audience and are reported

below. The conference targeted seven audiences: policy makers; donors and the private sector; women's advocates; program planners; scientists in research and development; researchers in the field; and community organizations. Some recommendations apply to several target audiences and, hence, appear more than once. The target audiences do not appear in a priority order. All of the audiences are important, with the synergy among them essential to progress.



POLICY MAKERS



Policy makers in developed and developing countries are responsible for deciding whether and to what scale to include the female condom in family planning, STD/HIV prevention and primary health care programs. Hence, this is a critical audience for action. It was recommended that they:

- Invest in operations research, pilot programs and evaluation of programmatic experience, while also moving ahead with introduction through family planning, primary health care and STD/HIV programs.
- Avoid the “either-or” trade-off type of decision paradigm, seeking instead program efficiencies, health financing reforms, donor coordination and support from the private sector.
- With limited resources, decide how to target and which groups to target, considering these issues: affecting the epicenter of STD/HIV epidemic, empowering women, providing protection for otherwise vulnerable women, sustaining product availability, including men and identifying geographical areas in which to concentrate efforts.
- Consider the formula: a (free) + b (social marketing) + c (commercial) = d (sustainability balance when managed properly), bearing in mind that sustainability has to cover local, regional, national and international areas.
- Incorporate indicators and instruments measuring knowledge, awareness, attitudes and practices in countries where the female condom is being introduced.
- Monitor and evaluate the effects of using different approaches for presenting the female condom including health-care facilities, social marketing, women's support groups and community-based distribution.
- Urge UNAIDS/WHO/UNFPA to create a group composed of leading NGOs, advocacy groups (including women's groups), donors and other stakeholders to focus on promotion of the female condom, including mobilization of international media.
- Maximize what is available while also facilitating new product designs.
- Determine the cost implications of various implementation strategies.
- Document lessons learned from successful interventions and strategies to help in replication.
- Develop country-specific strategic intervention plans.
- Use social marketing approaches to ensure sustainability.
- Where knowledge of STD/HIV is high, reallocate funds intended to increase awareness to increasing the accessibility of the female condom.



DONORS AND THE PRIVATE SECTOR

Closely related to policy decisions are funding issues. Donors and the private sector are grouped together in this report as a target audience because both provide a possible means of subsidizing a steady supply of female condoms. It is important to consider private commercial sources of funding as well as traditional donors. They are urged to:

- Invest in operations research, pilot programs and evaluation of programmatic experience, while also moving ahead with introduction through family planning, primary health care and STD/HIV programs.
- Avoid the “either-or” trade-off type of decision paradigm, seeking instead program efficiencies, health financing reforms, donor coordination, and support from the private sector.
- Ensure private sector involvement in distribution and awareness campaigns.
- Promote and sell existing product in various population segments to obtain better estimates of demand.
- Attempt to saturate the market in countries with evident demand.
- Use three-tiered price and distribution structure (free, partially subsidized, full-price).
- Provide private sector incentives for developing new products.
- Gather information on price sensitivity, total costs, and on other female initiated approaches such as microbicides.
- Establish an international task force to focus on increased accessibility.
- Compile lessons learned thus far in introducing this device.
- Support the development of guidelines on program design, including market segmentation and cost recovery.
- Justify the cost of the female condom as a public health investment.
- Focus the introduction and market development in countries that have shown high acceptability and in which some resources have already been identified.



WOMEN'S ADVOCATES

Many women's advocacy organizations may not be aware of the potential usefulness and importance of the female condom for women, both for STD/HIV and pregnancy prevention and as a means of empowering women in communicating with their partners about sexuality and other fundamental matters. These advocacy groups need information and support to become focused on this issue. Participants recommended efforts to:

- Build communication between men and women.
- Market the device to men and women, so that men are more likely to accept it.
- Provide peer support to women who are vulnerable to STDs to help them learn to negotiate the use of the female condom with reluctant partners.
- Use women's organizations as a vehicle for promoting the female condom.
- Develop grass-roots advocacy campaigns, using petitions and other approaches as both educational tools and strategies for action.
- Draw on existing strengths, including local research organizations and the existing infrastructure.



PROGRAM PLANNERS

Efforts must include men who can be reached and involve them in advocacy as well as pricing and related issues. Program planners in both family planning and STD/HIV prevention are also a critical audience to target, especially since they face many obstacles and competing priorities. They can:

- Promote the female condom for men as well as women and involve men in the effort, since studies show that some men like it more than the male condom.
- Integrate the product into existing service delivery infrastructures.
- Involve communities in increasing awareness and accessibility.
- Consider the female condom as a catalyst for improved communications and sexual dialogue between partners and for communications among groups in the community.
- Promote the female condom to couples as a device for good health and enhanced sexual pleasure.
- Develop guidelines on program design, including market segmentation and cost recovery.
- Use interpersonal and mass media introduction strategies simultaneously.
- Evaluate programs introducing the female condom on such factors as:
 - promotion as a dual method (for pregnancy and STD prevention)
 - impact of female condom on women’s ability to negotiate
 - impact on male acceptability and involvement
 - extended use in stable relationships.
- Familiarize and train providers in how to counsel women about this product.
- Determine the cost implications of various strategies for introduction, marketing, training, etc.



SCIENTISTS—RESEARCH AND DEVELOPMENT



Scientists in research and development hold the power and responsibility for answering several important questions. They need to:

- Study the efficacy of multiple re-use in terms of structural integrity and microbial retention; re-use of the ring; local lubricants; short-term, future and current re-use approaches.
- Improve the product—size and feel of rings, dipping vs. heat sealing, decrease cost of manufacturing.
- Develop alternative designs.
- Develop new products that are less expensive and can increase accessibility.
- Gather more data on effectiveness.



RESEARCHERS IN THE FIELD



At the same time, researchers in the field need to continue exploring programmatic issues, even as introductory efforts expand. Participants recommend that they:

- Disseminate research findings to the media, policy makers, the general public, donors, the private sector and the international community.
- Conduct culturally specific research on factors that influence acceptability and use—individual characteristics, partner interaction and service delivery interaction.
- Conduct operations research at higher levels of scale—introducing the device as outlined in the WHO/UNAIDS document.
- Assess factors that can improve effectiveness in pregnancy and STD/HIV prevention—counseling, communications and package inserts.
- Conduct cost effectiveness studies to compare the female condom to other barrier methods in terms of impact on pregnancy and STD/HIV.
- Monitor and evaluate the cost and effects of using different approaches for introducing and supporting the female condom including health-care facilities, social marketing, women’s support groups and community-based distribution.
- Evaluate programs introducing the female condom regarding:
 - promotion as a dual method (for pregnancy and STD prevention)
 - impact of female condom on women’s self-esteem and ability to negotiate
 - impact on male acceptability and involvement
 - extended use in stable relationships.
- Incorporate indicators and instruments measuring knowledge, awareness, attitudes and practices in countries where the female condom is being introduced.



COMMUNITY ORGANIZATIONS



Community organizations can work closely with many of the other target audiences, putting the female condom in a larger context of overall community priorities. They can:

- Form coalitions among nongovernmental organizations and community groups to mobilize government support to introduce the female condom.
- Use interpersonal and mass media introduction strategies simultaneously.
- Market the female condom in a gender neutral way, promoting intensely to both women and men.
- Use contextual messages such as “For men and women who care” (Zimbabwe).
- Urge governments to support expansion of choice for protection against HIV/AIDS, STDs and unintended pregnancies by allocating resources and adding the female condom to the menu of available options.
- Encourage distribution through community-based distribution systems.
- Include social support systems for women in intervention efforts.
- Gather more data on effectiveness.



FUTURE DIRECTIONS

“Will this conference be successful in helping move the female condom from research to the marketplace?” asked Dr. Ankrah, director of AIDSCAP’s Women’s Initiative, concluding the meeting. “Five years from now, will a woman in Bangkok be able to

obtain a female condom through an integrated STD prevention and family planning program? Will a woman in Rio de Janeiro be able to get a female condom through a women’s advocacy organization? These are hard questions we need to ask. These are ambitious goals we need to reach.”

There are many obstacles ahead, however, including the cost of the device, the current level of donor support, unexplored research questions and lack of familiarity with this new product. But there are many positive signs as well. Research already indicates it offers some protection from STD/HIV. Many women and men like it and will use it when it is available. They will also use it when they have enough support from peers. And social marketing projects have found that men and women will continue buying the product if it is available and affordable.

Women’s advocates want the female condom now, to offer more protection from disease through the only currently available woman-initiated method. Many advocates made this argument convincingly at the conference. On the other hand, researchers and donors said it was too expensive an investment at this point, until more research can show it to be effective in slowing the STD/AIDS epidemic. Introduction and marketing strategies are needed that extend protection to currently vulnerable people, without undercutting promotion of proven safe sex techniques (abstinence, male condom use, STI treatment).

A clear common ground emerged between these two viewpoints: avoid an “either-or” trade-off of decision approach. Instead, work simultaneously to scale up introduction efforts in some countries, seek private sector funding, continue exploring key research issues, and seek greater donor coordination.

“The female condom has symbolic value,” said Dr. Ward Cates, FHI senior vice president for biomedical affairs, in his closing presentation. It symbolizes the energy of expanding women’s rights throughout the world and investing in a reproductive health agenda that helps women more broadly. “It also represents an increased investment in barrier methods overall, for STD/HIV and pregnancy prevention.” Increasing access to the female condom expands choices for all individuals. What is the next step in taking the female condom to the marketplace?

Among the more than 40 recommendations developed during the two days, six were repeated more often than others. These six emerged as a consensus, as the underpinning of the common ground that developed among the disparate points of view. The six action steps can guide our work in the coming years, ensuring that this conference does make a difference in taking the female condom from research to the marketplace.

Consensus Recommendations

1. BEGIN LARGE SCALE INTRODUCTIONS IN TWO TO THREE COUNTRIES.

By going to full scale in countries where demand is high, many operations research questions can be answered. Without this, we will be asking the same questions several years from now.

2. PROMOTE THE FEMALE CONDOM FOR MEN AS WELL AS WOMEN.

By casting the female condom as a method *initiated* rather than *controlled* by women, it will be less threatening to men and have broader success. Men can then become involved more easily. Many men prefer this method to the male condom.

3. MARKET THE FEMALE CONDOM SIMULTANEOUSLY THROUGH INTERPERSONAL AND MASS MEDIA STRATEGIES.

Mass media strategies can build product visibility for “health and well being” and avoid stigmatizing it as a product only for disease prevention. Interpersonal strategies can provide practical training in female condom use and can focus on disease prevention issues, as well as contraception, providing support for successful introduction strategies.

4. EXPEDITE RESEARCH ON WHETHER THE FEMALE CONDOM CAN BE USED MORE THAN ONCE.

Because of the cost, the possibility of re-use is an urgent concern. Researchers estimated that using the current study sequence, which is designed to seek USFDA approval for multiple use, it will take at least five years before labeling for re-use could be approved. Women’s advocates felt this was unacceptable, likening it to delays in allowing experimental but hopeful AIDS treatments on the market.

5. PROVIDE INCENTIVES FOR ALTERNATIVE, LESS EXPENSIVE PRODUCT DESIGNS.

The currently marketed female condom will not get much cheaper than the current public price of US\$0.62 each, but those products under development may be less expensive.

6. DISSEMINATE INFORMATION BROADLY, INCLUDING TO THE MEDIA.

Providing more information, study findings and advocacy lessons on the female condom can broaden awareness among policy makers, program planners, and the public. Ideas include a UN-sponsored international task force, broadscale media campaigns, grass-roots advocacy efforts such as the Zimbabwe model, and others.



IN SUMMATION

In closing the conference, Martha Butler de Lister, resident advisor for AIDSCAP in the Dominican Republic, summarized the challenge ahead: “We need to move beyond our limits and unleash the power of our creativity to take action,” she said. “Thus, while further research is pursued, the call is for the product to be made available now to all who wish to, and need to, use it. This is

why empowerment is the crucial element here. People need to be empowered at the field level, but also at the technical, donor, policy and decision-making levels. We need to empower ourselves to embrace this cause. We need to mobilize all in support of this opportunity to impact the advance of STDs and HIV.”





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Agenda

THE FEMALE CONDOM: FROM RESEARCH TO THE MARKETPLACE

May 1-2, 1997
Hyatt Arlington

Women's Initiative
Family Health International/AIDSCAP
2101 Wilson Boulevard, 7th Floor
Arlington, VA 22201
Tel: (703) 516-9779
Fax: (703) 516-9781

GOAL: *Enhanced accessibility of the female condom.*

OBJECTIVE: *To share lessons learned since the 1993 Female Condom Conference and to develop strategies to enhance awareness, acceptability, availability, and affordability, based on the latest domestic and international research findings and experiences from the field.*

DAY 1, THURSDAY, MAY 1

Session I

9:00am–10:00am–Opening Remarks

Welcome

E. Maxine Ankrah, *AIDSCAP Women's Initiative*
Peter Lamptey, *AIDSCAP / Family Health International*
Duff Gillespie, *Center for Population, Health and Nutrition of USAID*
JoAnn Lewis, *Family Health International*

International Perspective A Woman's Point-of-View

Purnima Mane, *UNAIDS*
Priscilla Misihairabwi, *Women and AIDS Support Network/Zimbabwe*

Session II

10:00am–1:00pm–Mini-Workshops on the Seven Areas

Group 1 of Science

Board Room 1011

The Science of the Female Condom

Facilitator:

Jason Smith, FHI
Marianne Morse Callahan, CONRAD

Reporter:

Markus Steiner, FHI

Group 2 of Science

Ravensworth Ballroom–West

The Science of the Female Condom

Facilitator:

Christine Mauck, FDA/CONRAD
James Shelton, USAID/Mary O'Grady, AIDSCAP

Reporter:

Kathi Kotellos, AIDSCAP

Introduction

Mary Custus Lee Room

Gender-sensitive Strategies for Introducing the Female Condom to the General Public

Facilitator: Guy Stallworthy, PSI
Susan Witte, Columbia University School of Social Work

Reporter: Julie Denison, AIDSCAP

Product Delivery

Ravensworth Ballroom–East

How Will the Female Condom Reach the Consumer and Who will Ensure That It Does?

Facilitator: Christine Claypoole, PSI
Elizabeth Warnick, PSI

Reporter: Martha Riley, AIDSCAP

Price

Board Room 911

Price as a Pivotal Factor: How Can the Female Condom Be Made More Affordable?

Facilitator: Carl Hemmer, USAID (CLM)
Oscar Vigano, AIDSCAP

Reporter: Dawn Buglion, AIDSCAP

Policy

Robert E. Lee Room

Advocacy, Availability, Sustainability

Facilitator: Mitchell Warren, PSI-South Africa
S. Denise Rouse, DHHS/HRSA

Reporter: Kelly Matthews, AIDSCAP

Group 1 of Empowerment

Ravensworth Ballroom–Center

Overcoming Fears, Freeing Feelings: Issues of Control, Empowerment, Choices by the Sexes

Facilitator: Joanne Mantell, HIV Center
Cheikh Niang, ISE

Reporter: Maymouna Sy, AIDSCAP

Group 2 of Empowerment

Board Room 1111

Overcoming Fears, Freeing Feelings: Issues of Control, Empowerment, Choices by the Sexes

Facilitator: Elaine Murphy, PATH
Lydia Bond, IBIC

Reporter: Hally Mahler, AIDSCAP

Evaluation

Board Room 1211

Evaluating the Impact of this New Prevention Option

Facilitator: Tobi Saidel, AIDSCAP
Jan Hogle, AIDSCAP

Reporter: Kristen Ruckstuhl, AIDSCAP

1:00pm–1:45pm–Lunch

Session III 1:45pm–3:30pm–Cross Sharing I*A Cross Sharing Among The Seven Groups***Group 1 of Science and Evaluation****Robert E. Lee Room**

Facilitator: Marianne Morse Callahan, CONRAD
Jason Smith, FHI
Reporter: Markus Steiner, FHI

Group 2 of Science and Evaluation**Ravenworth Ballroom–West**

Facilitator: Jan Hogle, AIDSCAP
Tobi Saidel, AIDSCAP
Reporter: Kathi Kotellos, AIDSCAP

Group 3 of Science and Evaluation**Board Room 911**

Facilitator: James Shelton, USAID
Christine Mauck, FDA/CONRAD
Reporter: Kristen Ruckstuhl, AIDSCAP

Group 1 of Product Delivery and Policy**Mary Custus Lee Room**

Facilitator: Elizabeth Warnick, PSI
Christine Claypoole, PSI
Reporter: Kelly Matthews, AIDSCAP

Group 2 of Product Delivery and Policy**Ravenworth Ballroom–East**

Facilitator: S. Denise Rouse, DHHS/HRSA
Mitchell Warren, PSI-South Africa
Reporter: Martha Riley, AIDSCAP

Group 1 of Introduction and Empowerment**Board Room 1011**

Facilitator: Susan Witte, Columbia University School of Social Work
Guy Stallworthy, PSI
Reporter: Julie Denison, AIDSCAP

Group 2 of Introduction and Empowerment**Ravenworth Ballroom–Center**

Facilitator: Cheikh Niang, ISE
Joanne Mantell, HIV Center
Reporter: Maymouna Sy, AIDSCAP

Group 1 of Price and Empowerment**Board Room 1111**

Facilitator: Lydia Bond, IBIC
Elaine Murphy, PATH
Reporter: Dawn Buglion, AIDSCAP

Group 2 of Price and Empowerment**Board Room 1211**

Facilitator: Oscar Vigano, AIDSCAP
Carl Hemmer, USAID (CLM)
Reporter: Hally Mahler, AIDSCAP

3:30 pm–4:00 pm–Break

Session IV 4:00pm–5:30pm–Cross Sharing II

Expanded Cross Sharing Between the Seven Groups with Evaluation Participating in Each Group

Science, Empowerment, Product Delivery and Evaluation

Group 1

Ravensworth Ballroom–West

Facilitator: Christine Mauck, FDA/CONRAD
James Shelton, USAID
Reporter: Markus Steiner, FHI

Group 2

Ravensworth Ballroom–East

Facilitator: Joanne Mantell, HIV Center
Cheikh Niang, ISE
Reporter: Kathi Kotellos, AIDSCAP

Group 3

Mary Custus Lee Room

Facilitator: Jason Smith, FHI
Marianne Morse Callahan, CONRAD
Reporter: Hally Mahler, AIDSCAP

Introduction, Product Delivery, Price and Evaluation

Group 1

Robert E. Lee Room

Facilitator: Guy Stallworthy, PSI
Susan Witte, Columbia University School of Social Work
Reporter: Julie Denison, AIDSCAP

Group2

Board Room 911

Facilitator: Christine Claypoole, PSI
Elizabeth Warnick, PSI
Reporter: Martha Riley, AIDSCAP

Group 3

Ravensworth Ballroom–Center

Facilitator: Carl Hemmer, USAID (CLM)
Oscar Vigano, AIDSCAP
Reporter: Kristen Ruckstuhl, AIDSCAP

Price, Empowerment, Policy and Evaluation

Group 1

Board Room 1111

Facilitator: Tobi Saidel, AIDSCAP
Jan Hogle, AIDSCAP
Reporter: Maymouna Sy, AIDSCAP

Group 2

Facilitator: Mitchell Warren, PSI-South Africa
S. Denise Rouse, DHHS/HRSA
Reporter: Dawn Buglion, AIDSCAP

Board Room 1011

Group 3

Facilitator: Elaine Murphy, PATH
Lydia Bond, IBIC
Reporter: Kelly Matthews, AIDSCAP

Board Room 1211

DAY 2, FRIDAY, MAY 2

Session V

8:30am–10:30am–Expert’s Fair

Ravensthorch Ballroom

1. Social Marketing

Moderator: Judith Timyan, PSI/Bolivia
Bill Schellstede, AIDSCAP
Reporter: Dallas Fields, AIDSCAP

2. Communications and Empowerment

Moderator: Saraswathi Sankaran, DESH
Zena Stein, HIV Center
Reporter: Hally Mahler, AIDSCAP

3. International and National Advocacy / Policy

Moderator: Vicki Baird, Meridian Group, International
Priscilla Misihairabwi, Women and AIDS Support Network, Zimbabwe
Reporter: Kelly Matthews, AIDSCAP

4. FHI/AWI Kenya and Brazil

Moderator: Elisabeth Meloni Vieira, AIDSCAP/Brazil
Suzana Kalckmann, MCCS
Wangoi Njau, Center for the Study of Adolescence
Reporter: Molly Strachan, AIDSCAP/LACRO

5. Science

Moderator: Carol Joanis, FHI
Lillian Yin, FDA
Reporter: Kristen Ruckstuhl, AIDSCAP

6. Products in Development

Moderator: Jane Hunnicutt, HHH Development Co. 8:30am–9:00am
A. V. K. Reddy, Reddy Medtech 9:00am–9:30am
Reporter: Julie Denison, AIDSCAP

The Female Condom: Reality, Femidom, Femy

Moderator: Mary Ann Leeper, Female Health Company 9:30am–10:30am
Reporter: Julie Denison, AIDSCAP

10:30am–11:00am–Morning Break

Session VI 11:00am–12:15pm–Directional Workshops

Research, Policy and Interventions

Research

Ravenworth Ballroom–East

Moderator: Janet Harrison, CDC
Paul Feldblum, FHI
Reporter: Markus Steiner, FHI

Policy

Ravenworth Ballroom–Center

Moderator: Michael Free, PATH
Purnima Mane, UNAIDS
Reporter: Julie Denison, AIDSCAP

Interventions

Ravenworth Ballroom–West

Moderator: Patricia Coffey, Snohomish Health Dist.
Meena Cabral, WHO
Reporter: Kathi Kotellos, AIDSCAP

Session VII 12:30pm–1:30pm–Working Lunch

Ravenworth Ballroom

Participants Regroup into the Original Seven Workshops

Session VIII 1:30pm–3:00pm–Report Back to Plenary

Ravenworth Ballroom

Chair: Kwame Asiedu, AIDSCAP/AFRO

Session IX 3:00pm–3:30pm–Closing

Introduction

Tony Schwarzwald, AIDSCAP / Family Health International

Summary

Ward Cates, Family Health International

Vote of Thanks

Martha Butler de Lister, AIDSCAP Dominican Republic
E. Maxine Ankrah, AIDSCAP Women's Initiative



Participant List

LAST NAME	FIRST NAME	ORGANIZATION	COUNTRY
Adams	Jennifer	United States Agency for International Development/POP	USA
Affoh	Annick	AIDES	France
Allison	Adrienne	Centre for Development & Population Activities	USA
Apter	Felice	United States Agency for International Development	USA
Aral	Sevgi	Centers for Disease Control and Prevention	USA
Asiedu	Kwame	AIDS Control And Prevention Project/Africa Regional Office	Kenya
Bachman	Gretchen	Futures Group	USA
Baird	Vickie	Meridian Group, International	USA
Betances	Bethania	AIDS Control And Prevention Project/DR	Dominican Republic
Bloom	Amy	United States Agency for International Development (HIV/AIDS)	USA
Blum	Lisa	Female Health Company	USA
Naomi	Blumberg	United States Agency for International Development/CLM	USA
Bond	Lydia	International Behavioral Interventions & Communications	USA
Brady	Martha	The Population Council	USA
Butler deLister	Martha	AIDS Control And Prevention Project/DR	Dominican Republic
Cabral	Meena	World Health Organization	Switzerland
Calderone	Ricardo	AIDS Control And Prevention Project	USA
Camy	Elizabeth	Procept, Inc.	USA
Carter	Eli	Family Health International	USA
Castaneda	Yadira	Asociacion De Municipios De Honduras	Honduras
Cates	Ward	Family Health International	USA
Claypoole	Christine	Population Services International	USA
Clemente	Marcio Rodoealho	DKT	Brazil
Coffey	Patricia	Snohomish Health District	USA

LAST NAME	FIRST NAME	ORGANIZATION	COUNTRY
Cordero	Milton	AIDS Control And Prevention Project/DR	Dominican Republic
Covington	M. Lyvon	Food and Drug Administration	USA
Dallabetta	Gina	AIDS Control And Prevention Project	USA
de Zalduondo	Barbara	United States Agency for International Development (HIV/AIDS)	USA
de Schutter	Martine	Pan American Health Organization/ World Health Organization	USA
De Leon	Angela	AIDS Control And Prevention Project/DR	Dominican Republic
DeCastro	Marcia Freitas	AIDS Control And Prevention Project/Brazil	Brazil
DeLay	Paul	United States Agency for International Development(HIV/AIDS)	USA
Deluz	Ariane	National Center for Scientific Research	France
deZoysa	Isabelle	Consultant	India
Feldblum	Paul	Family Health International	USA
Fernandes	Maria Eugenia Lemos	AIDS Control And Prevention Project/Brazil	Brazil
Ferrero	Carlos	AIDS Control And Prevention Project/Brazil	Brazil
Fest	Daun	Population Services International/Haiti	Haiti
Flanagan	Donna	AIDS Control And Prevention Project	USA
Free	Michael	Program for Appropriate Technology in Health	USA
Getson	Alan	United States Agency for International Development	USA
Hall	Peter	World Health Organization	Switzerland
Harbison	Sarah	United States Agency for International Development	USA
Harrison	Janet	Centers for Disease Control	USA
Hemmer	Carl	United States Agency for International Development/CLM	USA
Higuero Crespo	Jorge A.	AIDS Control And Prevention Project/Honduras	Honduras
Hogle	Jan	AIDS Control And Prevention Project	USA
Howard	Susan	Howard Delafield International	USA
Hughes	Phil	Population Services International	USA
Hunnicuttt	Jane	HHH Development Co.	USA
Hussein	Fatma	Tanzania AIDS Project	Tanzania

LAST NAME	FIRST NAME	ORGANIZATION	COUNTRY
Jamieson	Nancy	AIDS Control And Prevention Project/Indonesia	Indonesia
Jerezano	Clara Rosa	Women's Government Office	Honduras
Joanis	Carol	Family Health International	USA
Kalchmann	Suzana	Mulher, Criança Cidadania e Saúde	Brazil
Kempter-Martin	Kathleen	HHH Development Co.	USA
Kotellos	Kathi	AIDS Control And Prevention	USA
Kumar	S. Muthu	Illaingnar Narpani Mandram	India
Lago	Tania DiGiaconodo	AIDS Control And Prevention Project/Brazil	Brazil
Lathem-Parker	Lorraine	Academy for Educational Development	USA
Latka	Mary	Columbia University	USA
Lawder	Kate	AIDS Control And Prevention Project	USA
Leeper	Mary Ann	Female Health Company	USA
Lewis	JoAnn	Family Health International	USA
Luoto	Joanne	National Institutes of Health	USA
MacNeil	Joan	AIDS Control And Prevention Project	USA
Mahler	Hally	AIDS Control And Prevention Project	USA
Malaichamy	V. Arul	Rural Multipurpose Social Welfare and Development Society	India
Mane	Purnima	Joint United Nations Programme on HIV/AIDS (UNAIDS)	Switzerland
Mantell	Joanne	HIV Center	USA
Mauck	Christine	Food and Drug Administration/CONRAD	USA
McIntyre	James	Reproductive Health Research Unit University of Witwatersrand	South Africa
McMahon	Bill	Futures Group	USA
Melngailis	Ilze	International Planned Parenthood Federation/WHR	USA
Meloni Vieira	Elisabeth	AIDS Control And Prevention Project/Brazil	Brazil
Misihairabwi	Priscilla	Women and AIDS Support Network	Zimbabwe
Morse Callahan	Marianne	Contraceptive Research and Development (CONRAD)	USA
Murphy	Elaine	Program for Appropriate Technology in Health	USA
Mwakitwange	Rosemary	Tanzania AIDS Project	Tanzania

LAST NAME	FIRST NAME	ORGANIZATION	COUNTRY
Niang	Cheikh	Universite Cheikh Anta Diop	Senegal
Njau	Wangoi	Center for the Study of Adolescence	Kenya
Novak	John	United States Agency for International Development(HIV/AIDS)	USA
Nwankwo	Emily	AIDS Control And Prevention Project/Africa Regional Office	Kenya
Nyamukapa	Daisy	Zimbabwe Ministry of Health	Zimbabwe
Paredes	Mayte	Honduras Ministry of Health STD/AIDS Div.	Honduras
Pimenta	Maria Cristina	Brazil Ministry of Health	Brazil
Pollack	Joy	AIDS Control And Prevention Project/Nepal	Nepal
Pollard	Colin	Food and Drug Administration	USA
Rau	Bill	AIDS Control And Prevention Project	USA
Reddy	A. V. K.	Reddy Medtech	USA
Reddy	Ravi	Reddy Medtech	USA
Rilling	Mark	United States Agency for International Development/CLM	USA
Ringheim	Karin	United States Agency for International Development/POP	USA
Rouse	S. Denise	U.S. Department of Health and Human Services	USA
Ruckstuhl	Kristen	AIDS Control And Prevention Project	USA
Sabatier	Renee	Southern African AIDS Training Programme	Zimbabwe
Saidel	Tobi	AIDS Control And Prevention Project	USA
Sankaran	Saraswathi	Deepam Educational Society for Health	India
Schellstede	Bill	AIDS Control And Prevention Project	USA
Schubert	Joan	Cooperative Assistance Relief Everywhere	USA
Schwarzwalder	Tony	AIDS Control And Prevention Project	USA
Shelton	James	United States Agency for International Development	USA
Smith	Jason	Family Health International	USA
Smith Romocki	LaHoma	Family Health International	USA
Soriano	Victor	AIDS Control And Prevention Project/Honduras	Honduras
Spierer	Jeffrey	United States Agency for International Development/POP	USA

LAST NAME	FIRST NAME	ORGANIZATION	COUNTRY
Spirtas	Robert	National Institutes of Health	USA
Stallworthy	Guy	Populations Services International	USA
Stein	Zena	HIV Center	USA
Steiner	Marcus	Family Health International	USA
Stout	Isabel	Population Leadership Project/USAID	USA
Sullivan	Patrick	HHH Development Company	USA
Taveras	Marina	United States Agency for International Development/Dominican Republic	Dominican Republic
Timyan	Judith	Population Services International/Bolivia	Bolivia
Vigano	Oscar	AIDS Control And Prevention Project	USA
Vogelsong	Kirsten	United States Agency for International Development/POP	USA
Warnick	Elizabeth	Population Services International	USA
Warren	Mitchell	Population Service International-South Africa	South Africa
Weiss	Ellen	International Center for Research on Women	USA
Wihofszky	Petra	ONUSIDA	Ivory Coast
Williams	Ekaa-Esu	AIDS Control And Prevention Project/Nigeria	Nigeria
Wilson	Anne	Program for Appropriate Technology in Health	USA
Witte	Susan	Columbia University/Social Work	USA
Yasmiin Mejia	Fanny	AIDS Control And Prevention Project/Honduras	Honduras
Yatim	Danny	Futures Group	Indonesia
Yin	Lillian	Food and Drug Administration	USA