

Global Consultation on Female Condoms
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“Review of past action plans and their implementation”

By Patrick Friel, PhD

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Introduction

I was sorry to learn that Stephen Lewis wouldn't be able to take part in this meeting on female condoms. I was looking forward to a passionate and articulate delivery that would capture our attention, focus our thoughts and inspire us to renewed action. As the UN Secretary-General's Special Envoy for AIDS in Africa, he's made powerful speeches on behalf of universal primary education and access to microbicides; I figured he'd be perfect for this occasion. After all, while female condom distribution has increased almost ten times since 1997 many of us would agree that it still has a long way to go. Certainly, the organizers of this meeting seem to agree that this is a good moment for reflection and self-criticism.

Because the topics for discussion in past FC meetings almost always related to further research, I fear an impression was created that the female condom was still under development. For some, I suppose, this latter phenomenon had the effect of creating the impression that FCs “are not ready for prime time” which in turn may have discouraged potential donors and users from taking them up. For others, however, it would seem female condoms are in hot demand. UNFPA has more than a dozen countries waiting in the wings for help in getting their female condom/dual protection programmes started.

Discussion of past Female Condom meeting “action plans”

The female condom “Reality” (“Femidom” in the UK, “Care” in Zimbabwe, etc.) has been the focus of a number of expert meetings in the US and around the world since it was approved by the USFDA in May 1993. To prepare this presentation I examined materials associated with at least seven such meetings beginning with the AIDSCAP meeting in 1993 on the “potential role of the female condom” and including several on dual protection.

For purposes of discussion, this presentation will focus on just four female condom meetings and the “action plans” they generated:

1) October 1993 AIDSCAP meeting, “The Potential Role of the Female Condom in International AIDS Prevention” attended by 58 participants, of whom all were US agencies and US contractors except WHO and IPPF

2) May 1997 AIDSCAP meeting, “The Female Condom: From Research to the Marketplace” which attracted 130 participants from 19 countries and 60 different organizations (and is therefore, more than any other, similar to the present global consultation)

3) December 2001 FHI “Technical Update on the Female Condom”, a small gathering of interested parties from USAID, FHI, Population Council and PSI, and, lastly

4) December 2004 female condom meeting in London of about 10 people, which was organized by the Global Campaign for Microbicides in support of the “Global Coalition on Women and AIDS.” The meeting’s purpose was to better understand the barriers and opportunities for increasing access to the female condom. (This latter meeting marks a commendable shift away from a mood of competition between these two female-initiated methods towards a mood of cooperation.)

1993 AIDSCAP meeting, “The Potential Role of the Female Condom in International AIDS Prevention”¹

By the time AIDSCAP organized the first large-scale female condom meeting in October 1993 much was already known about the new USFDA-approved product, i.e., the female condom from the Female Health Company in Chicago, Illinois. Participants reported that perfect use pregnancy rates for the female condom were low and that half the women in one study found the device “comfortable”. Depending on the study, 50-95 per cent of women who tried the device “liked it very much”. On the effectiveness side, Dr. Henry Gabelnick, CONRAD, presented a study by D. Soper, et al. which showed that consistent use of the female condom “prevented any cases of reinfection” by trichomoniasis vaginalis and chlamydia.

Participants in the 1993 meeting observed that while the FC was at least as good a contraceptive as other barrier methods such as the diaphragm, it was quite expensive. And, while they acknowledged that there are some possibilities for improving affordability, they stressed the importance of not compromising quality. They noted aptly that “Data on efficacy, especially regarding HIV/STDs, and acceptability are still limited. We know almost nothing about whether people will use the device on a sustained basis.” These statements would prove to be on the mark.

To foster the needed “concrete steps by the public sector and sustained interest on the part of both family planning and AIDS professionals”, the 1993 participants suggested that an interagency working group and newsletter might be established to exchange the results of FC research. They also suggested that agencies “such as CDC, WHO, USAID and NIH could prepare a two-year plan of action to identify high priority research and concrete steps of improving affordability”.

Whether such plans were ever fully executed is today a little hazy. (Certainly, the suggestions were made using modal verbs signaling the least definite degree of certainty.)

¹ A hard copy of the meeting report may be available on request from Family Health International (FHI).

Work did, nevertheless, proceed including USAID supported acceptability trials in 19 countries, investigations into re-use and procurement of 150,000 female condoms for purposes of “familiarization” among its country programmes. But, the device was still largely in the hands of researchers and had not yet been taken up in USAID’s regular commodity distribution programme.

Almost prophetically, 1993 meeting report concluded: “Yet without concrete steps by the public sector and sustained interest on the part of both family planning and AIDS professionals, it is safe to predict that the female condom will not be available to women in low income countries, and one potential weapon in the fight against STDs/HIV in developing countries will be lost.”

1997 AIDSCAP meeting, “The Female Condom: From Research to the Marketplace”²

The purpose of the two-day AIDSCAP meeting, “The Female Condom: From Research to the Marketplace” in May 1997 was to share lessons learned since 1993 and “to develop strategies to increase awareness, acceptability, availability and affordability of the female condom based on latest domestic and international research findings and experiences from the field”. Until today’s consultation, this was the largest female condom.

The meeting was the largest and most diverse ever organized on the female condom—until today—and its design was complex. Seven groups of participants—policy makers, donors and the private sector, women’s advocates, programme planners, scientists in research and development, researchers in the field and community organizations—were invited to focus on seven fields of inquiry: science, women’s empowerment, product delivery, product introduction, price, policy and evaluation. The innovative “cross-sharing” group exercises in the meeting were designed as a “holistic approach to exploring ways to increase accessibility of the female condom...” This point was echoed by Dr. E. Maxine Ankrah, Director of AIDSCAP’s Women’s Initiative. “At this second conference,” she said, “our goal is to enhance accessibility”.

The group recognized that there were many barriers to overcome: the high cost of the device, the lack of funding, provider resistance, gender issues, the lack of indicators and instruments for evaluation and concerns about cost-effectiveness. The cost-effectiveness issue actually seemed to highlight a division among the various groups in the meeting. “Women’s advocates” were said to be pushing for the female condom now; “researchers and donors”, on the other hand, said it was too expensive until more research shows it to be effective in slowing the AIDS epidemic. The dilemma was and is real: if we don’t invest in it, how can the female condom show success?

By 1997 there was in many quarters agreement that the main questions of safety, acceptability and contraceptive effectiveness had been adequately addressed. The Female Health Company device was approved by the USFDA in 1993. According to the authors of the 1997 report, the female condom is “clearly acceptable to both women and

² A copy of the meeting report can be found on the FHI website: <http://www.fhi.org/en/index.htm>

men in many situations”. The report cited a WHO/UNAIDS review, which summarizes 42 acceptability studies, in which many of the acceptors are first-time family planning users indicating that the method does not simply substitute for male condom use.

That said, the participants issued a total of 61 recommended “next steps to the marketplace” organized around the seven above-named seven target audiences—policy makers, donor and the private sector, women’s advocates, programme planners, scientists in research and development, researchers in the field and community organizations.

Some of the recommended “next steps” fall into the category of simple advisories, i.e., advice any professional would already know and any good programme manager would normally follow. For example, community organizations were urged to “gather more information on effectiveness” and women’s advocates were advised to “build communication between men and women”. Worst of all, none of these next steps, spread out over four pages, were prioritized and nor did they contribute to a strategic plan.

Some were more concrete and operational calling for operations research while moving ahead with introduction through family planning, PHC and STD programmes; develop indicators and instruments to measure KAP in countries where the female condom is being introduced; document lessons learned from successful interventions and strategies to help in replication.

Of the six “consensus” recommendations on female condoms that came out of the 1997 meeting, three were general and informational—promote to men as well as women, market using both interpersonal and mass media strategies and disseminate information broadly, including to the media. The first two general and informational recommendations were simply that, but the third—disseminate information broadly—touched on new ways of sharing lessons learned including creating a UN-sponsored international task force and a broad-scale media campaign. Who would take that up and pay for it?

Three of the “consensus” recommendations were specific and directive—begin large-scale introductions in two to three countries to permit operations research questions to be answered, expedite research on re-use, and provide incentives for alternative, less-expensive product designs. We know that within three years of the meeting WHO issued a carefully-crafted statement on re-use, which was revised in 2002, and that several new product designs were encouraged and have come to light, with at least two having had support from USAID and others.

What’s not clear is what is meant by “large-scale introductions in two to three countries to permit operations research questions to be answered”. Globally, female condom distribution has increased nine-fold between 1997 and 2003, but from a relatively low base. We know from UNFPA data on female condom distribution, from October 1997 through September 2002, that several comparatively large FC programmes exist: South Africa (6,111,000 female condoms), Zimbabwe (2,915,000), Ghana (1,495,000) and Brazil (8,644,040), including social marketing sales. Were these programmes large

enough to permit answers to the big operations research questions such as the utility of the Female Condom Programming Guide or the validity of the cost-effectiveness issue? Perhaps we'll find out later today when programme managers from South Africa and Brazil share with us information on their country programmes.

2001 FHI “Technical Update on the Female Condom”³

The purpose of the half-day-long technical meeting organized by FHI in December 2001 was to share the latest scientific and programmatic information on the female condom. Approximately a dozen participants came from USAID and FHI, including one person each from the Population Council, PSI and the Female Health Company. (The size of any audience is not known.) By the end of the meeting, the group issued fourteen “ideas” and suggested “next steps and recommendations for future research and dialogue on the female condom”. The main conclusions, which were presented “in no order of priority,” called for additional research: on effectiveness in preventing HIV/AIDS, cost-effectiveness, why providers resist talking about female condoms and randomized clinical trials of the male condom vs. the female condom. The final recommendation called for “more research...on how to conduct studies on the effectiveness and the impact of the female condom”.

Clearly the researchers who came to the smallish half-day meeting were mainly interested in research issues. To be fair, this was not a global consultation; it was a technical update. One of their conclusions said it best: “Intervention research needs to build on lessons learned. We need to get trend data over time, and make *one last big push* to develop the studies needed to answer critical questions.” (Emphasis added.)

The troubling thing about the calls for additional research is that it is not clear who the “we” is when they say something like “We need more information on continuation rates...”, or “we need client segment data on female condom users...” or “we need more efficacy data that relies less on self-reporting.” And, can we be sure that these are the “critical questions” for which we are making the “big push” so we can get down to the business of female condom programming?

The 2001 meeting nevertheless raised some interesting questions. The questions arose from priorities established by the USAID Female Condom Working Group that was formed in 1997 and was composed of representatives from both the Office of Health and Nutrition and the Office of Population. One of the questions dealt with the “fully-loaded cost” of a female condom programme and what could be expected from investments in the female condom. Given its high cost, according to the discussion, “the only way it [the female condom] can achieve an *acceptable degree of cost effectiveness* is if it protects a substantial proportion of high-risk sex acts that have little chance of being protected by a male condom.” This raises the questions: what is an “acceptable degree” of cost effectiveness and what are “large scale introductions”?

³ A copy of the meeting report can be found on the FHI website: <http://www.fhi.org/en/index.htm>

The following point was raised by several participants in the 2001 meeting: “A central question in program development is the balance between supply and demand.... How can programs launch major introductory campaigns if they are not sure what the supplies will be from donors? At this point, subsidized supplies are essential. Having an adequate supply seems to be a critical step to ensure that the product remains viable in the market.”

2004 Global Campaign for Microbicides for the Global Coalition on Women and AIDS, “Observations and Outcomes from the Experts’ Meeting on Female Condom”⁴

The most recent female condom meeting took place just over nine months ago. The Global Campaign for Microbicides (GCM) acting on behalf of the Global Coalition on Women and AIDS convened in London a small consultation of approximately 10 experts to better “understand the barriers and opportunities for increasing access to the female condom”. The meeting report opens with the observation that even though a female condom has been approved since 1993, there remain many barriers of which the most complex is the cost of the current product. The participants noted that “access to and use of the female condom for HIV prevention has not reached anticipated levels”. This raises the question: What are these “anticipated levels”? Would they, do you think, amount to more than 4 out of a thousand?

I won’t burden you with an attempt to examine male and female condom numbers country by country. Instead, let’s compare the average annual levels and cost of male and female condoms made available to all countries by donors between 2001 and 2003 (yearly fluctuations make 3 year averages more accurate representations of reality):

10.9 million female condoms + 2.7 billion male condoms = 2,710,900,000 (all condoms)⁵

Female condoms = $10,900,000 / 2,710,900,000 = .004$

Male condoms = $2,700,000,000 / 2,710,900,000 = .996$

In short, in the period 2001-2003, 99.6% all condoms were for males and 0.4% for females. Put differently, 4 out of every 1,000 condoms are for females.⁶ If this number seems low, what number would sound right? Are women getting a fair shake?

When these numbers are multiplied against their respective public-sector unit prices, we see that for every dollar spent on condoms, donors are spending about 5 cents for female condoms.

⁴ A copy of the meeting report can be found on the GCM website: <http://www.global-campaign.org/clientfiles/FemaleCondomMeeting-Dec2004.pdf>

⁵ The numbers of male condoms in the above calculation include only those reported by donors to UNFPA. Actual numbers of male condoms distributed each year may be two to three times higher, in the range of 6-9 billion units.

⁶ With their higher unit price, the estimated cost for female condoms is equal to about five per cent of the cost of the donated male condoms.

Among the outcomes of the Global Coalition meeting, the group agreed on several “actions” and a number of “next steps,” specifically: a) to organize an informal list-serve, b) to work with the GCWA to commission a background paper on positioning the female condom among discordant couples and c) to explore opportunities to “re-think” the re-use issue. The list-serve was organized but it failed to develop a following; a consultant has been identified to prepare a background paper; and, groundwork is being laid to pressure WHO to rethink their position on re-use.

An “action” item mentioned in the meeting report that to me is the most challenging concerns “Positioning female condom as an integral (not optional) part of HIV prevention, care and treatment strategies—both existing and future.” (As we shall see this position coincides with that of the Global HIV Prevention Working Group.) The report rightly proposes “advocacy” among three groups—users, gatekeepers and donors, but does not describe who will develop, pay for and execute this advocacy.

After the participants in the 2004 meeting reviewed the barriers with which we are by now all very familiar—both user-related and social and contextual ones—they focused on what they called the most complex barrier of all: the cost of the current product. The discussants explored the cost issue relative to demand, to impact, to other interventions and to sustainability. In reviewing the various barriers, one cannot miss the play of a familiar vicious cycle: because of perceived low demand, donors are unwilling to invest in female condom programming and procurement, women do not find the product accessible and the apparent low demand is perpetuated.

Discussion

Funding—The Global HIV Prevention Working Group, sponsored by the Bill and Melinda Gates Foundation and the Kaiser Family Foundation, has called for by 2007 a doubling of annual research funding to \$1 billion for HIV vaccines and to \$300 million for microbicides. The Working Group has also called for increases in funding for other prevention technologies such as female condoms, diaphragms, circumcision, treatment of viral STDs and oral chemoprophylaxis.

In addition, the Working Group has recommended that “male and female condoms should be readily available in all health care settings.” This latter goal is ambitious but achievable. Indeed, if donors were to begin to scale-up their funding for female condom programming to reach the target of one female condom for every 100 male condoms, the FC commodity cost would be \$18.6 million/year at current prices. Volume discounts and new product developments are expected to lower procurement costs even more.

Research—Since the female condom made its official appearance in 1993, meeting participants have expressed the need for “more research”. Many issues had been studied before its approval by the USFDA in 1993 including safety, efficacy and acceptability. Other studies since have focused on reuse, cost-effectiveness, gender roles, KAP and more. The meeting action plans do not communicate a clear sense of which research needs to be conducted by international agencies to gain broad approval and which

research needs to be undertaken by local implementing programmes to guide and fine-tune the promotion and distribution of the method.

A comprehensive listing of all Female Condom studies by topic, study population, country and/or region, year and cost should be compiled, collated and compared with a model research paradigm. Source of funding for the studies and the role of national researchers/institutions should be included. The results should be made available on the internet.

Integration: As an important human right married women and sex workers must have access to barrier protection both for family planning and disease prevention. Female condoms should be integrated into all RH commodity security strategies just as RHCS needs to be integrated into RH and HIV/AIDS programmes as a part of the health-care related elements of the MDGs. Barrier methods for dual protection, need to be integrated into all programmes that deal with FP, MCH, VCT, PLWHA, STD, PMTCT, ART and so forth, wherever and however our institutional and health services reach into the community at large. Wider access will help reduce the stigma associated with their use.

Accountability: Reading the female condom meeting reports one does not get the impression that the meetings are a part of a properly-developed, strategic approach that aims to broadly protect women at risk. Until the present, no meeting format included a focus on reviewing past promises and commitments. More importantly, the Baltimore meeting is organizing a representative and empowered working group to *ensure* that the commitments in this meeting are addressed. This is in contrast to the 1993 meeting report where the authors suggested that there “might” be a periodic update meeting and that a working group “might” be assembled to continue coordination. I think we are now heading in the direction of creating the basis for accountability.

In ongoing support of that aim it would be helpful to develop and maintain a collaborative and managed website to monitor the progress of “strategic efforts” undertaken by partners and to share that information widely. Better coordinated, strategic efforts undertaken by partners will give concrete meaning to the targets we set that will, in turn, fulfill the Global HIV Prevention Working Group mandate that “male and female condoms should be readily available in all health care settings.”

“Choice” and empowering women and girls: Women and girls need and deserve choice; it is a fundamental tenet of our family planning legacy that has many times over proven to expand access. As we’ve seen above, the higher cost of the female condom is small when we recognize that it is an important niche product that responds to the needs of women with few choices. Timidity is not a choice when we know that many married women, who are at elevated risk, are having the greatest difficulty convincing their husbands/steady partners to use male condoms.

In the end, the structural factors of poverty and women’s lack of social-economic-political power underlie their vulnerability to the STD/HIV/AIDS epidemic. Female condoms are a natural ally that can link to any women’s empowerment strategies: women

want and need sexual negotiation skills training to promote proper and sustained barrier method use. And, do we forget sometimes that male condoms are often “female-initiated” too?

Social Marketing: Surprisingly, female condoms are not found in every Social Marketing Programme! Why not? The answer I got recently from PSI is lack of funding. PSI is doing a good job with the resources they have. Since 1996 they have marketed 8.5 million female condoms in thirty countries of which many are very needy and half are in sub-Saharan Africa. Nevertheless, in the thirteen hardest hit countries in sub-Saharan Africa, PSI is marketing female condoms in only seven. They report no female condom sales in six: the C.A.R., Ethiopia, Kenya, Malawi, Namibia and Nigeria.

I’ll admit to having a bias towards social marketing programmes. I’m guided by the following basic principle: female condoms should be marketed in every developing country where social marketing offers advantages to vulnerable, low-income women and girls.

Finally...

The “Guide”—The “Female Condom Guide for Planning and Programming”, which was published by WHO/UNAIDS/FHC in 2000, is an excellent primer for strategic planning at the country level. I suggest we design and fund an assessment of its utility in a number of settings. For example, it would be useful to compare programmes developed with and without the Guide.

In conclusion, after reviewing the several female condom reports, it is obvious that USAID and its partners had always taken the lead. The female condom agenda today in large measure arises from the hard work and dedication of USAID and its cooperative agencies. It’s fair to say that the progress the female condom has enjoyed over the past 12 years would not have happened without their dedicated efforts and for that we are grateful.

At the same time, USAID’s dominance meant that the leadership center was located in just one agency and its collaborating agencies and contractors. Other bilaterals, multilaterals, foundations and national leaders were often on the sidelines. Fortunately, this state of affairs is in the process of changing because the work ahead of us is huge and it’s not just about rubbers. The way ahead looks bright with the appearance of new partners and a more disciplined regimen with emphasis on commitments and accountability.

See below for a summary of the lessons I learned while reviewing the female condom meeting “action plans” and some suggested things to do.

Some principles and a dozen things to do:

Principles:

1. Acknowledge that globally women are the majority of HIV cases and that in many countries married women have the biggest share of new HIV infections
2. Widespread and unshakable commitment to continue to give women “choice”
3. Coordinated, integrated, long-term strategic efforts are better than ones that are ad hoc, limited and one off
4. Bottom-up is better than top-down
5. Empowerment, which is critical to effective use of “female-controlled” methods, requires a complex social-economic-political structural intervention strategy

Things to do:

1. Generate stronger, broader and more decisive global leadership!
2. Formulate a “vision” imbued with a sense of urgency (married women increasingly at risk, women and girls need “choices”, time is passing, delay is deadly)!
3. Establish priorities, goals, targets, “barrier protection” strategies, advocacy strategies, M&E, mechanisms for accountability. In short, where do we want this to go and how will we know when we get there?
4. Expand donor base to include other bilaterals, foundations and the private sector. Assure sufficient human, financial and technical resources to meet programming targets for a minimum of the first five years.
5. Define research needs categorically: research necessary to attract additional donor investment; research needed to answer big questions with higher resolution; research to develop and fine-tune country programming.
6. Establish a managed “FC research and implementation clearinghouse” website to facilitate dissemination and utilization of lessons learned from studies and programme implementation across populations and settings.
7. Address the “cost-effectiveness” issue in a way that supports vulnerable women. Assess appropriate “anticipated levels” for female condom access by developing country women.
8. Integrate dual protection strategies with female condoms among FP, RH, STD, VCT, PMTCT and ARV programmes supported by WHO, Global Fund, PEPFAR.
9. Link FC programming as appropriate with structural interventions that address poverty and gender inequality.
10. Prepare a background paper on female condoms and microbicides. FC programming in developing countries should be viewed as a precursor for institutionalizing the capacity to make microbicides accessible to women.
11. For all future FC meetings prepare an analysis of the current status of research and implementation to facilitate tracking of progress towards our consensus targets and accountability (see no. 6, above).
12. Remember there is a link between sound programming strategies and successful resource mobilization, i.e., funds for FC programming. A clear and compelling business model is needed to show that we mean business.