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Failing Women, Withholding Protection

15 lost years in making the female condom accessible

Policy makers lament women's vulnerability to HIV infection, yet for 15 years they have failed to utilise a technology which can help women to protect and empower themselves. The female condom is the only female-initiated method which provides protection from HIV infection; it also prevents unwanted pregnancy. Studies have shown it is acceptable to users, increases the proportion of protected sex acts, and is cost-effective when provided in addition to male condoms. Yet most women cannot access female condoms. New female-initiated technologies such as microbicides will not be available for many years. Female condoms exist now; the push for universal access to them should begin now.



Summary

2008 marks 15 years since the female condom was invented, and, disgracefully, 15 years of failing to make them accessible to the women who need them. Despite the absence of any other female-initiated form of protection, and unprecedented rises in funding for the response to HIV, female condoms remain inaccessible, and their contribution remains untapped.

The urgent need for access to female condoms is evident in the feminisation of the HIV pandemic, the large unmet need for contraception, and the pitiful progress towards meeting Millennium Development Goals 5 and 6 on maternal health and halting and reversing the spread of HIV.

Why provide female condoms, when male condoms are readily available, much cheaper, and provide a comparable level of protection?

- Female condoms are a tool to assist women's empowerment. Women who use female condoms report an increased sense of power for negotiation of safer sex, and a greater sense of control and safety during sex. It will be many years until women have any alternative female-initiated means of protecting themselves.
- Providing both female and male condoms leads to more instances of protected sex and reductions in the incidence of sexually transmitted infections (STIs). Their additive effect, providing protection in instances which would not be protected by male condoms, makes them a cost-effective form of HIV prevention.

Studies have repeatedly shown high levels of acceptability for female condoms. Some users prefer them over male condoms, as they offer more flexibility regarding the timing of putting them on and taking them off, and have a more natural feel. However, many donors and policy-makers remain sceptical that sufficient demand for them exists. Yet examination of female-condom projects reveals significant demand, even though it is often deliberately suppressed and unintentionally undermined by stigmatisation and running out of stock. What is perceived as an issue of demand is actually one of supply. Expanding access to female condoms is held up not at the users' end, but at the start of the chain: how much money donors and governments are willing to invest in buying female condoms, supporting female-condom programmes, and developing low-cost female condoms.

What is behind the failure to act comprehensively to create access to female condoms? Responses from donors and policy-makers to the female condom mirror the common reasons for not using a male condom: responses formed by ignorance, culture, denial, 'poverty', and conservatism. Added to this are overarching errors of a lack of leadership, a huge funding bias against existing forms of primary HIV prevention, failure to scale up programming, and failure to invest in strategies to lower the cost of female condoms.

Of course, some efforts have been made in the past 15 years, which have accelerated since the launch of the United Nations Population Fund's (UNFPA) global Female Condom Initiative in 2005. The rapid expansion of sales and free distribution in the few countries at the forefront of female condom programming demonstrates the massive unmet demand for female condoms. But there is so much more to be done. Worldwide, in 2007,

roughly 423 male condoms were produced for just one female condom. Female condoms currently have a unit cost about 18 times higher than male condoms.

The levels of investment and programming needed to increase the choice of available female condoms, to lower prices and to expand production are highly feasible. Through collaborative action, donors, governments, civil society organisations and the private sector can begin the progress of achieving universal access to female condoms. Female condoms exist now, and concerted efforts to make them accessible must begin now.

Recommendations

- 1 UNAIDS and UNFPA, along with donor and development organisations, must provide visible global leadership to tap the potential of the female condom as a contraceptive and a prevention method against STIs including HIV. They must make stringent advocacy efforts, prioritise resources, and set meaningful targets to improve access. A short-term target of raising female condom distribution to five per cent of total condom distribution is achievable and affordable at a cost of around \$120m per year globally.¹
- 2 UN agencies (UNAIDS, UNFPA, UNIFEM, UNICEF, WHO, the ILO) and international donors including the Global Fund to Fight AIDS, Tuberculosis and Malaria must promote the female condom in their gender and health policies and provide concrete assistance to implementing agencies and governments. They must significantly boost investment in female condoms, and UNITAID should include them in its portfolio.
- 3 Governments, donors, and private investors must support female-condom research and development (R & D) to create choice and lower prices. In 2006, donors spent over \$1bn on developing new HIV-prevention technologies.² An investment of just \$20m would allow new female condoms to be brought to market. Patent laws should not infringe on efforts to develop new female condoms and to produce affordable generic versions, particularly patents stemming from publicly funded R & D. The United States' Food and Drug Administration should reclassify female condoms from being in Class III (high-risk devices) to Class II, the same class as male condoms, while still requiring adequate additional information and proof of effectiveness for significantly new condom designs.
- 4 National governments, civil-society organisations, and the private sector should collaborate on comprehensive long-term integrated female-condom programming, making female condoms available to all women and men, given their universal relevance as a contraceptive and STI-prevention method.
- 5 Civil-society organisations should demand that governments and international agencies include female condoms in their family-planning and reproductive disease (including HIV) prevention programmes, and in their funding plans to the United States President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund and UNITAID.

1 Introduction

The best approach to HIV prevention is one that provides the most options. There is no single magic bullet to stop HIV and AIDS – and there never will be. This means that world leaders have an ethical and moral obligation to provide people with the most comprehensive set of prevention options available. Right now that means making the female condom a fundamental component of HIV programs everywhere...

Mitchell Warren, Executive Director of the AIDS Vaccine Advocacy Coalition³

Since the beginning of the HIV pandemic, many girls and women have struggled to protect themselves from infection, even when fully aware of the facts of HIV transmission. Recognition of the complexities faced by women has been accompanied by verbal commitments to address the feminisation of AIDS, partly by investing in the development of new female-initiated means of HIV prevention. At the same time, there has been an unprecedented mobilisation of funding, with around \$10bn available for responding to HIV globally in 2007, a forty-fold increase in a decade.⁴

Incredibly, for the past 15 years the world has failed to make the most of the contribution which an existing technology, the female condom, can make to preventing both HIV transmission and unwanted pregnancy.⁵ While great progress has been made in expanding access to treatment, female condoms have been largely ignored; throughout the developing world an individual has a much higher chance of getting access to anti-retroviral treatment than getting a reliable supply of female condoms.⁶ Meanwhile, prevention efforts lag behind progress in expanding access to treatment: for every two people who are put onto anti-retrovirals, another five new HIV infections occur.⁷ Clearly there is an urgent need to make much better use of existing HIV-prevention technologies. While there is no global tracking of expenditure on female condoms, total funding in 2007 is estimated to have been no more than 0.3 per cent of the total funding for responding to HIV.⁸

This paper is about powerful institutions' neglect of duty by not providing leadership on female condoms, and failing to meet women's needs and demands for them with a consistent and proportionate effort to make them accessible and affordable. It concerns the ignorance, denial, and bias of the powerful, at the expense of the rights of women.

Box 1: Which female condom?⁹

From 1993 to 2005 the only female condom was the Female Health Company's FC (also referred to as FC1), made of polyurethane and using an outer and inner ring, which was partly developed with public funding. It is now being replaced by FC2, which employs the same design but using a cheaper material, nitrile, and less costly production methods. As FC1 and FC2 are the only female condoms approved by WHO for purchasing by UN agencies,¹⁰ the Female Health Company has enjoyed monopoly status, and most trials and pilot programmes feature their products. The Female Health Company holds a series of patents on the design of the FC female condom. It has been making a profit since 2006.¹¹ Its sales went up from 13.5 million in 2005 to almost 26 million in 2007, largely due to increased procurement by UNFPA and key donors.

There is another female condom, the Reddy condom made by Medtech Products Ltd in India, which has a triangular outer frame and an inner sponge to hold the latex pouch in place in the vagina. It was developed by Medtech without public funding. It is approved for use throughout Europe and many other countries, and around five million were sold commercially between 2003 and 2007.¹² It has not yet fulfilled all the requirements of the WHO pre-qualification procedure and so is not approved for purchasing by UN agencies.

A key product under development is PATH's woman's condom, which has a dissolving tampon-like capsule for easier insertion, dots of foam to keep the polyurethane pouch in position in the vagina, a flexible outer ring, and a separate lubricant. It may be available in China by 2010. PATH is seeking funding for trials to gain approval in China, and then internationally.

Meanwhile, the Mediteam company in Belgium is at an earlier stage of development of a latex female condom, which resembles a looser male condom with a soft flat collar.

2 The urgent need to make female condoms accessible

Although new but still unproven technologies may play important roles in HIV prevention in the future, there is no way at this time to evaluate their potential effectiveness in mitigating the impact of the epidemic.... Meanwhile, women at risk urgently need protection they can use in the here and now.

Mantell et al (2008)¹³

Why is access so urgent?

The consequences of HIV transmission

HIV infections were initially concentrated among men, but women and girls now account for half of all people infected. In sub-Saharan Africa 61 per cent of adults and 75 per cent of young people infected with HIV are female.¹⁴ In some countries being married is a risk factor for women to acquire HIV.¹⁵ The consequences of HIV infection are also skewed against women and girls, who do most of the caring, but are more likely to miss out on schooling, to suffer violence, and to lose property and face destitution as a result of HIV infection.

Although the rollout of anti-retroviral treatment is helping to reduce the number of deaths due to AIDS, it is still a leading cause of mortality worldwide, with an estimated 2.1 million deaths last year. Three-quarters of these were in sub-Saharan Africa, where AIDS is the primary cause of death.¹⁶ HIV-related morbidity and mortality have huge impacts on individuals' lives, and multiple negative repercussions for families, societies, and economies due to pressure on social services, lower productivity, and high dependency ratios. Investment in primary prevention is urgently needed to reduce the number of new HIV infections, and so reduce the cumulative growth in the numbers of people needing anti-retroviral treatment.¹⁷

The consequences of unmet needs for contraception¹⁸

Despite the range of highly effective contraceptive options available, there is a massive unmet need for contraception, particularly in the developing world. UNFPA estimates there are around 200 million women worldwide who would like to limit or space the children they have, but who are not using any form of contraception.¹⁹

WHO estimates that in developing countries more than one-third of all pregnancies are unintended, with major implications for each child, each woman, each family, and wider repercussions of high

population growth. A fifth of those unintended pregnancies are aborted, more than half by unsafe means. Globally, unsafe abortions cause five million women to be hospitalised each year, and account for 13 per cent of maternal deaths. Meanwhile, in sub-Saharan Africa, maternal health remains, according to the United Nations, 'a scandal, with the odds that a woman will die from the complications of pregnancy and childbirth during her life at one in 16, compared to one in 3,800 in the developed world'.²⁰ While global contraceptive prevalence has increased slowly, from 55 per cent in 1990 to 64 per cent in 2005, it remains low in sub-Saharan Africa at just 21 per cent. Meeting the unmet need for contraception would cut maternal deaths by around a quarter.²¹

The Millennium Development Goals²²

What does this mean for the Millennium Development Goals? For Goal 5, to improve maternal health, only the regions of Eastern Asia and the Commonwealth of Independent States are likely to meet the target of reducing maternal mortality by 75 per cent by 2015. None of the regions are expected to meet Goal 6's target indicator of halting and reversing the spread of HIV. Sub-Saharan Africa is likely to meet just one of the 18 MDG indicators, improved coverage of measles immunisation, though not the related goal of reducing child mortality. Throughout the developing world, and particularly in sub-Saharan Africa, unintended pregnancies and HIV infection add to the complex mix of factors which ensure continued gender inequality, high levels of morbidity and mortality, extreme poverty, and hunger.

How can access to female condoms help?

Condoms – male and female – are currently the only available technology which give users simultaneous protection against pregnancy and sexually transmitted infections (STIs), including HIV. They have the advantages of no side effects,²³ are reversible forms of contraception, and can be used without seeing a health-care provider. However, although years of male-condom promotion has achieved relatively wide access to male condoms, HIV infection rates among women continue to rise. For a number of reasons, providing female condoms alongside male condoms can help prevent HIV infection and unintended pregnancy, and help to empower women.

Female condoms are usually female-initiated

While some women report using female condoms without their sexual partners realising,²⁴ the majority have to negotiate its use. Many find this easier to do than with the male condom because they:

- can initiate its use;
- have greater ownership of the female condom;

- can put it on themselves (up to eight hours before having sex);
- do not require the same degree of co-operation from their partners;
- can 'carry-over' agreement from one occasion, and so avoid the 'every-time' negotiation of the male condom, particularly at the moment when it must be put on;
- know that their partners may prefer to transfer responsibility to them.²⁵

Of course, the task of negotiation becomes easier for couples who find that they like the female condom, for whom it can become a habit to use it.

Qualitative studies find an increased sense of power for negotiation of safer sex, and a greater sense of control and safety during sex, among women using female condoms.²⁶ This is particularly the case where women learn about female condoms as part of an empowerment process. As such, female condoms are a tool which can assist in women's empowerment.

Effective female-condom programming also enables women, men and health professionals to gain a better understanding of women's bodies and a greater ability to discuss sexuality and safer sex.²⁷ Expanded female-condom promotion would therefore pave the way for other female-initiated methods of HIV prevention, such as microbicides, when they become available.

Providing female and male condoms leads to more instances of protected sex and reductions in STI incidence

Long experience of family planning shows that increasing the choice of methods available leads to increased uptake and more consistent and continued contraceptive use, partly because women's contraceptive preferences vary during their lives.²⁸ The same applies when female condoms are made available in addition to male condoms:²⁹

- In a study in Brazil the proportion of protected sex acts among women who opted to use the female condom as well as the male condom rose from 33 per cent at baseline to 70 per cent.³⁰
- In a US trial the protected sex rate among female STI clinic clients rose from 38 per cent to 66 per cent some six months after female condoms were introduced. While ten per cent of the participants used only female condoms, the majority used a mix of male and female condoms.³¹
- In a study in Zimbabwe, 27 per cent of married women who used the female condom had never previously used a male condom,

and one-fifth of consistent female-condom users had not previously been consistent users of male condoms.³²

A recent review³³ of articles and abstracts about female condoms found that:

- five randomised studies of effectiveness strongly indicate the benefits of female-condom use in increasing protected sex acts;
- two studies show promising decreases in STI incidence (24 per cent³⁴ and 13 per cent³⁵) with the introduction of female condoms compared with male condoms alone;
- ten studies provide detailed information on patterns of long-term use, many suggesting that the female condom reaches women less likely to use male condoms.

The researchers concluded that although the data is limited, the evidence is convincing that female-condom programming is effective in increasing the proportion of protected sex acts and decreasing STI incidence.

Female-condom programming is cost-effective

A major brake on promotion of female condoms has been their price. They currently have a unit cost about 18 times higher than male condoms, while giving a comparative level of protection.³⁶ In a situation where a couple could use either a male or female condom, the male condom is clearly more cost-effective.

However, studies show that users do not generally switch from male condoms to female condoms, but often use female condoms in situations where they would otherwise have had no protection. For example, a project with sex workers in Madagascar first promoted male condoms alone. The proportion of protected sex acts rose from 57 per cent to 78 per cent. Following the introduction of female condoms, the figure went up again, to 88 per cent (and the rate of STIs fell by 13 per cent).³⁷ The female condoms enabled an additional ten per cent of protection, presumably among clients who refused to use a male condom. It is this additive effect which makes female condoms cost-effective in comparison to male condoms, in situations where it is difficult to increase the use of male condoms any further.

A UNAIDS mathematical model shows that the female condom is a cost-effective contraceptive and STI-prevention method in terms of disability-adjusted life years and costs averted.³⁸ Two studies have analysed the cost of expanded female-condom programming against the treatment cost savings to be gained through HIV infections averted. They conclude that the benefits outweigh the costs, and that programme effectiveness and cost-effectiveness improve substantially with scale.³⁹ The results would be even more

compelling if the studies had taken into account the full costs of HIV infection, and the benefits of the female condom for preventing unintended pregnancy.⁴⁰

Female condoms exist

Investment in research and development of new female-initiated means of protection from HIV is currently focused on vaccines, microbicides and, to a lesser extent, cervical barriers. They all potentially have the advantage of providing women with a more discreet method of protection, for those who want to conceal use from their partners. Unlike condoms, vaccines and microbicides would also provide a means of protection from HIV infection for women who want to get pregnant. However, the prospect of these new methods of protection does not undermine, but rather reinforces, the urgent need for female condoms:

- Neither vaccines nor microbicides nor cervical barriers are currently available. The very earliest that women may be able to use any of them is around 2014, but it could be much later.⁴¹ It is unethical to withhold a proven technology (male and female condoms) while awaiting the development of another.
- All the methods are expected to have lower levels of efficacy against HIV infection than male or female condoms.⁴² It is important, therefore, to make male and female condoms widely available before introducing the new methods, so that the maximum number of sex acts is protected by the most effective method or combination of methods.
- Vaccines will not prevent unwanted pregnancies or infection from other STIs; microbicides may be developed to also act as a contraceptive, but they are unlikely to protect against all STIs. So existing methods will be needed in addition to the new methods for family planning and sexual health.
- In addition to their own intrinsic value for women's health and empowerment, successful female-condom programmes will greatly assist the introduction of other female-initiated methods when they become available.

3 Voicing demand for female condoms

We have the study reports, we know that women use them, so why do people often portray the female condom as a product that is not user friendly? Is this something that is just in people's minds? Aesthetically, I must admit, the female condom is not beautiful. But that does not mean that one should disqualify the product. Is the male condom such a pretty thing?

Nilcéa Freira, Minister, Special Secretariat for Policies for Women, Government of Brazil⁴³

Despite the evidence from trials and limited use of female condoms, doubts about this technology persist. This section looks at the acceptability of female condoms to users and the question of whether demand exists for them.

Acceptability

Studies have repeatedly shown high levels of acceptability of the female condom; as long ago as 1997 a WHO review of 41 studies of the FC1 showed acceptance levels ranging from 41 per cent to 95 per cent.⁴⁴ Since then many more studies have been conducted. Indeed, in 2006 reviewers of 60 such studies recommended that 'research on the female condom must move away from assessing acceptability and focus on assessing effectiveness and improving impact in diverse settings'.⁴⁵

For some users, female condoms are not only acceptable, but preferable when compared to male condoms.⁴⁶ Some of the reasons include:

- Female condoms offer more flexibility regarding the timing of putting them on and taking them off.⁴⁷
- Synthetic female condoms have a soft, moist texture which feels more natural during sex. For men the sensation is closer to that of sex without a condom, because female condoms do not fit tightly around the penis as male condoms do.⁴⁸
- Many users believe that female condoms are stronger and so safer than male condoms, which helps them to relax and enjoy sex.
- Although female condoms were not designed for anal sex, some men who have sex with men prefer them over male condoms.⁴⁹
- Unlike latex condoms, synthetic female condoms are not damaged by oil-based lubricants nor affected by changes in

temperature and humidity, so they can be safely stored almost anywhere.

- Where female condoms have been marketed to the general public as a contraceptive, they escape the stigma attached to male condoms and notions of promiscuity.

However, as with every other method of HIV prevention and contraception, female condoms are not universally acceptable. Concerns include promoting women's promiscuity, fears about the condom becoming lost inside the vagina, distaste for the appearance of the product, or dislike of it when used. In particular, new users may reject the product after one or two tries. Giving them support to understand how to use the condom, and how to overcome any initial problems they may face, greatly improves acceptability.⁵⁰ Involving men in promotion campaigns is also important; worldwide, male-partner objection is a key reason for non-use or discontinued use of the female condom.⁵¹

Furthermore, improved designs and more choice in types of female condoms should lead to higher acceptability rates. For example, in a study in India of the Reddy condom, married women and men respectively rated 94.8 per cent and 94.5 per cent of uses as comfortable or neutral in terms of comfort during sex. They reported themselves as somewhat or very satisfied in 97.4 per cent instances of use.⁵² Studies of the PATH woman's condom show similarly high levels of comfort and satisfaction.⁵³

Box 2: Some users' comments about the female condom⁵⁴

'I like the female condom as I often have issues with negotiating safe sex with my partner. With the female condom I can take control and I feel more confident.'

HIV-positive woman, Australia

'I am tranquil and he is not fighting with me anymore when we are going to have sex. We don't have to fight because now, I don't have to keep asking him to use the condom. I use mine.'

Woman, Brazil

'I prefer them because I put it in place, I trust them more than male condoms (I've had several of them split), and I can leave it on for a while after climax without worrying. The only thing I don't like about them is their price.'

Woman, UK

'My strategy for safer sex is my ability to use the female condom, which I have control over... Sometimes my husband would complain... or have one story or the other for not wanting to use the condom. I just decided to use the female condom.'

Woman, Zimbabwe

'In the beginning I didn't like it, I found it terrible, but I continued using it to see if I could get accustomed to it. Now I like it.'

Female sex worker, Brazil

'Having sex using a female condom feels loads better than using a male condom.'

Man, USA

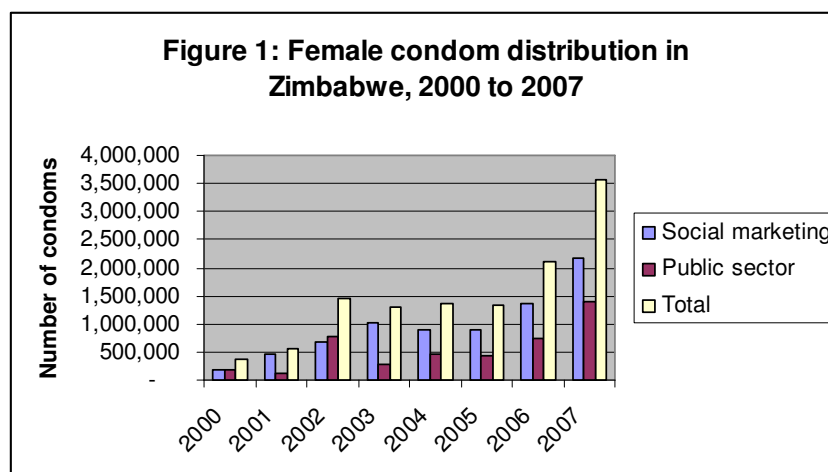
Demand and supply

Those who have worked in female-condom programmes know that there is demand for them, demand which sometimes greatly exceeds their forecasts.⁵⁵ However, uncertainty persists among some policy makers and funders, who see the tiny market share – about 0.24 per cent of all condoms are female condoms⁵⁶ – and conclude that demand is insufficient. That conclusion is not justified, for the following reasons:

- No global estimates of demand exist.⁵⁷
- The need for demand creation is normal for new products, and all the more so for social goods concerning taboos. The vast majority of potential users have never seen a female condom, let alone used one.⁵⁸ Their needs have yet to be transformed into demand.
- The history of technology development shows that doubts about potential market size and initial slow growth in demand are

common. The tampon, for example, took 17 years to build sizeable demand, but is now a normal product used by all kinds of women.⁵⁹

- In many female-condom programmes demand has exceeded supply and customers have not been able to get the product.⁶⁰ This has the effect of reducing confidence in the female-condom programme, and therefore also the product, and damaging long-term demand.
- Demand is deliberately suppressed in many projects: users are asked only to use female condoms in situations where they cannot use a male condom,⁶¹ or are supplied with far fewer female condoms than male condoms.⁶²
- Many small-scale female-condom programmes target the most vulnerable women, so do not attempt to create demand among the general population. In many settings this focus on sex workers has stigmatised female condoms, undermining demand among the general population.⁶³
- There are no large-scale female-condom programmes which have tried to create demand among all sexually active women. Therefore there are no experiences of fully meeting demand, nor of finding the level of market saturation. However, as Figure 1 illustrates, there is unmet demand. In Zimbabwe female condoms have been marketed as the *Care Contraceptive Sheath* since 1997. While demand had been rising steadily, increased investment since 2005 has seen massive change, with sales rising by 52 per cent in 2006 and 58 per cent in 2007, and public-sector distribution rising by 67 per cent in 2006 and 90 per cent in 2007.⁶⁴



Source: UNFPA (2008) 'The right of women and girls to remain HIV free: female condoms, a powerful tool for protection', FCI 2006–2007 progress report, May.

Of course, demand is always related to price. In the majority of female-condom programmes the unit price is heavily subsidised; demand would be much lower if consumers had to pay the full price.

However, given that there is a need for female condoms, that they are acceptable to a significant proportion of users, and that it is usual for access to contraceptives and methods of HIV prevention to be subsidised, the issue of demand should be reframed as being one of supply.

The hold-up in expanding access to female condoms is not at the users' end, but at the start of the chain. The main issue is how much money donors and governments are willing to invest in buying female condoms, supporting female-condom programmes, and developing low-cost female condoms.

4 The official response

UNAIDS is very much aware that the acceptability of the female condom is not a problem at the level of the women: many women give preference to it over other commodities. The problem is more of acceptability among policy makers.

Michael Bartos, Chief, Prevention Care and Support Unit, UNAIDS⁶⁵

There have been some efforts to increase access to female condoms, and their supply has increased substantially in recent years, but it is still pitifully low at almost 26 million for 2007, compared with roughly 11 billion male condoms.⁶⁶ That's one female condom for every 423 male condoms.

Why the failure?

The response of the UN, most governments, and many NGOs has mirrored the common reasons for not using male condoms: responses formed by ignorance, culture, denial, 'poverty', and conservatism.

Ignorance

Many decision-makers are poorly informed about female condoms, often relying on media stereotypes rather than seeking insights from scientific studies. As one review concluded: '[T]he technology itself seems to engender negative initial responses on the part of many donors, programme managers and providers, who ignore more positive acceptability studies and the few successful country experiences'.⁶⁷

Culture

While decision-makers do not publicly ridicule female condoms, the bias against them is sometimes explicit,⁶⁸ and often implicit in what organisations do not say and do. Most organisations lack leadership on the issue and fail to understand that female condoms are a core part of the response to HIV. Within USAID – one of the forerunners among donors with regard to female condoms – there is no evidence-informed policy guidance for its missions. Instead, decisions at country level are made according to the personal beliefs and values of a few individuals.⁶⁹

Denial

Decision-makers know that women's limited ability to negotiate male-condom use is a problem, yet many refuse to accept that the

female condom offers something more. Despite the advantages listed in Section 2, sceptics argue it is just an expensive condom which still requires negotiation. They ignore the men who don't like to use male condoms, and prefer female condoms. They are also deaf to the experiences of women who find that female condoms give them more power to negotiate safer sex and a greater sense of control and safety. Their denial is of women's right to have a female-initiated form of protection and so to have a little more power.

'Poverty'

Female condoms are more expensive than male condoms, and in situations of limited resources decision-making becomes a trade-off between the two.⁷⁰ The claim that female condoms are not affordable is the most publicly acceptable reason for failing to make female condoms accessible. Yet with funding of \$10bn for responding to HIV in 2007, this 'poverty' is more a failure to find money for female condoms and addressing the feminisation of HIV. For women whose partners will not use a male condom, a female condom is their only means of protection. They have the right to protect themselves.

Conservatism

While the male condom is far from being a problem-free product, it and its controversies are well known. After many years of promotion, it is widely used, including by decision-makers, and fully endorsed by UNAIDS. In contrast, the female condom is unknown, its status is unclear and therefore dubious, and it is less used.⁷¹ Its association with unseen female bodily territory and with women taking control of their bodies and their sexuality also causes psychological discomfort for some.

Overarching errors

Lack of leadership

There has been a distinct lack of leadership on female condoms within the UN (UNAIDS, UNFPA, UNICEF, UNIFEM, WHO) and the majority of donor agencies (especially the World Bank and the Global Fund). As a result, global efforts to develop female condoms and promote their use have been sporadic and un-co-ordinated.

An analysis of 36 speeches made by UNAIDS' Executive Director from January 2006 to June 2008 reveals just three mentions of female condoms. By comparison, he referred to microbicides and to vaccines in half the speeches, and to treatment in all but two of them.

Lack of leadership on female condoms is also evident in the way in which female condoms are almost ignored in some UN documents,⁷² added in as an afterthought in others,⁷³ or included in the phrase

'male and female condoms' without any reference to the challenges of embarking on female-condom programming.⁷⁴

Lack of funding for female condoms

It is not known how much has been spent on the female condom, but analysts agree that it has been uneven, not sustained, and insufficient.⁷⁵

A key problem is funding bias:

- There have been unprecedented increases in funding for responding to HIV, but primary prevention efforts are receiving far too little attention.⁷⁶ There is still a large gap between the number of condoms – male and female – needed, and the number available.⁷⁷
- Within research and development funding for female-initiated prevention methods, there is a bias in favour of new high-tech approaches, such as microbicides and vaccines.⁷⁸ In 2006 alone, public donors and philanthropists contributed \$217m to microbicide development, and \$776m to vaccine development.⁷⁹ By comparison, in the ten years from 1998 to 2008, they invested a total of \$6.48m in developing PATH's woman's condom. Its design was finalised in 2004, but the approval process is now two years behind schedule due to lack of funding.⁸⁰

Failure to scale up female-condom programming

The majority of female-condom interventions have been short-term, with donors preferring to fund trials, pilot programmes, and studies rather than making long-term commitments to expanding access.⁸¹ The quality of programming has also been problematic, with many countries reporting that they are frequently out of stock of female condoms, sometimes for long periods.

With limited and sporadic investment in female-condom programming, demand for female condoms had, until recently, grown slowly, and had little effect on their price. However, reductions in the fully loaded cost of female condoms (i.e. the product plus programme costs less income generated) have been achieved in social-marketing programmes.⁸² More efficiency gains could be achieved through long-term integrated programming of female condoms within HIV-prevention and family-planning efforts.

Failure to reduce the price of female condoms

While the cost of female condoms has always been acknowledged as a significant problem, the following strategies to reduce their price have not been vigorously pursued:

- creating demand to reduce the unit cost through the economies of scale of increased production;
- investing in new designs which are much less costly to make, or which are reusable;⁸³
- investing in not-for profit production of female condoms;
- encouraging competition in the market to drive down suppliers' prices (in particular, to help bring new products to market, the United States' Food and Drug Administration (FDA) should reclassify female condoms from being in Class III to Class II, the same class as male condoms, while still requiring adequate additional information and proof of effectiveness for significantly new condom designs);⁸⁴
- allowing generic versions of female condoms, particularly those stemming from publicly funded research and development.

Muted advocacy

Compared with the vocal demands for access to anti-retroviral treatment, advocacy for access to women's condoms has been muted. In part, women and NGOs may have fallen victim to the same misconceptions and negative reactions as donors and policy makers. Women are also less used to demanding things for themselves, and may be labelled prostitutes if they ask for tools for safer sex. There is also the reality that women's groups lack the resources to take on the vast range of issues concerning gender injustice and inequity that they face.

There are some signs of growing advocacy. For example, in South Africa the Thohoyandou Victim Empowerment Program is mobilising civil-society groups to jointly advocate for expanded access to female condoms. If necessary they will take the government to court over the very low quantities of female condoms it provides compared with male condoms, on the grounds of gender discrimination. Oxfam's initiative (see Box 3) is also advocating for expanded access to female condoms.

Some action

It is not the case that no progress has been made over the past 15 years. UN agencies (mainly UNFPA), donors (chiefly USAID, DFID, KfW, DANIDA, and CIDA), governments (particularly Brazil, South Africa, Zimbabwe, and Ghana⁸⁵) and NGOs have produced documents about female condoms, organised meetings and consultations, and funded or supported product development, training, promotion, and distribution of female condoms. This report

does not attempt to list their achievements, but notes that some progress has been made.

In 2005 UNFPA launched its Global Female Condom Initiative, which aims to support governments to scale up female-condom programming. The initiative promotes female condoms as a dual protection method which should be an essential component of both HIV-prevention and reproductive-health programmes. It currently has 47 countries enrolled, comprising 17 in Africa, six in Asia, and 24 Caribbean nations.⁸⁶ While positive change is evident in some countries, there is still a very long way to go. Many programmes run out of stock of female condoms, and supply-chain management remains problematic in even the best programmes.⁸⁷ The number of female condoms available is still tiny in the context of the numbers of sexually active women, which makes the female condom a 'niche product' for a few women rather than a normalised product for many women.

Box 3: The Universal Access to Female Condom (UAFC) programme, initiated by Oxfam

This programme is complementary to UNFPA's Global Female Condom Initiative. Oxfam formed the Female Condom Consortium with the Dutch Ministry of Foreign Affairs, World Population Foundation, and IDA Solutions.

The UAFC programme has three components:

1. Investment in research and development to lower the unit cost of female condoms.
2. Large-scale female-condom programmes in three African countries: Nigeria, Cameroon, and a third country (dependent on funding) to demonstrate that demand can be created, supply chains can be managed, and education can lead to safer sexual behaviour and female empowerment.
3. International advocacy for greater investment in female condoms, and linking and learning for more effective programming.

Through these three strategies the consortium aims to make a real contribution towards universal access to female condoms in these three countries, and to demonstrate that large-scale female-condom programming can work. The programme is funded by the Dutch government, DANIDA, and the Hewlett Foundation. SIDA, NORAD, and the EU have pledged funding.

5 Recommendations for change

The report [on female condoms⁸⁸] is a critique of the current US government's position, yet the same concerns can equally be levelled at other major players, including UNAIDS and WHO. What is currently lacking is high level commitment that would ensure improved distribution efforts within the public health-care system, drive down costs...and ensure that sufficient resources are available to enable the scale-up of programmes and promotional strategies...The failure of recent trials to show the efficacy of new microbicide candidates and the diaphragm, make the promotion of the female condom as a life-saving intervention more pertinent than ever.

Editorial, *Lancet Infectious Diseases*, June 2008⁸⁹

It is symptomatic of the lack of leadership on female condoms and lack of investment in them that, 15 years after their invention, we do not have:

- any assessment of global demand for female condoms;
- global targets for public provision of female condoms;
- calculations of global funding requirements for providing female condoms;⁹⁰
- global estimates of how many HIV infections and unwanted pregnancies could be averted through the use of female condoms;
- an information portal for data from female-condom trials and programming;
- a vibrant global campaign for female condoms;
- a global strategy for the development and production of affordable female condoms.

Most significantly, the majority of the world's women do not have access to female condoms. This can and must be changed, by moving from 15 lost years to action to make female condoms accessible.

1. UNAIDS and UNFPA, along with donor and development organisations, must provide visible global leadership to tap the potential of the female condom as a contraceptive and a prevention method against STIs including HIV. They must make stringent advocacy efforts, prioritise resources, and set meaningful targets to improve access. A short-term target of raising female condom distribution to five per cent of total

condom distribution is achievable and affordable at a cost of around \$120m per year globally.⁹¹

2. UN agencies (UNAIDS, UNFPA, UNIFEM, UNICEF, WHO, the ILO) and international donors including the Global Fund to Fight AIDS, Tuberculosis and Malaria must promote the female condom in their gender and health policies and provide concrete assistance to implementing agencies and governments. They must significantly boost investment in female condoms, and UNITAID should include them in its portfolio.
3. Governments, donors, and private investors must support female-condom research and development (R & D) to create choice and lower prices. In 2006, donors spent over \$1bn on developing new HIV-prevention technologies.⁹² An investment of just \$20m would allow new female condoms to be brought to market. Patent laws should not infringe on efforts to develop new female condoms and to produce affordable generic versions, particularly patents stemming from publicly funded R & D. The United States' FDA should reclassify female condoms from being in Class III (high-risk devices) to Class II, the same class as male condoms, while still requiring adequate additional information and proof of effectiveness for significantly new condom designs.
4. National governments, civil-society organisations, and the private sector should collaborate on comprehensive long-term integrated female-condom programming, making female condoms available to all women and men, given their universal relevance as a contraceptive and STI-prevention method.
5. Civil-society organisations should demand that governments and international agencies include female condoms in their family-planning and reproductive disease (including HIV) prevention programmes, and in their funding plans to the United States President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund and UNITAID.

Notes

All website URLs listed were last accessed in June 2008.

¹ Assuming male condom distribution of 11 billion per year, 580 million female condoms would equal five per cent of the total. At an estimated price of \$0.22, this equals \$127.6m, less those which would be privately purchased (currently around 86 per cent of production is purchased by public bodies.)

² HIV Vaccines and Microbicides Resource Tracking Working Group (2007) *Building a Comprehensive Response: Funding for HIV Vaccines, Microbicides and other New Prevention Options: 2000 –2006*, www.hivresourcetracking.org.

³ CHANGE (2008) press release, 22 April, www.preventionnow.net.

⁴ www.unaids.org/en/PolicyAndPractice/ResourcesAndFunding/default.asp.

⁵ In terms of efficacy, research shows that the FC1 and FC2 female condoms are comparable to other barrier methods in preventing pregnancy and STIs, www.unfpa.org/hiv/female.htm.

⁶ As of the end of 2007, approximately 31 per cent of people in need of anti-retroviral treatment in developing nations were accessing it (data.unaids.org/pub/PressRelease/2008/20080602_treatment_report_en.pdf). By comparison, in 2007 roughly 22 million female condoms were distributed to less-developed countries with a combined population of approximately 1.4 billion women aged 15–49 (esa.un.org/unpp/index.asp?panel=2). This is equivalent to 1.6 per cent of those women each having access to a single female condom. For 31 per cent of those in need to gain access to a supply, we would have to make ludicrously low and incorrect assumptions: for example, that only one per cent of the women were in need of female condoms, and that a yearly supply constitutes just five condoms.

⁷ UNAIDS (2008) 'AIDS: exceptionalism revisited', lecture by Peter Piot, UNAIDS Executive Director, London School of Economics and Political Science, 15 May, www.unaids.org. This is the lowest estimate seen during research for this paper; the highest is six new infections for every person on treatment (Stated by Anthony Fauci, the Director of America's National Institute of Allergy and Infectious Diseases at the International AIDS Society meeting in July 2007, www.medicalnewstoday.com/articles/77589.php).

⁸ Rough estimate based on: 25.6 million female condoms sold by FHC in 2007, 86 per cent of which were purchased by the public sector (personal communication, Patrick Friel, 20 June 2008), multiplied by a fully loaded cost of \$1.37 (PSI 2005 figure of \$1.28 + inflation, cited in PATH & UNFPA 2005); research studies generous estimate of \$1.3m; staff costs not included in fully-loaded price, high estimate of 12 full-time at salary of \$70,000 pa each. Total of \$32.8m compared to total estimated expenditure on HIV response in 2007 of \$10bn.

⁹ The Female Health Company's condoms are marketed under many brand names, including *Reality*, *Femidom*, *Dominique*, *Femy*, *Myfemy*, *Protectiv*,

Care, Confidorm, and Velvet, www.femalehealth.com. Medtech's Reddy condom is sold under brand names including *Reddy, V Amour, L'amour, VA WOW Feminine condom, and Sutra*, www.medtechproducts.net. PATH is a not-for-profit organisation, which has followed a user-driven design process aimed at developing a female condom with very high user acceptability, www.path.org. Mediteam does not have a website; personal communication from Chantelle Couvreur of Mediteam via Rino Mayers of IDA Solutions, 5 June 2008.

¹⁰ This mechanism has been put in place while an international standard for female condoms is developed, which will take at least another two years who.int/reproductive-health/stis/female_condom.htm.

¹¹ Female Health Company (2007) 'The Distance Travelled', Female Health Company Annual Report 2006, www.femalehealth.com/fhcoinvestor.html#annual. The nitrile FC2 has allowed the company to lower the price to public-health agencies and to increase its gross profit margin ('The Female Health Company Reports 267 per cent Increase in Second Quarter Earnings', press release 14 May 2008, www.femalehealth.com/fhcoinvestor.html#annual).

¹² Personal communication, Rino Meyers, IDA Solutions, 3 July 2008.

¹³ J.E. Mantell, Z.A. Stein, and I. Susser (2008) 'Women in the time of AIDS: barriers, bargains, and benefits', *AIDS Education and Prevention* 20(2): 91–106.

¹⁴ UNAIDS & WHO (2007) 'AIDS Epidemic Update 2007', www.unaids.org.

¹⁵ UNAIDS & WHO (2006) 'AIDS Epidemic Update 2006' reports that in Thailand a large proportion of new infections were among groups thought to be at low risk, with one third being married women, while in Ghana, 'as in many other countries, marriage appears to be a significant risk factor for women...while mobility is a strong risk factor among men. Married women were almost three times more likely to be HIV-infected than women who had never been married'.

¹⁶ UNAIDS & WHO (2007) *op.cit.*

¹⁷ M. Over (2008) 'Prevention Failure: The Ballooning Entitlement Burden of US Global AIDS Treatment Spending and What to Do About It', Center for Global Development Working Paper Number 144, April 2008, www.cgdev.org/content/publications/detail/15973.

¹⁸ All statistics in this subsection taken from Guttmacher/WHO (2007) 'Facts on Induced Abortion Worldwide', www.guttmacher.org/pubs/fb_IAW.html.

¹⁹ UNFPA (2007) 'Donor Support for Contraceptives and Condoms for STI/HIV Prevention 2006'.

²⁰ UN (2007) 'Africa and the Millennium Development Goals 2007 Update', www.un.org/millenniumgoals/docs/MDGafrica07.pdf.

²¹ UN (2007) 'The Millennium Development Goals Report 2007', mdgs.un.org/unsd/mdg/Resources/Static/Products/Progress2007/UNSD_MDG_Report_2007e.pdf

²² Data in this sub-section is taken from UN (2007) 'The Millennium Development Goals: 2007 Progress Chart',

mdgs.un.org/unsd/mdg/Resources/Static/Products/Progress2007/MDG_Report_2007_Progress_Chart_en.pdf.

²³ The exception is that latex condoms can cause natural rubber latex allergy. The prevalence of this allergy is unclear. Studies in the west suggest that one – six per cent of the population may be sensitised to natural rubber latex, but not all develop symptoms (www.hse.gov.uk/latex/about.htm). UNAIDS cites a figure of up to eight per cent (UNAIDS (1997) 'The Female Condom and AIDS', Point of View, Best Practice Collection, April). Non-latex male condoms are available commercially in some developing countries, but are not easily accessible via the public-health systems.

²⁴ For example, in one study, 13 per cent of women reported using the female condom without their sexual partner's knowledge (D. Kerrigan, S. Moble, N. Rutenberg, A. Fisher, and E. Weiss (2000) *The Female Condom: Dynamics of Use in Urban Zimbabwe*, Horizons, the Population Council, list.popcouncil.org/pdfs/horizons/fcz.pdf).

²⁵ In a study in South Africa 65 per cent of female condom users said it was easier to convince their partner to use a female condom compared with a male condom mainly due to the transfer of responsibility (M. Bekinska, E. Marumo, J. Smit, and Z. Mabude (2005) 'Country Experiences from South Africa', presented at the Global Consultation on Female Condoms in Baltimore in September 2005, www.path.org/projects/womans_condom_gcfc2005.php). Some people object to this shifting of responsibility from men to women as the male condom is the only male-initiated form of contraception. However, many women argue the opposite, preferring to be in control of protecting their own bodies.

²⁶ A. Welbourn (2006) 'Sex Life and the Female Condom: Some Views of HIV Positive Women', *Reproductive Health Matters* 14(28): 32–40; P.R. Telles Dias, K. Souto, and K. Page-Shafer (2006) 'Long-term Female Condom Use Among Vulnerable Populations in Brazil', *AIDS and Behavior* 10: S6–S75; S. Hoffman (2006) 'The Female Condom: Challenging Misconceptions About Acceptability and Use', presented at the Global Health Council's event 'Expanding Access to Female Condoms to Stem the Spread of HIV' in Washington, DC on 14 June 2006, www.globalhealth.org/images/pdf/public_policy/hoffman_061406.pdf.

²⁷ A. Kaler (2004) 'The future of female-controlled barrier methods for HIV prevention: female condoms and lessons learned', *Culture, Health & Sexuality* 6(6): 501–16; Hoffman (2006) *op.cit.*; Welbourn (2006) *op.cit.*.

²⁸ J.E. Mantell *et al.* (2008) *op.cit.*; A.L. Gray, J.A. Smit, N. Manzini, and M. Bekinska (2006) 'Systematic Review of Contraceptive Medicines: "Does Choice Make A Difference?"', RHRU, University of Witwatersand, South Africa, <http://mednet3.who.int/EML/expcom/expcom15/applications/sections/ContraChoiceReview.pdf>.

²⁹ UNAIDS & WHO (1997) *The Female Condom: An Information Pack*, April.

³⁰ R.M. Barbosa, S. Kalckmann, E. Berquo, and Z. Stein (2007) 'Notes on the female condom: experiences in Brazil', *International Journal of STD & AIDS* 18: 261–6.

³¹ Though not at the same time! L. Artz, M. Macaluso, I. Brill, J. Kelaghan, H. Austin, M. Fleenor, L. Robey, and E.W. Hook (2000) 'Effectiveness of an intervention promoting the female condom to patients at sexually transmitted disease clinics', *American Journal of Public Health* 90(2): 237–44.

³² Kerrigan *et al.* (2000) *op.cit.*.

³³ G.Vijayakumar, Z. Mabude, J. Smit, M. Bekinska, and M. Lurie (2006) 'A review of female-condom effectiveness: patterns of use and impact on protected sex acts and STI incidence', *International Journal of STD and AIDS* 17(10): 652–9.

³⁴ A. Fontanet, J. Saba, V. Chandelying, C. Sakondhavat, P. Bhiraueus, S. Ruggao, C. Chongsomchai, O. Kiriwat, S. Tovanabuttra, L. Dally, J.M. Lange, and W. Rojanapithayakorn (1998) 'Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: results from a randomised controlled trial', *AIDS* 12 1851–9.

³⁵ T.H. Hoke, P.J. Feldblum, K. Van Damme, M.D. Nasution, T.W. Grey, E.L. Wong, L. Ralimamonjy, L. Raharimalala, and A. Rasamindrakotroka (2007) 'Temporal trends in sexually transmitted infection prevalence and condom use following introduction of the female condom to Madagascar sex workers', *International Journal of STD & AIDS* 18(7): 461–6, ijsa.rsmjournals.com/cgi/reprint/18/7/461.

³⁶ The public-health price for UNFPA/UNAIDS/WHO purchases from the Female Health Company is currently \$0.55 (personal communication, Rino Mayers, IDA Solutions, 19 June 2008) against a price of male condoms of around \$0.03. The Reddy condom can be purchased for \$0.45 (personal communication, Rino Mayers, IDA Solutions, 3 July 2008).

³⁷ Hoke *et al.* (2007) *op.cit.*.

³⁸ UNAIDS (1999) *Launching and Promoting the Female Condom in Eastern and Southern Africa*, UNAIDS Best Practice Collection, May, www.unaids.org.

³⁹ E. Marseille, J. Kahn, K. Billingham, and J. Saba (2001) 'Cost effectiveness of the female condom in preventing HIV and STDs in commercial sex workers in rural South Africa', *Social Science and Medicine*, 52: 135–48; D. Dowdy, M.D. Sweat, D.R. Holtgrave (2006) 'Country-wide distribution of the nitrile female condom (FC2) in Brazil and South Africa: a cost-effectiveness analysis', *AIDS* 20 (16) 2091–8, www.aidsonline.com. The 2006 study showed less compelling savings, but only accounted for the cost of anti-retroviral treatment, excluding the costs of other treatment associated with HIV including hospitalisation, and of other STIs. All such studies are highly sensitive to the many assumptions made for the input parameters, including changing prices for treatment and condoms.

⁴⁰ Kaler (2004) *op.cit.*.

⁴¹ Five years' time is the earliest the public might access a microbicide (www.global-campaign.org/about_microbicides.htm). A vaccine is much further away: in a recent survey, nearly two-thirds of AIDS scientists believed it would be more than ten years (www.independent.co.uk/news/science/is-it-time-to-give-up-the-search-for-an-aids-vaccine-814737.html).

⁴² Male and female condoms are around 95 per cent effective when used correctly and consistently. The International AIDS Vaccine Initiative notes that 'even after people receive the vaccine, they will still need to take other prevention precautions (such as using condoms and microbicides)' (www.iavi.org/viewpage.cfm?aid=1685), while the Global Campaign for Microbicides expects that correct and consistent use of male and female condoms will be the preferred option, with microbicides' role being giving some protection to people who cannot or will not use condoms (www.global-campaign.org/more_microbicides.htm).

⁴³ Personal communication, 6 June 2008.

⁴⁴ UNAIDS & WHO (1997) *op.cit.*.

⁴⁵ Vijayakumar *et al.* (2006) *op.cit.*.

⁴⁶ Data in these bullet points is taken from: Telles Dias *et al.* (2006) *op.cit.*; Mantell *et al.* (2008) *op.cit.*; M. Skaer and V. Ebin (2006) *In Our Own Hands: SWAA-Ghana Champions of the Female Condom*, www.popcouncil.org/pdfs/qcq/QCQ17.pdf; Kerrigan *et al.* (2000) *op.cit.*; UNAIDS & WHO (1997) *op.cit.*; and information from the Female Health Company, www.femalehealth.com.

⁴⁷ Male condoms require an erection, and so can only be employed during sex, whereas female condoms can be inserted up to eight hours before sex. This means no interruption in sex play, and avoids the renegotiation and potential conflict caused when women have to ask their partner to stop and put on a male condom. It also precludes taking risky decisions in the 'heat of the moment'. Furthermore, with male condoms, penetration leads directly to ejaculation, after which the man must withdraw or risk having the condom slip off. With female condoms the process doesn't have to be so linear, as there is no need to maintain an erection to keep the condom in place. Penetration can be mixed with other kinds of sex play. Following ejaculation, the couple can stay together if they wish, with no need to part straight after male orgasm.

⁴⁸ In addition, some women and men get added sexual stimulation from the inner and outer rings of FC1 and FC2. This can make sex with a female condom more pleasurable than sex without protection.

⁴⁹ In one study 21 per cent of receptive partners and 26 per cent of insertive partners preferred FC1 over male condoms when having sex with someone of unknown HIV status. This figure rose to 60 per cent for HIV-positive insertive partners having sex with an HIV-negative partner. (C. Renzia, S.R. Tabet, J.A. Stucky, N. Eaton, A.S. Coletti, C.M. Surawicz, S.N. Agoff, P.J. Heagerty, M.Grosse, and C.L. Celuma (2003) 'Safety and acceptability of the Reality™ condom for anal sex among men who have sex with men', *AIDS* 18(5): 727–31, www.aidsonline.com).

⁵⁰ In a study in Brazil, less than a fifth of female condom users initially adopted the technology without any problem, but all did adopt it with support to overcome those 'teething problems' (Telles Dias *et al.* 2006 *op.cit.*). The participants identified the following issues as influencing their acceptance and subsequent adoption of the female condom: (1) practising condom insertion on a pelvic model; (2) being warned that there would likely be a period of adjustment during which it is usual to experience difficulties; (3)

encouragement regarding use of the product, including its advantages; (4) testimonials from others who liked and adopted the method; (5) learning strategies to negotiate condom use with sexual partners; (6) information on female genital anatomy; and (7) information on STIs. In another trial, users of female condoms initially reported problems of slippage in ten per cent of uses, but this had gone to 0 (out of 129 uses) by the end of the study (Fontanet *et al.* (1998) *op.cit.*).

⁵¹ Hoffman (2008) *op.cit.*, citing four other studies.

⁵² Prastut Consulting (2007) 'Product Usage Study Report, Natural Latex Female Condom', April 12, inspiral.tv/imglib/VA-Standalone_study_Analysis_and_report.pdf

⁵³ PATH reports from its trials that over 90 per cent of couples were satisfied with the condom's performance for ease of use, stability, comfort, and sensation. Ninety-eight per cent of women and 99 per cent of men found the sensation of sex to be okay to very satisfactory: www.path.org/files/TS_update_womans_condom.pdf.

⁵⁴ Quotes taken from: Welbourn (2006) *op.cit.*; Telles Dias *et al.* (2006) *op.cit.*; ZWRN (no date): '*Stories of Women Living with HIV and AIDS: Sexual Rights and Access to Treatment among HIV Positive Women in Zimbabwe*, Zimbabwe Women's Resource Centre and Network. UK and USA quotes from personal communications.

⁵⁵ For example, PSI in Zimbabwe initially forecast sales of 4,000 female condoms a month, but sold an average of almost 19,000 a month for the first four months, slowing to an average of over 13,000 a month in the following 25 months (Kerrigan *et al.* (2000) *op.cit.*).

⁵⁶ In 2007, worldwide about 26 million female condoms were distributed, compared with around 11 billion male condoms (CHANGE (2008) *op.cit.*).

⁵⁷ CHANGE attempted to find a global estimate of demand for female condoms in order to advocate that USAID should fund its share of meeting demand. However, they were unable to find any such estimate (personal communication, Lauren Sisson, CHANGE, 5 May 2008). Its non-existence is confirmed by Bidia Deperthes of UNFPA (personal communication, 17 June 2008).

⁵⁸ For example, in market research in Ghana, 60 per cent of respondents had never heard of the female condom, and just 0.4 per cent had ever used it (Skaer & Ebin (2006) *op.cit.*).

⁵⁹ M. Latka (2001) 'Female-initiated barrier methods for the prevention of STI/HIV: Where are we now? Where should we go?', *Journal of Urban Health* 78 (4) 571–80.

⁶⁰ SWAA Cameroon (communication from Adrienne Germaine), Ghana (Skaer & Ebin (2006) *op.cit.*), and Tanzania and Malawi (World Population Fund & Oxfam Novib (2007) 'A Matter of Choice Rather than Noise', report on an international meeting on the female condom, 12–14 September 2007, Oegstgeest, The Netherlands, available from the resources page of www.preventionnow.net).

⁶¹ For example, in Fontanet *et al.* (1998) *op.cit.*, sex workers were asked to propose a male condom, and only to use a female condom if the client refused. This approach maximises cost-effectiveness.

⁶² In one Zambian study couples were counselled about the benefits of condom use, but were given only ten female condoms against 60 male condoms at each visit to the clinic. Despite female condoms making up only 14 per cent of their condom supply, the couples reported using them in around 24 per cent of sexual acts after 12 months; it is plausible that their use would have been higher if the supply were not so restricted. This is not mentioned in the study, nor in any citations or reviews of it. (E. Musaba, C.S. Morrison, M.R. Sunkutu, and E.L. Wong (1998) 'Long-term use of the female condom among couples at high risk of human immunodeficiency virus infection in Zambia', *Sexually Transmitted Diseases* 25(5): 260–4, www.stdjournal.com).

⁶³ World Population Foundation & Oxfam Novib (2007) *op.cit.*.

⁶⁴ UNFPA (2008) *op.cit.*.

⁶⁵ World Population Fund & Oxfam Novib (2007) *op.cit.*.

⁶⁶ CHANGE (2008) *op.cit.*.

⁶⁷ G.F. Brown, V. Raghavendran, and S. Walker (2007) 'Planning for Microbicide Access in Developing Countries: Lessons from the Introduction of Contraceptive Technologies', International Partnership for Microbicides, July 2007, ipm-microbicides.org/pdfs/english/ipm_publications/2007/ipm_rh_paper_en_2007_0730v6.pdf.

⁶⁸ For example, the Aidsmap website (www.aidsmap.com, accessed on 5 June 2008) features three paragraphs on female-controlled methods of safer sex. The first gives the context. The second states that the female condom is the first product to give women more control, but then gives four negative opinions. The last of these – that a man can deliberately insert his penis in the vagina around the side of the condom without the woman knowing – is not an issue reported in trials. The third paragraph is about microbicides, making two positive comments, including that they potentially have the benefit of protection against STIs.

⁶⁹ A key finding of recent research into USAID's role in promoting female condoms found that 'US agencies responsible for female condom programming and procurement do not have policies that promote the integration of female condoms into HIV prevention and family planning programs. Whether the US procures female condoms in a given country is highly dependent on the personal biases of USAID mission staff' (CHANGE (2008) *op.cit.*) The report also mentions how the lack of specific policy guidance on female condoms affects US-funded agencies such as Population Services International (PSI); although PSI is one of the largest distributors of female condoms, female condoms remain a marginal product within its network, with programming dependant on the presence of female condom 'champions' in individual offices.

⁷⁰ For example, in an on-line conference in May 2008 about female condoms, one contributor from Uganda stated: 'female condoms are quite expensive, particularly for cash-strapped countries where funds for condom

procurement and promotion have to be requested as a donation from development partners/donors. Sometimes we have to make a choice and convince ourselves that it would be more cost-effective to bring in 2 million male condoms than 100,000 pieces of the female condoms'. She also noted that she would prefer not to have to choose, but to give people access to both. Of course, the trade-off is rarely applied outside of the condom sphere, for example, to compare procurement of female condoms with that of jet fighters.

⁷¹ Conservatism is also evident in provider bias. Within HIV prevention, staff are generally more comfortable with promoting the male condom. Family-planning staff have a preference for 100 per cent effective oral contraceptives over harm-reduction strategies (Kaler (2004) *op.cit.*).

⁷² For example, a joint statement by WHO, UNAIDS, and UNFPA entitled 'Position Statement on Condoms and HIV Prevention (July 2004)' begins: 'The male latex condom is the single, most efficient, available technology to reduce the sexual transmission of HIV and other sexually transmitted infections'. Yet the female condom is as efficacious as the male condom. The document includes 38 references to 'condoms' but only one to 'female condoms': 'Female condoms can provide women with more control in protecting themselves', www.unfpa.org/upload/lib_pub_file/343_filename_Condom_statement.pdf

⁷³ When accessed on 29 April 2006, a UNAIDS web page began with the same sentence as the previous footnote, but then added: 'Along with the female condom, it [the male condom] is a main component of comprehensive strategies to reduce risks of sexual exposure to HIV'. However, in the process of researching this brief, the page was updated to read: 'The male latex condom is the most efficient and available technology to reduce the sexual transmission of HIV and other sexually transmitted infections. The female condom is increasingly available and is equally effective in reducing the sexual transmission of HIV. Condoms have played a decisive role in HIV prevention efforts in many countries. Both male and female condoms are a main component of comprehensive strategies to reduce risks of sexual exposure to HIV', www.unaids.org/en/PolicyAndPractice/Prevention/Condoms/default.asp.

⁷⁴ For example, UNAIDS' 2007 *Practical Guidelines for Intensifying HIV Prevention, Towards Universal Access* mentions 'male and female condoms' throughout, but gives no special attention to the challenges of expanding access to female condoms despite all the known problems of negative perceptions, costs of procurement, the need to train health providers, and so on.

⁷⁵ Brown *et al.* (2007) *op.cit.*; CHANGE (2008) *op.cit.*. Mantell *et al.* (2008) *op.cit.* failed to find figures for global investment in research and development of female condoms; investment in procurement and programming is also difficult to track because many donors provide support through non-earmarked funds.

⁷⁶ Over (2008) *op.cit.*. As Peter Piot stated recently in his opening speech to the Implementers' Meeting: 'First we need to work much harder on prevention. Although some countries are, for the first time, recording lower rates of new infections, most AIDS responses still pay too little attention to

HIV prevention...One problem is lack of demand. Imagine what could happen if there were a strong constituency – along the lines of South Africa's Treatment Action Campaign –marching for HIV prevention too'. (UNAIDS (2008) 'Opening Speech at the Implementers Meeting', Peter Piot, UNAIDS Executive Director, Kampala, 3 June 2008, www.unaids.org).

⁷⁷ For 2006, UNFPA estimated that 18 billion condoms were needed, and about 11.4 billion were available (UNFPA (2007) *op.cit.*).

⁷⁸ For example, on World AIDS Day 2004 Peter Piot of UNAIDS stated (emphasis added) 'To reverse these inequities we must focus attention and resources on increasing access to prevention and treatment services for women. We need to make female condoms readily accessible in more parts of the world. *And even more urgent* is the need for investment in a microbicide that a woman can confidently and confidentially use to protect herself from HIV', data.unaids.org/Media/Speeches02/sp_piot_wad2004_01dec04_en.pdf.

⁷⁹ HIV Vaccines and Microbicides Resource Tracking Working Group (2007) *Building a Comprehensive Response: Funding for HIV Vaccines, Microbicides and other New Prevention Options: 2000 –2006*, www.hivresourcetracking.org.

⁸⁰ Personal communication, Joanie Robertson, PATH, 14 May 2008.

⁸¹ Kaler (2004) *op.cit.* states '...investment in large scaling-up of activities is crucial, as is moving beyond piloting and acceptability studies...Sadly, it may seem safer to invest in endless piecemeal trials rather than taking the leap to scale-up, but the public health impact of acceptability trials is negligible'.

⁸² PATH & UNFPA (2006) *Female Condom: A Powerful Tool for Protection*, www.unfpa.org/publications/detail.cfm?ID=298. The fully loaded cost per female condom in PSI programmes was \$2.96 in 2000, down to \$1.28 in 2005.

⁸³ With the exception of the Female Health Company's development of FC2, which has resulted in around a 30 per cent reduction in price compared to FC1. Regarding re-use, WHO funded several studies of FC1 and produced protocols to assist in risk-reduction, but never recommended reuse of FC1. Studies showed that it could be washed, re-lubricated, and re-used up to seven times without damaging its structural integrity: www.who.int/reproductive-health/stis/reuse.en.html.

⁸⁴ PATH & UNFPA (2006) *op.cit.* Currently the FDA classifies female condoms in Class III, the same category as pace-makers and other invasive devices which are life-supporting or life-sustaining, and which present a high or potentially unreasonable risk of illness or injury to a patient (Williams ED (2007) *The Medical Device Approval Process and Related Legislative Issues*, CRS Report for Congress, updated July 12 2007). This makes the clinical trials very expensive, a severe deterrent to manufacturers. It has also affected device improvement: the Female Health Company only changed the material for FC2 and not the design, to minimise the time and cost of approval processes. FDA approval is required for USAID procurement: USAID is currently procuring the more expensive FC1 because FC2 has not yet passed FDA approval. Male condoms are in Class II, devices which pose a moderate risk to patients, and do not face the same regulatory challenges.

⁸⁵ For an analysis of the characteristics of these leading programmes, see M. Warren and A. Philpott (2003) 'Expanding Safer Sex Options: Introducing the Female Condom into National Programs', *Reproductive Health Matters* 11(21): 130–39.

⁸⁶ As of May 2008, they are Botswana, Burkina Faso, Central African Republic, Congo DR, Côte d'Ivoire, Ethiopia, Liberia, Malawi, Mauritania, Mauritius, Mozambique, Nigeria, Senegal, Sierra Leone, Tanzania, Zambia, Zimbabwe, Cambodia, India, Loa PDR, Mongolia, Myanmar, Papua New Guinea, Anguilla, Antigua & Barbuda, Aruba, Barbados, Belize, Bermuda, Bonaire, Cayman Islands, Curacao, Dominica, Grenada, Guyana, Jamaica, Monsterrat, St. Eustatius, St. Kitts/Nevis, St. Lucia, St. Maarten, St. Vincent, Suriname, Tortola, Trinidad and Tobago, Turks and Caicos (UNFPA (2008) *op.cit.*).

⁸⁷ SWAA Cameroon (communication from Adrienne Germaine), Ghana (Skaer & Ebin (2006) *op.cit.*), and Tanzania and Malawi (World Population Fund & Oxfam Novib (2007) *op.cit.*).

⁸⁸ CHANGE (2008) *op.cit.*.

⁸⁹ *The Lancet Infectious Diseases* 8(6): 343, www.thelancet.com (free registration required to access documents).

⁹⁰ Personal communication, Bidia Deperthes, UNFPA, 16 June 2008.

⁹¹ Assuming male condom distribution of 11 billion per year, 580 million female condoms would equal five per cent of the total. At an estimated price of \$0.22, this equals \$127.6m, less those which would be privately purchased (currently around 86 per cent of production is purchased by public bodies.)

⁹² HIV Vaccines and Microbicides Resource Tracking Working Group (2007) *Building a Comprehensive Response: Funding for HIV Vaccines, Microbicides and other New Prevention Options: 2000 –2006*, www.hivresourcetracking.org.

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World Population Foundation

WPF is a Dutch non-profit organisation aiming at the improvement of reproductive and sexual health and rights in developing countries. WPF supports local organisations to enable men, women and young people to decide freely and responsibly about their sexual lives and the number and spacing of their children and to ensure that they have the information and means to do so. WPF advocates in the Netherlands, Europe and around the world for supportive policies and resources. Every human being has the right to choose and the right to a safe and voluntary reproductive life.

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