The Female Condom:  
Opportunities & Challenges in South Asia

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Foreword

Evidence from throughout the world underscores women’s disproportionate and growing vulnerability to HIV infection. The physiological susceptibility—at least two to four times greater than men’s—is compounded by social, cultural, economic and legal forms of discrimination. This calls for an urgent need for greater focus on strategies that address women’s disproportionate risk of infection, enable them to negotiate safe sex, and provide tools to protect themselves from infection. Health and human rights advocates have been demanding that scientists develop fertility regulation methods that are safe and reversible, under the control of the user, which protect the user against STIs and HIV, and do not need to be provided by a health service. The female condom comes closer to these requirements than any other available method.

Condom programming (male and female) in the context of STI/HIV prevention is one of the three core areas of the UNFPA mandate of preventing HIV infection and promoting reproductive health. Endorsement for the female condom has also been given in the UNGASS on HIV/AIDS Declaration of June 2001. The twenty-first Special Session of the UN General Assembly for the review and appraisal of the implementation of the Program of Action for ICPD+5 also recognized that services should include access to preventive methods such as the female condom.

A number of countries in South Asia have experience in small pilots for acceptability and programming for the female condom. This review attempts to capture the available scattered experience from the region, synthesizes policy and programmatic considerations and identifies issues, lessons learnt and ‘what works’ to enhance understanding in the regional context. Three new UNFPA country programmes in South Asia have included support to the female condom in their forthcoming programme cycles. It is hoped that the paper would facilitate development of strategically planned interventions for female condom programming and help concerned actors at all levels in increasing access and quality to this method in the region. We would look forward to hearing about your experiences in this area.

Increasing access to the female condom will expand choices to all individuals.

Wasim Zaman
Director

September 2002
Kathmandu
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1. INTRODUCTION

1.1 Women & HIV/AIDS

Evidence from throughout the world underscores women’s disproportionate and growing vulnerability to HIV infection. The table below on estimated number of young people -male and female- living with HIV/AIDS in South Asia shows that in India, where HIV prevalence is highest in the region, nearly double the number of young women are estimated be living with HIV/AIDS as compared to young men. Trends indicate that the rate of new infections of HIV is highest among women/young girls in the region. In Nepal, for example, the ratio of women infected by HIV has increased and these latest July 2002 estimates give nearly equal numbers of young men and women infected today.

<table>
<thead>
<tr>
<th>Countries in South Asia</th>
<th>Female 15-24</th>
<th>Male 15-24</th>
<th>% of adults living with HIV/AIDS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>980</td>
<td>1700</td>
<td>1100</td>
</tr>
<tr>
<td>Bhutan</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>India</td>
<td>430,000</td>
<td>890,000</td>
<td>220,000</td>
</tr>
<tr>
<td>Maldives</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Nepal</td>
<td>4000</td>
<td>8300</td>
<td>4100</td>
</tr>
<tr>
<td>Pakistan</td>
<td>4600</td>
<td>9500</td>
<td>5800</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>490</td>
<td>740</td>
<td>400</td>
</tr>
</tbody>
</table>

Women are biologically two to four times more vulnerable to HIV infection from sexual intercourse than men. Reasons for this include - larger vaginal surface area, more viruses in sperm than vaginal secretions and micro lesions that can occur during intercourse may be entry points for the virus. Besides this, more than four-fifths of new infections in women result from sex with husbands/primary partners. It is now well recognized that unequal power in relationships between men and women, lack of economic, social and political power in society, unequal access to resources including health care, and gender norms and stereotypes underlie women’s vulnerability to STI and HIV infection, and pose obstacles to both men and women adopting behaviors to protect themselves from HIV. This calls for an urgent need for greater focus on strategies that address women’s disproportionate risk of infection, enable them to negotiate safe sex, and provide tools, such as female condoms, to protect themselves from infection. The purpose of this paper is to examine experiences with this tool in the South Asian context.

1.2 Female condom: Rationale

The WHO/UNAIDS monograph The Female Condom: An information Pack April 1997 encourages the introduction of the female condom as a new method of preventing both pregnancy and infection and as an additional tool in efforts to respond to the needs of women and men in sexual and reproductive health. The document articulates that “The public health rationale for introducing a method that provides protection against pregnancy and STI/HIV is clear. Globally, health and human rights advocates have been demanding that scientists develop fertility
regulation methods that are safe and reversible, under the control of the user, not systemic in action, which protect the user against STIs and HIV, and do not need to be provided by a health service. The female condom comes close to these requirements than any other family planning method.”

Endorsement for the female condom has also been given in the UNGASS on HIV/AIDS Declaration of June 2001. Also the twenty-first Special Session of the UN General Assembly for the Review and Appraisal of the implementation of the Program of Action for ICPD+5 recognized that services should include “access to preventive methods such as the female…….condom” [42]. The following year the twenty-third special session of the General Assembly, Beijing plus five, called for the development of safe, affordable, effective and easily accessible female-controlled methods including methods such as microbicides and female condoms…….[43] as a matter of priority.

1.3 Scope of the document

Section 2 of the document provides summary information on the product technology and biomedical update on effectiveness and re-use aspects from current research and studies. This paper, however, is designed to focus on policy and program aspects and thus does not provide an analysis of the scientific information.

After the brief of the technology, the document discusses four areas. First, in section 3, is the South Asian experience with the female condom. Pilot experiences, acceptability studies, and available research are reviewed from the region. Second, section 4, synthesizes policy and programmatic considerations in terms of cost effectiveness, acceptability, use among specific populations, channels for promotion and distribution and lessons learnt. Thirdly, the dimension of gender and female condom as a tool for empowerment is examined in section 5. This includes sexual behavior and trust constructions and negotiation for safer sex for HIV prevention. The fourth area covers newer barrier methods including second-generation female condoms and progress on development of other barrier methods for infection prevention, such as diaphragms, cervical caps and microbicides, is reviewed in section 6. Section 7 provides a brief on UNFPA and female condom mandate and support. Finally, section 8 summarizes key regional issues emerging from the review and provides suggestions for increasing access and quality. Section 9 concludes.

2. THE FEMALE CONDOM: TECHNOLOGY & BIOMEDICAL UPDATE

The US Food and Drug Administration approved the female condom in 1993 for one-time use for prevention of pregnancy and, in cases where women's partners will not use a male condom, for prevention of STDs as well. The Female Condom: an information pack, 1997 [1], The female condom, A guide for planning and programming 2000 [2], Female condom Research Briefs 2001 [72] provide information on what is known about its safety, effectiveness and acceptability. A brief summary only from this and update from recent studies and paper is presented in this section. Readers may refer to the references for background information to establish common ground.
2.1 The product

The female condom (FC) is a polyurethane sheath measuring 17 cm in length and 7.8 cm at its widest diameter, which is inserted into the vagina before having sexual intercourse. It forms a strong, soft, transparent sheath that lines the vagina to create a barrier against sperm and sexually transmitted infections. See figure 1 [Source 71].

A small ring at the closed end is used for insertion and to help maintain the device at the upper end of the vagina, while a larger and thinner outer ring remains outside of the vagina when the condom is inserted. The sheath is designed to cover the external genitalia and the base of the penis during intercourse. The condom is pre-lubricated with dimethicone lubricant, an inert, non-spermicidal silicone-based fluid. It is a single use, non-biodegradable, disposable device.

The Female Health Company based in England is the sole manufacturer of the female condom. The product is known by several brand names: Reality®, Care, Femidom, Femy, Dominique, Feminine, My Femy, others.

2.2 Effectiveness in pregnancy & disease prevention

Studies conducted worldwide have indicated an important public health role for this method [1]. In laboratory tests polyurethane female condoms have proved to be impermeable to sperm and to infectious organisms including HIV. Although data from clinical studies on both efficacy and disease prevention are few, contraceptive effectiveness and disease prevention rates seem comparable to those for male condoms - annual estimated accidental pregnancy rates for consistent/correct use have been give as 5% for female and 3% for male condoms [10]. A recent randomized controlled trial among Japanese family planning clients demonstrated pregnancy rates of 0.8% among consistent/correct users and 3.2% among “typical users” [11].

There is limited information on clinical effectiveness in preventing STI/HIV transmission. A randomized trial conducted in Thailand brothels revealed that STD incidence was reduced by 23% among prostitutes using both male and female condoms above and beyond the reduction observed with male condoms only [12]. Results from the UNAIDS study on 1997 found that when the female condom was made available, the incidence of STD infection fell by 34% and the number of unprotected sex acts by 25%. Trussel et al [11] estimate that perfect use of the device may reduce the annual risk of acquiring HIV by more than 90 percent among women who have sexual intercourse twice weekly with an infected male partner. Another estimate is that consistent and correct use of the female condom reduces the risk of sexually transmitted infection [including HIV] by between 94% and 97% per act of intercourse. However in a recent Kenyan cluster-randomized community intervention trial [13], the female condom intervention did not reduce STI prevalence compared with male condom promotion only. The generation of additional effectiveness data on STD/HIV will continue to be important. But additional effectiveness research will be valuable only to the extent that it
involves epidemiologic studies of actual use with end points of pregnancy, STD and HIV [9].

One study [17] in this review also examined the potential of the female condom in protecting women at risk from traumatic coitus and resulting colporrhexis [the term for a complete or almost complete rupture of the vaginal vault with little or not associated injury to the cervix and the lower uterine segment]. Though the study proposes the use of female condom to prevent such traumatic coitus injury this dimension needs further examination.

2.3 Reuse considerations

Based on the recommendations of a consultation convened in January 2002, WHO does not recommend or promote reuse of the female condom. However, given the diversity of cultural and social context and personal circumstances under which female condom re-use may be acceptable, feasible and safe, and since the balance of risks and benefits varies according to individual settings, the final decision on whether or not to support reuse of the female condom must ultimately be taken locally. If the female condom were to be reused, the protocol for preparing the device for reuse must include a dis-infection step. A protocol has been developed for the safe handling and preparation of used female condoms intended for reuse [27]. Box 1 provides a summary of key results of new research related to reuse.

Box 1. Summary of key new research related to reuse.

- Batches of new unused female condoms were subjected to seven cycles of dis-infection, washing, drying and re-lubrication, reflecting the steps in the draft protocol, but at considerably higher concentrations of bleach and longer durations. All female condom batches met the manufacturing quality assessment specifications for structural integrity after test cycles [WHO-Sponsored research conducted in London].

- The organisms that cause gonorrhoea, chlamydia, herpes, AIDS when added in high titers to bull semen, were killed by a solution of common household bleach in two minutes [WHO-sponsored research conducted in Johannesburg, South Africa].

- No significant adverse effects were associated with up to five uses of a single female condom in couples not at risk of pregnancy or STI or HIV infection. Dis-infection, washing, drying, re-lubrication and reuse of device were not associated with penile discharge, symptomatic vaginal irritation or adverse colposcopic findings in study volunteers [USAID-sponsored research conducted by FHI in Norfolk, VA, USA]

Source: [27]

In terms of programmatic considerations, female condoms would be more economical if they could be reused. Some women are already reusing FC and in part may be motivated by lack of access to the device as well as its apparent robustness. The critical issue is the ability of women to detect damage after reuse. Studies, such as the FHI Zambia one among 37 female condom users [26], have shown that some women had used FC up to four times. This study concluded that levels of reuse would rise as availability expands particularly in resource-poor settings. Providers of female condom have an opportunity to shape responses to reuse for the better, rather leaving women to devise their own ‘common sense’ solutions.
3. EXPERIENCES IN SOUTH ASIA

There is very limited experience and published or grey literature on the female condom from South Asian countries. A web search on list of references and abstracts of articles on FC from the FHI database [74] provided over 110 articles on the subject, none were from South Asia. Of the 30-odd papers on female condom presented at the XIV International AIDS Conference at Barcelona, July 2002 only one abstract was from South Asia, Bangladesh [28].

This review of FC experiences in South Asia informs of small pilot research/acceptability studies have been commissioned in 4 countries since five years or so (Bangladesh, India, Nepal and Sri Lanka) with specific population groups through NGOs and others. Female condom availability in the other developing countries too is still largely tied to small pilot projects. However countries, such as Brazil and South Africa are moving from the experimental to large-scale expansion. Also, in India, just recently in May 2002, with DFID support a multi centric acceptability study in three states, social marketing and part-manufacturing project has been initiated in collaboration with Hindustan Latex Limited, an Indian public sector corporation. This section provides a brief from of South Asian country experiences with female condom. Though studies are small pilots, some qualitative perspectives can be drawn from this limited experience.

3.1 India

Pilot studies with female condom have been conducted in India since 1997/98 with small population groups on acceptability. This section provides a brief from the five studies reviewed. Also, as mentioned above, there is the very recent initiative of acceptability study/social marketing with Hindustan Latex Limited. Besides, international NGOs such as CHANGE [Center for Health and Gender equity] have also initiated some research related to dual protection strategies and the female condoms in reproductive health programmes in India. Other social marketing companies such as PSI, who have marketed the female condom now for several years in many countries, and DKT-India are also conducting assessments in three other states in India [29]. However, though pilots have been conducted for over five years, as of date, there is yet to be an established program making available the female condom through public, private or social marketing sector in India. A brief on the key initiatives is given below.

(i) Market studies-Hindustan Latex Limited: India is on its way, for the first time, to getting its own brand of the female condom. In the last three months [4] Hindustan Latex Limited [HLL], a government owned contraceptive maker, has been reviewing feasibility reports and marketing strategies to introduce the FC in India. A three-phase trial is on in conjunction with the Chicago-based Female Health Company [FHC] and the FC could hit medical stores by early 2003 according to a recent media report [4].

HLL found in its pilot study that the targets most likely to benefit were commercial sex workers. Its important for them since the men most often are too inebriated to use a condom or so not want to use one at all. The study, conducted with NGOs in districts of Andhra Pradesh areas where sex workers are active, involved 55 case
studies and how-to-use sessions with vagina models. Some respondents mentioned that they started charging more from their clients; some were put off by the baggy intimidating look of the condom. The social ramifications of the study would need to be studied.

FHC has received a grant from the British Government for marketing and manufacturing the FC in India with HLL. The grant from the Business Linkages challenge fund will support FHC and HLL’s three-year $2.84 million project that includes an expanded market study of the female condom in multiple sites in India [73]. FHC and HLL have convened a Technical Advisory Committee to provide strategic guidance to the project. The National AIDS Control Organization will chair the committee. After the necessary approvals, HLL will part manufacture the product. This would address the challenge of costs. At a global public sector price of nearly 10 times that of a costly male condom, the price needs to be lowered to be cost-effective. HLL has entrusted Lowe India in Chennai to brand the product and launch an ad campaign by the year-end. The names for the Indian market are decided as “Rani” for the rural market and “confidem” for the urban. But marketing it is not going to be easy. The biggest challenge will be the stigma associated with insertion [4].

(ii) NGO pilot studies: Several small acceptability studies have been conducted in the country since 1998. TRUE voluntary organization conducted a pilot study on female condom acceptability among sex workers in Srirangam temple town in Trichy district in South India. The users perspectives from the small study showed that the sex workers, between the age of 18-25 years, found wearing the female condom easy though complained of discomfort after putting on for first time and were happy that they had a method they could individually decide on preventing themselves from infection [70]. A pilot study done by NGO DESH based in Chennai concludes that women would only agree to introduce the device to their husbands by talking about its importance for the family’s welfare. Thus according to the DESH study in South India “A women’s empowerment approach with the female condom needs to work towards building communication between men and women” [5].

A 1998 pilot study in India [62] has also analyzed acceptability of FC as a protective device and factors contributing to its use and non-use. Fifty-eight participants were interviewed after they had each used three FCs. A small incentive was given for participation. The participants were 28 housewives from two urban slums, 15 housewives, and 15 sex workers from a semi-urban area, 67% 23-32 years old (19% younger and 14% older), 38% illiterate, 5% high school-educated. Duration of the study was 15 days. The abstract informs that many women felt they could use FC for their own protection with better control over their sexual relationships. In March 1998 a comparative and acceptability study with two female condoms Reddy MedTech latex one and Reality polyurethane female condoms was conducted in Chennai, India among 51 couples supported by the Tamil Nadu State AIDS control Society. The three-month study provides comparative data on users perceptions to the product [ring, sponge, size, difficulty in insertion/removal, pleasure, breakage rates, others] and concludes that the introduction of the female condoms with proper education of the products will greatly enhance acceptability and usage. Overall the study participants became ‘more positive about female condoms after usage’ [8].
3.2 Bangladesh

Only one paper, also presented at the recent Barcelona meeting, is available from Bangladesh. This Care Bangladesh acceptability study for female condoms was carried out both in brothel based and street based 211 sex workers in Bangladesh [28]. The study reports that most of the respondents (93%) reported they used male condoms while only 8% mentioned they used both male and female. Only 3 percent of the respondents in the study said they had used FC within last six months and have reused it up to 10 times. The reasons for not using FC were mentioned that it is not available, expensive, difficult to insert, clients do not like it, too big size, felt pain and hard and discomfort during intercourse. The respondents mentioned that the advantages of using female condom were if their clients do not want to use the male condom. Some of the clients said it was useful when they are forced into group sex. About 20% respondents thought the FC could reduce resistance from their male partner. About 10% respondents wanted to use FC with subsidize price, most of them were ready to use if given free of cost. The study concludes that FC should be sold at promotion prices to sex workers [28]. CARE-Bangladesh is prepared to help programmes develop an approach to using female condom in commercial sex settings [5].

“I sat today with the street sex workers of Durjoy, in Bangladesh, the sex worker organization associated with SHAKTI. Sales of the female condom rose from 200/month to 500/month to 700/month just in the last 3 months. As I sat and listened, one young woman told of 10 men taking her to a field, rape really, they didn't pay; she asked them to use condoms and they refused, so she excused herself, went off as if to the toilet, and inserted her female condom and got through the 10-man scene without anyone of them noticing. That's empowerment! Does the world need this device, or what?
Carol Jenkins, USAID, Cambodia, Source [75]: [Http://archives.healthdev.net/gender-aids/msg00174.html](http://archives.healthdev.net/gender-aids/msg00174.html)

The above brief note of an FC experience in Bangladesh was posted in the gender-AIDS e-group and highlights the female condom’s role in provision of a means to women to avoid infection until the day the deeply rooted structural barriers towards safety can be changed.

3.3 Nepal

Research on FC is very recent in Nepal. A study to assess feasibility and acceptability for the female condom was conducted in March 2002 in selected blocks in Kathmandu valley. The pilot study, by the NGO, Ama Milan Kendra in collaboration with CEDPA/Nepal, the female health company and the National STD/AIDS Control Programme was designed to address the questions of additional value of the female condom as they affect married women living in Nepal, namely, receptivity of Nepali women to use the female condom for dual protection. This five-month study is just been completed and the report is being finalized. A focus group discussion was conducted with the women and providers from the acceptability study on 3 September 2002. Box 2 below provides a summary of perspectives of Nepali women from Tikathali Village Development Committee, [just outside Kathmandu] on the female condom as well recommendations from the group on the product and service delivery aspects in the local context.
Box 2. Perspectives on the female condom from users and providers
Tikathali VDC, Lalitpur. Nepal

The findings below are from a focus group discussion conducted on 3 September 2002 with 15 women users of the female condom and individual interviews with the acceptability study project staff from the NGO Ama Mila Kendra. The group was primarily married parous women from the village [VDC Tikathali] just outside Kathmandu who were users of other spacing contraceptives.

Product related
- Several women in the group articulated that they found the internal ring big and thick and suggested a slimmer and smaller internal ring [as slim as the outer ring]. They found otherwise no problem with the product.
- It was suggested that a more user friendly packet of the female condom would be if it could be smaller in size - this would make it easier to carry as well as more discrete. The current size of the packet was considered big and thus difficult to keep privately.

Reasons for use
- The reasons for use of FC among others were side effects of Depo Provera and CuT [which were the most commonly used contraceptives in Tikathali village].
- The advantage was also when husband’s were drunk and did not/could not use male condom
- If the FC was easily available the women mentioned that they would use this instead of pills, depo which have hormonal side effects and associated bleeding problems
- Providers informed that they found it was difficult to convince sterilization clients to use the female condom- all the women who opted in the study were those using other contraceptives and had 2-3 children. Sterilized women in Tikathali mentioned that they believe in their husband and do not want to use to protect themselves from infection.

Use related
- Insertion of the condom was initially difficult for most women; the nepali word used for this was “jhanjhat” [problematic]. However, after 3-4 times insertion became a bit easier and comfortable. Women did not give up trying even though difficult the first few times due to support and counseling from the project staff.
- Disposal- Women mentioned problem of disposal of the condoms- it was problematic as well as not good to bury the condom –dig in mud- because it would not decompose. The common method used was burning along with household waste. Women reported that even burning of the female condom took a long time
- Noisy- some women mentioned that the husband did not like the noise. Also in a small house in the village the noise causes more problems where children and elders are in close vicinity.
- Lubrication was much appreciated and stated to be better than male condom and making use comfortable.
- The women in Tikathali inserted the female condom sometimes 2-3 hours before expected intercourse, but mostly after initiation/indication of the same by the husband.

Service Delivery
- Cost: Maximum price they would be willing to pay was Rs. 2 particularly the women mentioned that all other contraceptive products were free for them so they would not be able to buy this as an expensive product.
- Source: From female providers only. The women mentioned they would not be able to buy the product from a village shop at all.

Spousal views
- One group member mentioned [with two children and earlier using depo] mentioned that when she switched to female condom her husband did not like and said that she did not trust him.
- Women also mentioned that in case of female condom they missed the ‘skin-to-skin” touch when their wives were using depo provera.
- Generally women mentioned that their husbands were initially hesitant but later agreed- some women insisted [this was from a school teacher herself].

Recommendations from the group
- Product should be less noisy
- Inner ring smaller and slimmer, outer ring smaller slightly
- Product to be available through female providers- FWVs, others [not shops]
- Cost of the product maximum Rs. 2.                                                                                 Source: F. Usmani [58]
3.4 Sri Lanka

From Sri Lanka two contrasting experiences with different target groups—sex workers and family planning clients—have been reported as discussed below.

(i) Sex workers: The female condom has undergone an acceptability study among 40 commercial sex workers in Colombo in April / May 2002, and some interesting findings were presented at a meeting on Friday. Of 35 commercial sex workers who reported back after using the female condom, 32 had liked it “very much” or “fairly well”, while 28 had preferred it to the male condom. Their clients liked the female condom and found it “exciting” to watch the insertion, 20 of the sex workers had claimed, with one elaborating that her client said “it was like a blooming flower”, according to Community Development Services (CDS), a non-governmental organization which looks into the health aspects of this marginalized group and conducted this study. Though the condoms had been given free to the sex workers, they had made their clients pay more than the usual rate as charges for the condom. Eight of the clients had requested the sex workers to bring a female condom next time and agreed to pay for it. Thirty-two sex workers had also found it to be noisy, though some of them had stated the noise caused some amount of arousal and excitement. More research and acceptability studies among different groups of women in the country are envisaged by the Female Health Foundation before marketing [30].

(ii) Family Planning clients: The verbatim communication on the experience two years back by the Family Planning Association of Sri Lanka is being given below since it conveys lucidly the experience in this context as well as highlighting need for different programming strategies depending on the contexts.

“……About two years ago, we had received few hundreds female condoms to be used in our clinic. We put them out for sale at Rs. 10/- per condom at our sales counter, and promoted among people who come to our clinic. We also carried a few similar advertisements in newspapers indicating the availability of female condoms at our sales outlets. In order to see the acceptance of the female condoms specially among young couples, the Doctors gave them free samples, and requested them to report back after usage as to how they feel about it. Most of these young couples reported back stating that they did not like to use female condoms on a second occasion. Ladies felt that it was somewhat messy and the young men had indicated that they were disturbed when female condoms are in place. Most of them had used one or two condoms and returned the balance. Inquiries from the sales counter indicated that very few users had come to purchase female condoms for the second time, and even those who received free female condoms at their first visit to the clinic, did not indicate willingness to purchase when they come to the clinic next time. It should be noted that 98% of our clients are people who come to choose for a convenient method of family planning and condoms are generally taken only by new couples. We hardly have any commercial sex workers visit to our clinic. Even if they do, they never admit that fact. Our original plan was that if we found the female condoms are accepted in our clinic, we would then import some and distribute them into the pharmacies through our normal condom social marketing programme. However, since the demand for female condoms in our clinic was very little we did not pursue this matter any further. Our current experience does not indicate that it would become sufficiently popular for us to make it available in the open market by investing the limited capital we have”.

Source: Daya Abeywickrame [31]

Expanded access and use of the female condom requires targeted policy advocacy and strategic planning and programming. The next section discusses these aspects.

4. POLICY AND PROGRAMMATIC CONSIDERATIONS

Technology is simply the means. The hard part, programming, is actually getting the product into the hands of informed users. The end, of course, being women and men having safer sex acts with efficient protection. This section discusses
policy and programming issues related to developing strategic and effective approaches addressing costs, acceptability, promotion and distribution, experiences with specific vulnerable population groups and lessons learnt to inform development of strategic programs in the region.

4.1 Acceptability analysis from the region

The female condom is the only existing method of STI and HIV prevention that can be initiated and controlled by women. As can be seen from the review in section 3 on experiences from South Asia, the female condom, as in other parts of the world, is acceptable to women and men from the region. Many liked and not so liked features from the studies in this region are very similar to those articulated globally in international reviews. However, majority of South Asian studies have been conducted among sex workers [Bangladesh, India, Sri Lanka]. Only the Nepal study is among married women members of mothers groups and the small Sri Lanka experience with family planning clients. Women here are also in need of a method in their control in contexts such as - to protect themselves when forced to have sex with husbands or partners who abuse alcohol, commercial sex work, when male condom use cannot be negotiated due to power dynamics. It may be noted that male condom use in the region is also fairly low. Other specific regional contextual features include (i) in terms of the product -the size of the internal ring being felt to be large- since women here by and large have a smaller stature and (ii) disposal issues and noise in small joint family contexts. Cost issues and gender and power dynamics are similar to most developing countries vis-à-vis FC acceptability. As in case of a Nairobi study [18], women users of female condom in a focus group discussion in Nepal reported that use of the condom gave them the courage to raise the topic and discuss sex with their husbands.

A 2000 review [9] has summarized the best and least liked features. These include, for best liked, (1) the fact that women can place it autonomously and can trust that it is not torn or otherwise sabotaged by the partner; (2) the high level of protection it can provide when used correctly, and its soft and lifelike feel. Among the least liked features given were (1) the need to practice insertion and to use the device several times before mastering it, (2) the fact that it can be seen by the partner [women are more likely to practice safer sex with female controlled methods that can be used secretly [19] (3) for some the inner ring,

According to a recent article since it took 17 years before the tampon was accepted and used by women, the acceptance of the female condom is perhaps also likely to see a time lag [45]. For some women cultural proscriptions against touching the genitals create initial hesitancy in trying the FC. But the disposition of regulatory agencies and the attitudes of health care providers have unfortunately exaggerated this reticence, thereby effectively reducing access to these methods [9].

Regarding men’s acceptability, studies mention that men prefer the female condom to the male condom in that it does not interrupt sexual activity [can be inserted in the vagina up to eight hours prior to intercourse]; feels more similar to unprotected sex; is not dependent on the male erection; does not constrict the penis; and does not require immediate withdrawal after ejaculation. Curiosity and novelty of the FC encouraged men to try it- men like discovering tricks, having
experiences and new things as in the case with the female condom. Male and female condom use is hindered by male partner objections, suspicion of the device among residents and bias against FC by clinic providers. Data show that while many men do use male condoms, they often are unwilling to do so consistently. In these situations, access to the female condom can dramatically increase the total number of protected sex acts.

4.2 Costs and cost effectiveness

The female condom was launched in 1992 in Switzerland and as of the end of 2001, more than 70 countries were managing female condom programmes, ranging from small trail projects to national-level distribution through public, non-government organization and social marketing sectors.

Presently 10 million female condoms are sold per year. The female condom is sold in developed countries for about US $ 2 each. To lower the price of female condoms to the consumer, UNAIDS in 1996 negotiated a contract with FHC for a reduced price of about US$ 0.38 per condom for bulk purchases. (The price for male condoms in bulk on the world market is currently below 3 US cents apiece). This included distributing female condom to over 60 countries. Some of these countries then make the female condom available free in public health programmes and others sell them at very low, subsidized prices that are below the cost of the actual product. In South Africa female condoms are available free in some clinics and sold for 30 cents in others. PSI Zimbabwe’s social marketing brand “Care” is sold in pharmacies at a price of about 0.27 US $ per box of two. In Lusaka, Zambia in a social marketing program female condoms were sold at a price comparable to that of the subsidized male condom.

The cost of female condom continues to be a major barrier to broader distribution and use. The price can be reduced by (i) Economies of scale - this might bring the price down a little but not significantly; (ii) Another way to get the production price down is to break the technology barrier to create a much less expensive material (iii) the private sector is one important option to pursue and (iv) Another critical issue is funding from donors, who must coordinated efforts as expeditiously as possible where HIV/AIDS prevention is concerned.

Given its high price and the limited resources available, tradeoffs must be made regarding 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? The Kenya FHI community intervention trial [section 2.2 above] highlights the need for further research for evidence in this area. The model by Health Strategies International [HIS], based on UNAIDS funded research, uses data related to epidemiological, behavioral and costs, from within a country, which is analyzed within this model to determine whether allocating funds to female condoms programmes is a reasonable option. A cost effectiveness research in preventing HIV and STDs in CSWs in rural South Africa [66] using a simulation model concludes that the program would generate substantial net savings if HIV prevalence in CSWs is 25% than 50.3%. The paper concludes that a well-designed FC program oriented to CSWs and other women with casual partners is likely to be highly cost effective.
Table 2 below provides the cost effectiveness analysis for female condom interventions in different sub-groups [6].

<table>
<thead>
<tr>
<th>Intervention groups and individual interventions</th>
<th>Place and year of publication-Reference</th>
<th>Cost per HIV infection prevented US $</th>
<th>Cost per DALY gained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condom distribution plus STD treatment for CSW</td>
<td>Sub Saharan Africa [Modes et al 1991]</td>
<td>11-17</td>
<td>1</td>
</tr>
<tr>
<td>FC targeted to CSWs</td>
<td>Kenya [Homan et al, 1990]</td>
<td>275</td>
<td>12</td>
</tr>
<tr>
<td>FC targeted to high risk women</td>
<td>Kenya [Homan et al, 1990]</td>
<td>1066</td>
<td>48</td>
</tr>
<tr>
<td>FC targeted to medium risk women</td>
<td>Kenya [Homan et al, 1990]</td>
<td>2188</td>
<td>99</td>
</tr>
</tbody>
</table>

Source: Creese et al [2002]

The 2002 cost analysis review [6], despite limited evidence, concludes that there is a strong economic case for giving priority to preventive interventions as well as tuberculosis treatment. UNAIDS and other published research also highlights that incorporating the female condom into prevention programmes can be cost saving as it reduces the number of unprotected sexual acts, the incidence of STDs and the costs related to treatment and care.

4.3 Female condom use among specific groups

Young people, intravenous drug users and mobile/migrant populations have been identified as the three priority themes for South Asia by the UNAIDS regional co-sponsors. The section has thus been included to review female condom programming in these as well as other vulnerable sub-populations, though there is very limited of information available on the same.

(i) **Young people:** Two papers from the recent Barcelona AIDS Congress provide experiences of female condom programming with adolescents and young people [35,36]. In the recent Brazil adolescent programme [35] that assisted 375 adolescents it was reported that 62.1 percent accepted to use female condoms and 27.5% are using them frequently. 6.2% gave up its use. Most of the adolescents that gave up its use reported generic reasons as didn’t like it or found it ugly. Some adolescents reported that they were afraid or ashamed to use it. The study concludes that the context of a young assisting another of trying to stabilize a horizontal relation to facilitate the exchange of information is fundamental for FC programming in young people. The paper from Spain [36] on analysis from four university students discussion groups of sexually active students reports that use of female condom is conditioned by the type of the couple [steady vs. casual]. Girls associated its use in sporadic relationships and boys associate it with being in a steady relationship and cthe study concludes that it is necessary to develop programmes to improve the use of the female condom in girls and boys considering the differences between them and suggests macro information campaigns to be organized to help create a culture of use among the youth. Also, in the context of young people, use of the female condom depends on political and not solely individual decisions in many contexts.

(ii) **Commercial Sex workers:** Studies from many Asian countries Bangladesh [28], Thailand [67], Singapore [68] and China [69] all explored the FC in the context of sex workers and their clients. The Bangladesh paper is discussed in section 3.2. A
high proportion of CSWs reported positive experiences and perceptions in the Thai study. 80% participants said they were satisfied with the female condom and would use it again in the future and would recommend it to their friends. However, the female condom was used in only 29% of the total number of sexual acts reported, and 98% of CSWs said they would prefer to use a male condom for sex work. Many of the women were concerned that the physical appearance of the condom would reduce its acceptability to their clients. This was the most frequently cited reason for not using the female condom in the future. In the Singapore sex worker study 76% thought that the female condom was an acceptable method of protection against STDs. In the China study, with 314 CSWs, 97.4% expressed that they would use FC in future. The rate of CSWs who reported liking the FC increased from 60% at pre-intervention to 93.5% at post intervention leading to the conclusion that through active intervention the knowledge, attitudes and uses of FC can be improved greatly. In the context of sex-work women face few possibilities to negotiate male condom use and FC offers the protection in these cases. An additional benefit also reported was that sex workers’ income was not affected by suspending their job during menstruation because the use of FC allows them to continue without interruption. While a promising device in the context of this vulnerable Asian population, the female condom must also become more acceptable to men if it is to enable women to be in control of their own protection from pregnancy and STD/HIV.

(iii) Drug-using women: Small US trials of female condom use among drug using women [14, 15] or other women at high risk, such as STD clinic patients, [16] have indicated a high level of interest in the method and feasibility of use in these populations. Female condom was introduced to drug involved women in Rio. Three month follow up interviews indicated high rates of female condom use for women who returned: 62.3% reported trying the condom at least once and 43.4 reported continuous use [22].

(iv) Female condom use among HIV-infected women: There are few prospective studies of female condom use among HIV infected women. A Brazil study in 76 HIV infected women [56] found high rates of use (87%), acceptability (68%) and continuation (78%) of female condom use during the 90 days study interval. There was an expressive reduction on proportion of unprotected sexual acts [from 14% to 6%]. Protected sex acts were more prevalent in sero-discordant couples and in previous consistent condom users. Factors influencing decision making attitudes around the use of protection for men and women living with AIDS needs further exploration [55].

(v) Men who have sex with Men [MSM]: Although designed for use by women, the female condom has also been used by men having anal sex with men. The acceptability and safety of the female condoms for anal sex among MSM has also been studied [37,24]. In a Seattle study with 76 men including 5 HIV+ couples, about 20% of men reported willingness to use reality [female] condoms in the future with unknown HIV status partner. Those reporting willingness of use reality condoms were more likely to be receptive partners who reported past problems with male condoms and did not report safety problems or discomfort problems with female condoms during the study and HIV+ insertive partners. The study concludes that safety outcomes (condom breakage, semen but spillage, rectal bleeding) were not significantly different for male and female condoms but
slippage was more common with female than male condoms and design modifications may be needed for anal sex [37]. Another assessment of the use of female condoms for anal sex by HIV sero-negative men in the US shows that of the 1084 men who had heard of using the female condom for anal sex, 13 percent reported using it in the prior 6 months for both receptive and insertive sex. The study reported complaints such as pain, discomfort, difficulty in inserting others and also like the previous, suggests that there is need to redesign female condoms to increase acceptability and use by men [15].

4.4 Promotion and distribution channels

Female condom could reach consumers through the same channels as the male condoms- pharmacies, kiosks, market stalls, clinics, community based distribution, peer educators and many other places. Some service delivery options are discussed here.

(i) Female condom in family planning settings: Condoms have received little promotion by family planning clinics, and HIV/AIDS prevention has not by and large been incorporated into routine FP tasks. A poster presented at the July 2002 Barcelona AIDS Congress provides experience with a dual protection intervention with the female condom in six family planning clinics in Ibadan [34]. Little is known about FC adoption and continued use when it is incorporated into routine care in family planning clinics, and the significance of FC when FP service provision is modified to focus on dual protection1. The experience with 144 interviews concludes that despite willingness to adopt dual protection strategies, women are constrained by various social, cultural and other factors beyond their control. Husbands are identified as strong determinants of FP and dual protection decision-making and the study suggests more sensitization and education for both clients and their husbands for strengthening HIV/STI prevention.

In an intervention in Nigeria, the female condom was introduced along with the male condom as part of the dual protection strategy in family planning clinics. The program included training of providers in discussing dual protection, HIV/STI communication and counseling skills, providing and explaining how to use both male and female condoms and condom negotiation skills. The results from this study showed that in the first year of the program, there was a modest increase in male condom, but a significant interest in the female condom and an increased discussion of dual protection by providers. [59]

(ii) Public sector service delivery: Programs in South Africa and Brazil have introduced and are providing the female condom through the public sector. In South Africa, the National Department of Health with assistance from FHI is expanding female condom distribution beyond family planning service delivery points. In the context of dual protection promotion female condoms will be distributed at sites targeting individuals at elevated risk for STI transmission, such as, men in the workplace, adolescents and sex workers [65].

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1 Dual protection is protection from pregnancy and STI/HIV infection, either through the use of male or female condom alone or the use of a condom in addition to another contraceptive method.
Female condom has been an important component of the Brazilian AIDS program since 1998. The response in terms of both initial uptake and continued use of the FC has exceeded the expectations of the Ministry of Health and provided important information for the Ministry to develop a coherent Female condom policy. The expanded National program is now delivering protection to over 13,000 women throughout Brazil. The experience shows that the use of the female condom has been highest among those women and men who were reached through programs that favored community effort and educational outreach [65].

(iii) Social Marketing: Social marketing programs are now providing female condoms in many countries in Africa, Asia, and Latin America, primarily under the auspices of Population Services International [PSI]. In Zimbabwe PSI was introduced FC in 1997. The brand product -Care- retails at US $ 0.24 for a packet of two. Pharmacists have reported that as many men as women are purchasing the condom. At first, the product was sold only at locations with a provider who could instruct women in its use. Now that women are familiar with Care, the device is available at supermarkets and convenience shops. Product promotion of the female condom in social marketing projects has been through mass media; brand advertising in newspapers and magazines; radio advertisements have featured endorsements by prominent health authorities; special event and in-store promotions [20]. Female condom social marketing has now been tested and expanded in at least eight additional countries. Retail price is highly subsidized and ranges between 8 and 30 US cents per female condom [21].

(iv) Innovative promotional channels used for FC: An interesting experience from Harare is on the use of hairdressers in promoting the female condom and safer sex in the PSI/Harare programme. The program design was to enable women to buy the female condom in a friendly relaxed environment. Given the amount of time hairdressers spend with their clients and the excellent communication skills they engage in dealing with clients, the hairdressers were found to make great peer educators.

4.5 Policy & Advocacy Issues

Notwithstanding endorsement of the female condom in global and national documents, policy makers need to make choices in making the female condom more accessible, particularly in terms of availability, cost, sustainability and targeting of limited supplies. They have to decide how much to endorse and promote the female condom. Will it undercut other, more effective interventions? Or the male condom? In the end be an effective intervention? How supply could be sustained even if advocates were to create a demand for the product? This section highlights some advocacy areas in the regional context.

(i) Advocacy for resources: In the recent years, the female condom has become available in some settings, but widespread access to this important method is constrained by low investment by donors in both supplies of female condom and the program support necessary to increased use. 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 condoms with women.
(ii) Engendering policy & programming: The analysis highlights the need for advocacy to expand integration of dual protection strategies into existing reproductive health / family planning programs. In South Asia, the HIV AIDS epidemic is rapidly growing- particularly in parts. Gender inequities underlie both men and women’s risk in South Asia for this devastating disease. It is thus critical that strategies such as dual protection and female condom be understood in the South Asia context and introduced in the most effective way as part of HIV prevention in the region. There is need to understand how programs and policies for dual protection can challenge existing gender norms, change the balance of power between men and women in sexual relationships and address the risks women face in negotiating condoms [both male and female].

Gender approach in female condom policy has been documented from the Brazil program. This program introduced an innovative approach of training of the health professionals and community health workers of the government and non government organisations in a gender perspective. It is seen as a key issue that women are aware of their vulnerability to STI/HIV and are motivated to rethink their practices. Women’s groups are set up to improve negotiation with their sex partners. In these meetings gender issues such as power relations are related to the affective sexual relationships [56]. The Brazilian experience shows the necessity to advance in the introduction of gender perspectives in prevention actions.

(iv) Grass root advocacy: Grass roots advocacy provides women with a means of addressing broader cultural and political barriers to FC use. One successful example is available from the Women and AIDS support network [WASN] which coordinated a petition campaign throughout Zimbabwe by 30,000 women for access to female condoms. This influenced policy makers to launch a nationwide introduction of the female condom in 1997. Sales were expected to be only 4,000 a month, but in the first two months 80,000 FCs were sold. “The petition was an educational tool,” explained WASN’s Misihairabwi. “It raised awareness. Women demanded to learn more. They wanted to know why they don’t have the female condom. The petition created an interest. They would ask health workers during immunizations about it”. Grass root advocacy can also help to draw on existing local resources wherever possible, including local research organizations and existing infrastructure.

4.6 Lessons learnt

Lessons learnt to date have shown that there is a demand for the female condom, although some of it may be ‘novelty demand’. A review of four successful female condom programmes identifies six key similarities which may be useful in increasing access to female-controlled prevention methods: an identified target audience to whom messages and product are well delivered, ensuring users have an ongoing, consistent supply, training to desensitize providers and prevent possible biases from negatively influencing potential users; face-to-face communications to equip potential users with information and skills; a mix of public and private sector distribution sites, and a long assessment period to gauge actual use of the female condom beyond the novelty phase [38]. Programming in many contexts suggests that FC may require use of peer-support groups to encourage wide adoption and it can be culturally inappropriate in some contexts.
[44]. Nevertheless, studies from several countries indicate that with appropriate levels of education, training, and support, women find the female condom both effective and empowering, allowing them to negotiate safe sex.

Many of the lessons learned from female condom introduction are not specific to the product; rather they are fundamental issues that must be addressed when introducing new technology. These include: obstacles in changing people's behavior, overcoming deeply rooted biases [especially among providers]; breaking down gender disparities, addressing existing dynamics between sexual partner and between providers and clients; addressing the stigma of sexuality and allocating resources between different technologies [44]. Other barriers to empowerment include need for education about basic reproductive anatomy and perhaps also a lack of female pelvic models to teach correct use.

5. Gender and Empowerment dimensions

Despite encouraging results on efficacy of the female condom, its value for HIV/AIDS/STI prevention remains unclear, not least because unequal power relations between men and women impact significantly on the ability of women to control the use of any prevention technology. The female condom potentially gives women the power to initiate use of a method to prevent HIV/STIs 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.

5.1 Sexual behavior and sexual negotiation

Women’s socio-economic position affects their ability to enter into sexual relationships with men as equal partners. Even where there is a measure of equality, powerful norms about sexuality and sexual behavior construct constrain women’s behavior. Several studies from the regions, such as the Mumbai study [46], report that women have stated that, because of economic dependence and fear of physical violence, they must submit to their husband’s sexual demands without opposition. Difficulty in sexual communication appears prevalent in countries as culturally disparate as USA, Brazil, India [47, 48]. An earlier survey of spousal communication in Asian countries found that almost a third of the women interviewed never talked to their husband’s about sexual matters [49]. There is however evidence to suggest that in circumstances where women are able to influence the forms and contexts where sex occurs, HIV-related risks may be lowered. Thus central to the long-term success of HIV prevention are forms of protection over which women have more control and to which men offer less resistance [50]. The female condom is one such potential tool.

5.2 Tool for empowerment: Contextual Issues

While a number of studies have focused on the acceptability of the female condom, little research has been conducted into the ways in which its introduction might affect power dynamics and sexual communication/negotiation between men and women. The extent to which the female condom may empower women in their negotiations with men depends also on the form and context within which sexual
relations occur. Strong anecdotal evidence exists to suggest that the level of this empowerment may vary. An important study on two contrasting communities in South Africa highlighted the contextual differences affecting women’s empowerment in relation to the female condom [25]. Findings from this study suggested that women from one of these communities—Nhlungwane—were able to begin using the female condom because existing levels of political environment made them confident enough to negotiate its use with sexual partners. This political involvement also encouraged other women in the community to follow their example. These women who were aware of the constraints on their lives and the threats to their health as a result of economic dependence on men, saw the female condom as a potential means of managing risk. They shared their experiences thereby became resources on which to draw in communicating the use of female condom [45]. Other studies also point to the importance of introducing the female condom in the context of group-based interventions in which women can gain support for change both from the intervention itself and from one another [51,23].

A UNAIDS exploratory qualitative investigation in four countries [23] examined the role of the female condom in empowerment of women in protecting their reproductive health and more generally, making decisions and negotiating protection within their sexual relationships. The study summarizes that FC will be most successful in enhancing sexual communication and women’s empowerment in the contexts of sex workers [who already have experience in negotiating safer sex with clients]; couples where men are already supportive of family planning; where the male condom is unpopular, thus rendering the FC a preferable option. It suggested that FC may have less impact on sexual communication and negotiation where there is little or no tradition of talking about sex, where women believe themselves to be at low risk of infection and where partners “trust in love” as a means of protection against STDs/HIV. Somewhat paradoxically this study suggests that the female condom can be introduced with success in certain contexts and circumstances without major disruption to the present balance of power in heterosexual relationships. However, since the female condom may be used as a tool in the development of women’s sexual confidence and autonomy, this may open up the possibility of greater equality in sexual relations, between men and women.

5.3 Male involvement

The strongest reason for discontinuation reported in many contexts was the unwillingness of the male partner. The woman can choose the timing and introduce the FC but most of the time she still needs her partner’s approval. By casting FC as a female initiated rather than controlled by women method will make it less threatening to men and should have broader appeal in the regional context.

Suggestions for “non-threatening approaches” include a gender-neutral packaging. A Zimbabwe study mentions that if there is too much focus on women’s empowerment, men feel threatened. The product should be marketed for AIDS prevention but without stigmatizing it and marketed towards women while involving men. Also, when female condom use is presented in the form of pregnancy prevention, the association of condoms with infidelity is overcome [10]. Partner negotiations have to proceed without insinuations of infidelity or guilt. It
will be useful if strategies are aimed at information provision and attitudinal change rather than confrontation and female dominance. Some of these ‘non-threatening’ strategies include: laying the female condom on the bed so the male partner raises the subject of its use and telling the partner the doctor had recommended the method to avoid the negative side effects associated with the pill. The FC thus, when perceived as lying firmly within the female domain, does not as such challenge male power or virility. This has been found to be a positive factor in encouraging men to accept its use. However, some men have expressed concern that the female condom would facilitate greater freedom for women including opportunities to engage in sex outside of marriage [23].

There seems to be overall consensus from the literature that since the decision-making on sexuality issues rests with men, programming of FC must design strategies to reach more especially to the men. However, more research is needed on how could the product be best introduced to men and how could men introduce it to their partners. What are the best intervention strategies to promote continued use as well as other cross-cutting issues closely connected to gender related introduction - price, re-use, product delivery at particular outlets, others.

5.4 Constructions of trust and HIV prevention

Using the female condom other than for contraceptive purposes is likely to entail acknowledging that a partner is not trustworthy. This is particularly difficult in situations where monogamy is prized and individual failure is stressed in the context of a partner’s infidelity. It may be easier to promote female condom use in social contexts where it is openly acknowledged that men may have multiple partners, but where they resist taking responsibility for this in relation to their own sexual practices and condom use. In Nepal women mentioned that they found it easier to introduce the female condom to men as a contraceptive device rather than as protection against HIV/STIs [section 3].

Research on HIV/AIDS interventions indicates that many heterosexual women implement the construct of trust when deciding if preventive measures are necessary. Findings from an interesting personal construct model [61] suggest that women with well-defined networks of implications on their non-preferred pole of the trust/mistrust construct resist HIV-prevention messages that require them to mistrust their partner. In a Brazil intervention [52], educational strategies associated with FC distribution were developed taking into account that safe sex does not depend exclusively on the woman herself having a fixed partner, and accepting possible partners role in the risk process (considering that men are culturally stimulated to have other sexual partners or may have other risk factors like injecting drugs). In this study women reported improving their risk perception [and consequent self protection] following the intervention.

To conclude, there are indications that the introduction of the female condom can increase women’s sense of self-efficacy and self worth in ways that have effects on their lives beyond the immediate issue of condom use. This possibility of both the intervention of introducing and the condom as having some transformative value is valuable indeed. An important evaluation issue in the context of South Asia is the impact the female condom might have on women’s empowerment. 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 empowerment in general. The costs of female condom promotion could be shared across a variety of health and empowerment programs if these more general salutary effects can be demonstrated.

6. NEW FEMALE BARRIER DEVICES

Another way to address the cost as well as acceptability issues is to attempt to create a less expensive newer device. A brief on some new female barrier methods is thus included in this review.

6.1 Female condoms

(i) Next generation female condoms: Experience with the Reality female condom has shown that women and men are interested in and will use new barrier devices if they are acceptable and easy-to-use. PATH’s Phase I research with users in Colombia, the Philippines, Thailand, and the United States found that some features of the currently available product did not adequately meet user needs; incorporating that research into “next-generation” design for vaginal condoms is needed. PATH is currently working to develop features for an improved vaginal condom. Current Phase II research focuses on developing features that address users’ needs such as ease-of-insertion, stability in place, comfort, general ease-of-learning, and sensation, and will indirectly increase consistent and proper use in real-life settings.

(ii) The female panty condom: HHH Development company product “Janesway” is under clinical trials. A disposable model of latex and cotton, it is attached to a female panty in a way that it looks like lingerie. Men have liked it better than the male condom in initial research. A focus group testing of the female panty condom in four African countries [39] informs that sex workers interviewed were very enthusiastic about the idea of a new female panty condom. Many thought it could be used in their business especially for “quickies”. Many respondents agreed that an important target group for the panties would be adolescents. In Senegal it was mentioned that the female condom panty could be a means for women to protect themselves from STIs in polygamous marriages [39].

(iii) Reddy Medtech is developing a condom with a unique design that employs a small sponge in the pouch to keep it in place. The Reddy female condom is made of natural latex [same material as male condom]. The closed end of the pouch has a regular recess in which a polyurethane sponge is incorporated.

6.2 Other female barrier devices

Diaphragms and cervical caps are evolving. Future versions of diaphragms and cervical caps should be easier to insert and remove, yet harder to dislodge during sexual intercourse. They will be made of silicone rubber, which has a stronger shelf life than does latex rubber [40].

(i)Diaphragm as an HIV prevention tool: The Bill and Melinda Gates Foundation is supporting a $ 28 million grant in Southern Africa to test whether the simple latex
diaphragm used of birth control also can reduce a woman’s risk of HIV infection. The concept of using a diaphragm to protect against HIV infection was first raised in 1989 by AIDS research pioneer Dr. Jay Levy. The four-year diaphragm study which will enrol 4500 women was approved following a paper presented at the International AIDS Conference at Barcelona showing that women in Zimbabwe who could not get their partners to wear condoms would use latex diaphragms as a HIV-prevention tool. It is not expected that the diaphragm will completely protect a woman against HIV, but there is substantial biological evidence that protecting the cervix from infected semen could improve the odds significantly.

Studies involving some 2800 US women articulate some disadvantages of the conventional diaphragm: they must be fitted by a provider, are made of latex rubber, can be unwieldy to insert and remove, and should not be left in place for longer than 24 hours [41]. Two diaphragm like devices have been designed to resolve some of these problems: the Lea’s Contraceptive [a cup shaped barrier with a loop for removal] and the SILCS intravaginal barrier [developed by PATH]. Both these come in one size; thus clients need not be fitted for the devices. Both are made of silicone rubber [40].

(ii) Cervical Caps: Conventional caps can be worn up to 48 hours. However, they are made of latex, must be fitted by a provider, and can be difficult to insert or remove. Two new cervical caps are under development. The first called Fem Cap, is made of silicone. It is shaped like a hat with an upturned brim and it is easier to insert than conventional caps. The second new cervical cap is the Oves Cap, a silicone device, that can be left in place for three consecutive days. Equipped with a removal loop it is disposable after one use. All cervical caps have the disadvantage of requiring a fitting because they come in at least two sizes. Research is needed to determine whether cervical caps provide any effective protection against STDs, although it is theorized that HIV entry via the cervix may be impeded by cap use [40].

(iii) Microbicides: A microbicide is any substance that can substantially reduce transmission of STIs when applied in the vagina or rectum. It can potentially be produced in many forms, for example, gel, cream, film, suppository or sponge. A microbicide should be able to be used as an adjunct or back up to condoms. It should be useful for individuals or couples unable to use condoms consistently and as a mouth rinse for protection after oral sex. It might also be possible to develop a microbicide that can be used vaginally for reducing pre-natal transmission prior to delivery or post coitally to reduce infection in cases of forced sex or condom failure. Various approaches are being used in the development of a microbicide. These include testing existing spermicides for microbicidal potential [eg Nonoxynol-9, Octoxynol-9, bandalonium chloride] and exploring new compounds that kill or immobilise HIV/STIs. Currently the only products that have been tested in phase III HIV/STD effectiveness trials are products containing Nonoxynol-9 [the Today sponge, VCF, others]. Nonoxynol products have been marketed as spermicides for 50 years. However the results of the HIV/STI effectiveness trial that have been conducted to date have been disappointing and difficult to interpret. The development of microbicides is now gaining momentum as was shown by the recent Microbicides Conference 2002 at Antwerp. They are now increasingly recognised as an important approach to HIV prevention [44]. Detailed discussion on this is beyond the scope of this paper. Or more information refer to
7. UNFPA AND FEMALE CONDOM PROGRAMMING

7.1 The Fund’s Mandate

UNFPA aims at ensuring the availability of, access to and proper and consistent use of high quality male and female condoms, taking into consideration the needs and perspectives of the users. Within the United Nations System, UNFPA is the lead organization for the procurement of condoms and reproductive health commodities. UNFPA’s Executive Director, Ms Thoraya Obaid, in her urgent call for more donor support for reproductive health commodities said, “The most alarming consequences of the financial shortfall, where a condom crises exists today, are in the area of HIV/AIDS prevention. Widespread availability of male and female condoms, combined with effective efforts to change people’s behavior, is central to any prevention strategy. But in all the affected countries, the supply of condoms is far short of what is needed” [64]. UNFPA has identified condom programming as one of its 3 core areas of focus for HIV prevention. A UNFPA programme brief articulates that “Neither male nor female condoms, however, are being optimally employed in the fight to prevent STIs/HIV. Condom programming for HIV prevention is a strategic approach to ensure that sexually active persons at risk of STIs/HIV are motivated to use condoms, have access to quality condoms, and can use them consistently and correctly. Achieving sufficient magnitude to impact the HIV pandemic requires full mobilization of political will and resources, and overcoming institutional, community, and individual barriers to access and use of condoms. User needs and perspectives are at the heart of effective condom programming for STI/HIV prevention” [63].

On the female condom specifically, the UNFPA strategy is that “Although not a panacea, the female condom gives women a complementary option where they have greater control in initiating use which may aid in equalizing the gender imbalance that currently exists”. Female condoms are included in the UNFPA’s supplies of reproductive health commodities. Through the Global Strategy for reproductive health commodity security of which condom programming is a component, UNFPA is committed to improving access to and use of male and female condoms. For further details on The Fund’s strategy for implementing Reproductive Health Commodity Security as well as its HIV/AIDS prevention mandate refer to www.unfpa.org

7.2 Female condom programming in South Asia

UNFPA has supported female condom commodity and programming in several countries globally. Since 1999 more than 19 million female condoms have been supplied to several countries in Africa, Asia and Latin America through joint efforts of UNFPA, UNAIDS, WHO, FHC and various national partners. However, no documented programme or research support is available for increasing choices of women to include the female condom from UNFPA’s programmes in the seven South Asian countries. We have been informed about UNFPA support to a small pilot on female condom in Sri Lanka few years back. Table 3 below, compiled from
review of the new UNFPA country programs in the region, informs of proposed initiatives in female condom from Bangladesh, India and Nepal in the new programming cycle.

Table 3. Female condom programming in UNFPA Country Programs in South Asia

<table>
<thead>
<tr>
<th>Country</th>
<th>Female condom component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh CP-6 RH sub-program 2003-05</td>
<td>“In delivering quality RH services different categories of providers will be required to be trained. In this connection training on contraception including emergency contraception, female condoms, RTI/STI case management. Review, update and print 10,000 copies of the national family planning, and RTI/STI guidelines for health and family planning service providers of different levels so as to ensure information on contraception including emergency contraception, female condoms, STI, HIV sexual and reproductive health counseling are updated and gender components are included.”</td>
</tr>
<tr>
<td>India CP-6 2003-07</td>
<td>“In Rajasthan, pilot projects to test the operational effectiveness of emergency contraception, to promote female condoms and to up scaling Cu 380 A use, will be supported. Social marketing of condoms and other contraceptives will be supported. The two elements of support will be to expand demand among priority target groups through a package of interpersonal communication and generic campaigns through mass media. BCC interventions for improving STD management and promoting condom use will be supported…”</td>
</tr>
<tr>
<td>Nepal CP-5 2002-06</td>
<td>Prevention of RTI/STD/HIV/AIDS and syndromic approach of RTI/STD will be strengthened through capacity building of DDCs, DHOs, service providers and community mobilization in selected districts, through awareness/advocacy strategies and ensuring availability of condoms.</td>
</tr>
</tbody>
</table>

Besides the above, the UNFPA UBW Asia and Pacific component includes female condom programming in interventions with sex workers and clients. This review on South Asia opportunities and challenges is envisaged to facilitate development of strategically planned female condom interventions in these as well as other projects.

7.3 UNFPA support: Some global examples

(i) Ghana Partnership for FC: The Ghana female condom project is an example of a true partnership and is currently being documented by UNAIDS for use to support other countries. The Ministry of Health of Ghana launched the female condom in May 2000 after extensive strategic planning with UNAIDS, UNFPA, the Ghana Social Marketing Foundation and the Society for Women and AIDS in Ghana [SWAA] and the FHC. The national government, UN agencies, local NGOs and a product manufacturer worked together to deliver this HIV/AIDS prevention option for men and women. The partners hope that the experience can serve as a model for other countries not only to distribute the female condom but to plan strategically for more comprehensive AIDS prevention programs. In March 2001, UNFPA purchased one million additional female condoms for the project, double the order from 2000. [65].

(iii) Introducing female condom in Angola. UNFPA in July 1999 supported a major intervention of government at central and provincial level on the female condom. UNFPA, besides commodity, provided support for advocacy and awareness campaigns including a major initiative with the National Radio of Angola as well as print and TV promotions. UNFPA Angola also supported a research study on FC.

(ii) A UNFPA-supported female condom Burundi Study: Box 2 below give a brief from a UNFPA study in Burundi. The study findings, on acceptability issues in the local context, were disseminated through e-groups to inform policy and programming of this method.
Box 3. UNFPA supported study: Mixed reaction to female condom in Burundi

The results of a study in Burundi show that Femidom empowers women by enhancing their control over their bodies, and protects them, especially against men under the influence of alcohol or drugs, when there is a reduced chance of male condom use. The 2001 study, funded by the UN Population Fund and conducted by the Society for Women with AIDS in Africa-Burundi, involved 320 women and lasted two months. Other reported benefits over male condoms include comfort, softness, greater sexual satisfaction, and a better smell. However, 49 per cent of the respondents in the survey found Femidom difficult to use and ill-adapted to local sexual practices. Some women find it difficult to use because of the nature of the female genitalia. "In short, the reluctance over its use limits its level of acceptance" the study said. It recommended that Femidom be sold at subsidized prices because of the population's weak purchasing power. It also called for an information campaign on the proper use of Femidom, and a special effort to change male attitudes to it.


8. KEY ISSUES & RECOMMENDATIONS

8.1 Key Regional issues

As can be seen from the above review, FC experiences in South Asia have been in small research pilots in four countries. Though Bhutan has been mentioned as having received a consignment of female condoms [71], no information on the use of the same is available. No information on female condom related research is available from Pakistan or Maldives. Experience in the region highlights that donor commitment to the female condom to date has been very limited. The recent DFID support to India would perhaps contribute towards addressing this and programming to scale in selected states.

The analysis of the available South Asia research findings raises the following five key issues:

(i) In three of the four countries [except Nepal] acceptability studies for the female condom were targeted to sex workers who were found most likely to considerable benefit from FC. The issue is should programmes in the region target this vulnerable group? Would this strategy inhibit/stigmatize integration of the FC in broader reproductive health programmes?

(ii) The experience from Sri Lanka as well as other countries [see section 4.4(i) below on the Nigeria experience] implies need for more intensive counseling/education, integrating peer support groups for preparing women to introduce FC and to empower women to approach their sexual partners about use of this method and ensure sustained use, male involvement and education to increase men’s acceptability.

(iii) The product size particularly the inner ring size may be an issue for the average small stature of women in South Asia as articulated in Nepal. Developing another size for the product and approvals for the same would perhaps take quite a while.

(iv) Sexual constructs, socio-cultural and gender dimensions [discussed in section 5] would have considerable influence FC use in the region.
Another critical issue is need for strategic planning/programming of pilots for scaling-up/replication and addressing cost considerations.

8.2 Increasing access & quality

(i) Strategic FC planning: Experiences reviewed in this paper, provide lessons learnt and "what works" in FC programming. Lessons learnt to date have shown that there is a demand for the female condom, although some of it may be ‘novelty demand’. A review “what works” which may be useful in increasing access to female-controlled prevention methods includes: an identified target audience to whom messages and product are well delivered, ensuring users have an ongoing, consistent supply, training to desensitize providers and prevent possible biases from negatively influencing potential users; face-to-face communications to equip potential users with information and skills; a mix of public and private sector distribution sites, use of peer-support groups, and a long assessment period to gauge actual use of the female condom beyond the novelty phase [38]. Successful use of FC depends on the whole package of care, including positive promotion and publicity, support from health care workers, and involvement of both men and women as users of the method. Strategic planning for how the female condom is best presented to women and their partners, and interventions that are context aware and context specific would be required [23].

(ii) Integrated programming for FC: There is clear evidence that the female condom is best used within, and integrated into the context of broader, local social norms about sexuality and reproduction. To increase access and quality to meet women’s need in the region, the FC introduction needs to be as part of a comprehensive plan to empower women to prevent the spread of HIV/AIDS. Four parts of the comprehensive plan would include: to ensure availability of affordable effective female-controlled prevention technologies through expanding access to female condoms, integrating HIV prevention with other RH programmes; economic empowerment initiatives, creating gender sensitive prevention programmes.

(ii) Targeting interventions-vulnerable populations/areas: A large supply of commodity is required to go beyond the novelty phase - or programs have to take the number of female condoms that are available and target certain audiences. High acceptability/use by CSWs in the region highlights priority needs of this vulnerable population particularly in low prevalence South Asian countries. The other option is to make it widely available in a few limited areas, and then measure and assess the effort - impact of the FC. Mass strategies in defined geographical areas would avoid presenting the FC as a device used primarily for casual sexual encounters. Research from the region is also needed to further understand subgroups adherence to traditional gender norms so as to better target sub-groups of individuals.

(iii) Research/Operations research in South Asia context: Good data is needed for evidence-based planning and to avoid basing programs on assumptions. Suggestions for research include evaluations to focus on service delivery issues; impact on incidence of certain STDs [chlamydia, gonorrhoea, others] as well as change in percentage of protected sex acts, what indicators best demonstrate degree of effectiveness, evaluation of various product introduction strategies to
determine which work best under what circumstances and what combination of training support groups, community based distribution, clinical and other distribution system is most effective. Follow up work needs to be undertaken to ascertain the extent to which the use of the female condom can be sustained over time without the need for wider social and attitudinal change. There is need for qualitative research, in the regional context, to understand to what extent women’s capacity to negotiate safer sex with their partners could be enhanced by introduction of the female condom. Simply making the female condom available is unlikely to shift the balance of power between men and women in the absence of other supportive interventions.

8.3 Some specific recommendations for UNFPA in the region

UNFPA is encouraged to particularly examine support to (1) Strategic and integrated ‘Demonstration Projects’ in FC as discussed in section above. A specific niche area vis-à-vis the Fund’s long experience and reproductive health mandate for HIV/AIDS prevention would be to support introducing dual protection counseling interventions which include the female condom in RH/FP programmes drawing on experiences from Nigeria, Brazil and lessons learnt from Sri Lanka; (2) Supporting research areas as suggested in above para (iii); and (3) The review has highlighted several issues and areas for focused advocacy efforts and for building partnerships for FC programming in the region.

9. TO CONCLUDE

There are many barriers and constraints, including the cost of the device, the current level of donor support, unexplored research questions and lack of familiarity with this product in the region. But there are many positive signs as well. Research indicates that FC offers some protection from STI/HIV. Many women and men like it and will use it when 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. There is need to 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 is not envisaged as a panacea or a replacement for the male condom. It is another choice that adds to those few currently available to women in developing countries.

‘The female condom needs more financial and programme support from donors, NGOs, and the international community to ensure that women who would benefit most have access to it.’

Peter Piot, Executive Director, UNAIDS
10. BIBLIOGRAPHY

2. The Female Condom. A guide for planning and programming. WHO and UNAIDS. 2000. (WHO/RHR/00.8, UNAIDS/00.12E),
7. The female condom can prevent the spread of HIV/AIDS Now. Center for Health and Gender Equity. www.genderhealth.org
8. Comparative and Acceptability study between HTL[m] female and Reality female condom. Rani, U; Devi, R; Raj, KK; Viswanathan MK et al. March 1998.
12. Fontanet AL; Saba J, et al. Increased protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom; a randomized controlled trial. AIDS 1998; 12:1851-1859.
21. Social Marketing. Expanding access to essential products and services to prevent HIV/AIDS and to limit the impact of the epidemic. UNAIDS & PSI. 2002


26. Female Condom Re-use examined. In Network Number2,2000 Volume 20


28. Sharifuzzaman M. Female condom can lead to safer sex when clients do not agree to use condom. CARE-Bangladesh. Abstract MoPeF4025.

29. Mitchell Warren. Personal communication. E-mail dated 10 September 2002


31. Daya Abeywickrame. Personal Communication E-mail 10 September 2002


40. New Barrier devices may be easier to use. Network Volume 20, Number 2, 2000.


42. Key Actions for the further implementation of the Program of Action of the International Conference on Population and Development [Key Actions] para 71.
43. Report of the Ad Hoc Committee of the whole of the twenty-third session of the General Assembly, Further actions and initiatives to implement the Beijing Declaration and the Platform of Action, para 103(b).


50. Elias C and Coggins C1996. Female-controlled methods to prevent sexual transmission of HIV. Aids, 10 [Suppl.3] S43-S51.


58. Usmani, Farah. Findings of focus group discussion with female condom users from mothers group conducted in VDC Tikathali, Lalitput, Nepal. 3 September 2002.


60. Health and Development Networks [HDN] coverage of Microbicides 2002 is part of a collaboration with the Global Campaign for Microbicides. [http://www.hdnet.org]


64. Female Condom Update #1. Female condom in the news. August 2001.

65. Female Condom Update#2. Notes from the field: recent programme experiences. September 2002.


70. Promotion of Female condoms- A pilot study for feasibility assessment. TRUE Voluntary Organisation. 3-J Kovai Road Karur. Tamil Nadu India


73. HLL to produce female condoms in India. AIDS-INDIA@yahoogroups.com. 27 May 2002

74. Family Health International. www.fhi.org

