INTERNATIONAL PARTNERSHIP *for* MICROBICIDES

PLANNING FOR MICROBICIDE ACCESS IN DEVELOPING COUNTRIES:
Lessons from the Introduction of Contraceptive Technologies

George F. Brown
Vimala Raghavendran
Saul Walker

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1. EXECUTIVE SUMMARY

As scientific efforts to develop effective microbicides advance, the next great challenge is ensuring that women in developing countries can access and use this new HIV-prevention technology. Similar challenges have confronted the reproductive health field over the past four decades as new contraceptive technologies emerged from research and development and were introduced into family planning programmes. Examining these experiences offers lessons that may benefit microbicide access efforts.

A review of the introduction histories of three novel contraceptives – intra-uterine devices (IUDs), implants and female condoms – offers valuable lessons for the introduction of microbicides. Such a review also highlights many common challenges with new technologies. Unanticipated problems have limited use of these methods in many countries and resulted in skewed utilisation patterns across regions. Political, ethical and religious opposition in some countries has prevented widespread use. Lack of sustained donor support and inadequate funding and distribution of supplies continue to be problems. The initial enthusiasm for each new method by the sponsoring agency or donor frequently faded in the face of negative attitudes and media reports. In some cases, interest in second-generation products has contributed to a continuing "roller-coaster" of positive and negative attitudes.

Contraceptive services have been provided through a mix of civil society, government, social marketing and private channels. These same sectors will be important for generating demand and achieving high coverage rates for future microbicides. Civil society organisations in the family planning field helped demonstrate demand and have been innovative risk-takers, but many are limited in scale. The government sector often strives to provide services to all, especially the poor, but inadequate human resources and infrastructure have often resulted in low coverage, unreliable availability and variable quality of care. Social marketing in many settings has been effective in generating demand and getting subsidised products and services to specific groups, although some have raised concerns that the very poor may be excluded due to co-payments. The private sector generally reaches those willing to pay more for products and services, and is most sustainable from the perspective of international donors, but lacks adequate coverage. In the absence of regulatory oversight, poor quality services and goods and/or high prices can pose problems with private sector provision.

The following lessons learned from the introduction and distribution of contraceptive technologies can benefit planning for microbicide access:

1. **Beware the "magic bullet syndrome."** Set realistic targets for uptake and impact.

2. **Cost matters.** Product and programme costs will influence donor/policy maker decisions on introduction and scale-up. Cost-effectiveness analyses will be important to inform policy decisions.

3. **Choice matters.** Providing a range of

prevention options is important to meet individual users' changing needs and preferences.

4. **Strong, sustained stakeholder support.** Ensuring policy-level approval, donor and provider support, and user demand is necessary at many levels.

5. **Perseverance is essential.** Establishing widespread supply and demand for a new technology takes years, and long-term planning that accommodates inevitable setbacks is important.

6. **Pay close attention to real and perceived method side-effects and media response.** Addressing user concerns as they arise can help avert later problems and potentially devastating media responses.

7. **Strong procurement and logistics systems are essential.** Ensuring effective distribution and avoiding stock-outs is vital.

8. **Every country and cultural setting is different.** Appropriate positioning and pricing of microbicides depends on a good understanding of the local context, including gender relations.

9. **Build on existing health structures.** Capitalise on the multiple delivery channels established by existing HIV/AIDS and sexual and reproductive health programmes. New vertical programmes may support rapid introduction, but are often difficult to sustain and rely on continued prioritisation by donor and country policy makers.

10. **Plan for scale-up.** From the outset, build the evidence base for funding and support. Defining what constitutes early success is essential for managing expectations.

11. **Second-generation products offer new access opportunities.** These may need renewed marketing to justify price increases and overcome any problems associated with first-generation microbicides.

12. **Expect the unexpected.** Be quick to respond.

The current focus and popular support for an intensified and comprehensive global response to HIV and AIDS is unprecedented in global health. This commitment and the new resources it brings may provide opportunities for accelerated microbicide introduction by mitigating some of the constraints faced by contraceptive technology introduction and scale-up. Further research and modelling can help illuminate how changing environments and the specific qualities of an eventual microbicide will affect product introduction. At the same time, however, many of the challenges noted above are likely to remain salient. Successful microbicide introduction will require both learning from the past and anticipation of future opportunities and challenges.

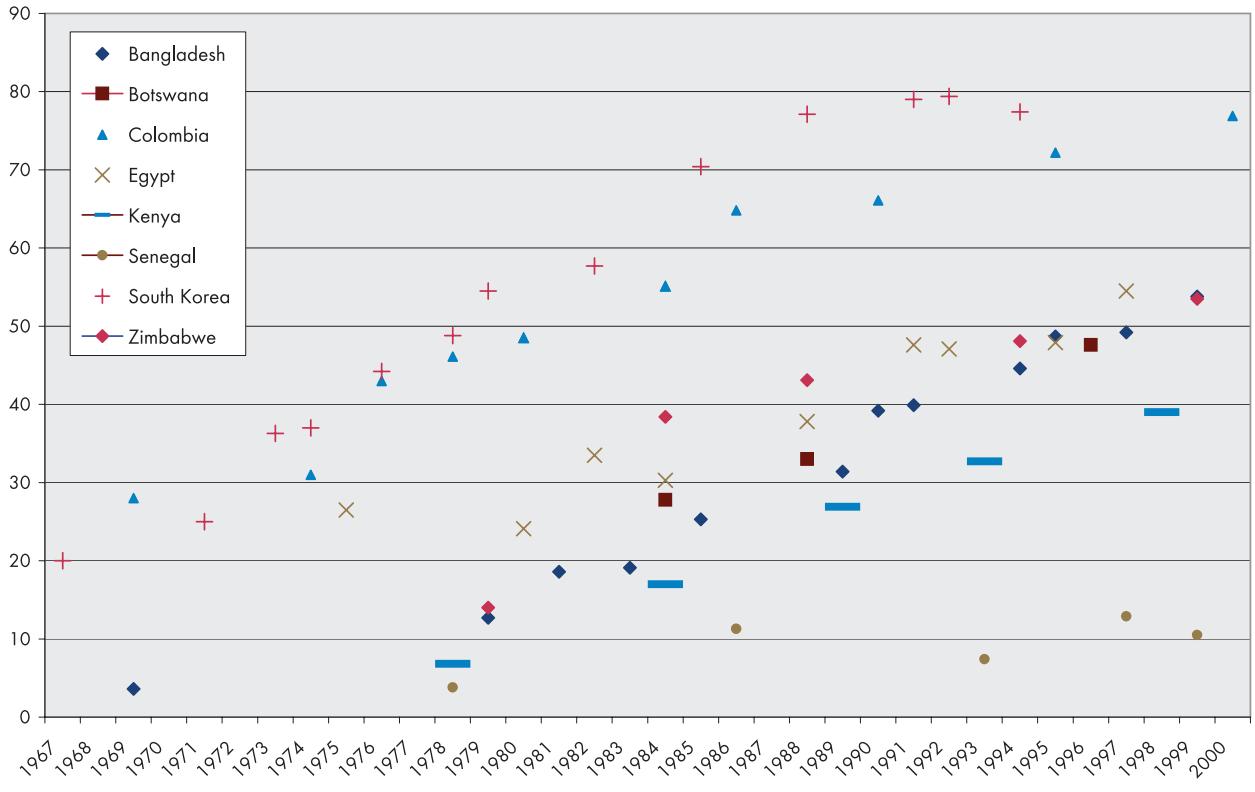
2. THE CONTRACEPTIVE REVOLUTION

The "contraceptive revolution" of the past four decades represents one of the most effective programmes in the history of international development (Bulatao 1998a). Since the 1960s, fertility rates in the developing world have dropped dramatically, from more than six children per woman to three, and contraceptive prevalence has risen from less than ten percent in 1960 to 60 percent in 2005 (Ross, Stover and Adelaja 2005). While other development advances, notably improved female literacy, economic growth, poverty reduction and urbanisation, are major factors, the efforts of family planning programmes to make contraceptive information and services available to millions of women and men have significantly influenced this dramatic decline (Bongaarts 1997; Ross and Stover 2001). These achievements have been greatest in Southeast Asia, Latin America, North Africa and the Middle East (ORC Macro 2006).

International efforts to provide family planning information and services began in the late 1950s when increased attention was directed towards the rapid rate of population growth in the developing world and its negative impact on economic development, the environment and food production (e.g., Coale and Hoover 1958).

In the early 1960s, new technologies, notably oral contraceptives and modern intra-uterine

Figure 1: Percent of currently married women (ages 15-49) using contraception, by year (Source: US Census Bureau 2006): sub-Saharan African countries indicated in green



devices (IUDs), became available. Many public health and population experts expected that adoption of these methods would quickly reduce fertility rates (Freedman 1966).

As Figure 1 makes clear, however, widespread use of contraception took decades to achieve, particularly in some of the sub-Saharan African countries. At present, despite nearly half a century of modern family planning programming, 201 million women globally – 30 percent of women at risk of unintended pregnancy – need family planning services to meet their reproductive goals but are not using any contraceptive method (Singh et al. 2004).

Providing a wide range of contraceptive options expands choices for women and has been shown to increase overall contraceptive use. However, the contraceptive method mix among countries varies enormously, and at least 34 countries rely on a single method for more than 50 percent of all use (Sullivan et al. 2006). Many country-specific reasons explain these skewed patterns of use, including user preferences, provider biases and restrictive government policies. These same factors will influence use of existing and future HIV-prevention technologies, including microbicides.

The way a product is initially introduced has a significant impact on its future market share, which, in part, explains the widely different patterns of contraceptive method choice from country to country. The introduction histories of three contraceptive technologies – IUDs, implants and female condoms – offer lessons for future microbicide access efforts. These three methods were chosen because each presented a novel form of contraception at the time of introduction; was introduced with a planned and sustained international access effort; experienced and documented successes, challenges and failures; and saw the introduction of next-generation technologies within the same product line.
The channels through which a product reaches consumers also affects end-users' access to and use of the product. This paper will examine four delivery approaches that have been used in contraceptive distribution – public sector, civil society, social marketing and the private sector – for their applicability to microbicide introduction.

3. PRODUCT INTRODUCTIONS

INTRA-UTERINE DEVICES (IUDS)

The IUD is the most popular reversible modern contraceptive method in the world (UN 2004), but its use varies greatly by region and by country. The Copper T380A IUD is a T-shaped plastic device covered with copper. Inserted into the uterus by a minor gynaecological procedure, it is highly effective for up to 12 years. Its side-effects include inter-menstrual bleeding and cramping. Expulsion can also sometimes occur. The device is probably the world's most cost-effective contraceptive, costing about US$1.50 for public sector use (Appendix 1), and is available in most parts of the world. In 2003, the United Nations (UN) estimated there were 145 million IUD users worldwide. This number is heavily influenced by China, which has 96 million IUD users, or two-thirds of the world's total. Notably, India and sub-Saharan Africa have very low rates of IUD use (see Table 1).

Table 1: Percentage of women of reproductive age in married or consensual unions using IUDs (Source: UN 2003)

High Use
China and Vietnam (36 - 38%) Former Soviet Union (9 - 56%) Scandinavia, France (20 - 36%) Egypt, Lebanon, Syria, Turkey, Jordan, Tunisia (15 - 36%) Cuba (44%)
Moderate Use
Eight Latin American countries (10 - 14%) Iran, Indonesia (8%)
Negligible Use
Sub-Saharan, East and West Africa (1 - 4%) Asia, excluding China and Vietnam (0 - 5%) India (2%) Brazil (1%) North America (1%)

History of Introduction

As the first national family planning programmes were being established in the early 1960s, the first modern IUD – the Lippes Loop, an inert plastic device – was introduced. Many international and national policy makers believed that the IUD, requiring a single insertion and no need for repeated action by the user, was the key to family planning success in countries with low literacy (Freedman 1966). While early programmes promoted the "cafeteria approach" to contraceptive services, ostensibly making all methods available, special efforts were made to accelerate IUD use. International conferences on the IUD took place in 1962 and 1964 to mobilise the support of key international policy makers and health officials. By 1970, improved copper-bearing IUDs became available, culminating in the Copper T380A.

The IUD was popular in the United States (US) in the 1960s, but use declined substantially in the 1970s following the introduction of a defective device, the Dalkon Shield, which caused uterine infections and some deaths. Although this device was withdrawn from the market by the late 1970s, negative attitudes about IUDs, including the misconception that all IUDs carry a risk of pelvic infection, have lingered (Espey and Ogburn 2002). The Dalkon Shield experience also had a ripple effect in some developing countries, raising fears of infection with IUD use. However, most European countries continue to have moderate to high levels of IUD use (UN 2004).

A newer, progestin-releasing IUD, Mirena, was introduced in 1990. It is as effective as the Copper T, but causes less bleeding. As it is more expensive than the T380A (about US$22.00 in the public sector), it has had limited use in developing countries. The possibility of lowering the price through bulk or generic manufacture is under consideration, and other progestin-releasing IUDs are being developed. Several donor agencies are currently supporting efforts to increase IUD use in selected African countries, with some initial success (Jacobstein and McGinn 2005).

Factors Affecting the Skewed Use of IUDs

As one of the few modern contraceptives available in the 1960s, the IUD, along with oral contraceptives and female sterilisation, became institutionalised in more mature family planning programmes (Bulatao 1998b). However, as seen in Table 1, IUD use varies substantially by region. Factors contributing to this skewed uptake include:

Country-specific and cultural factors: The IUD is popular in certain countries for specific reasons. For example, in China, the government's population limitation policies play a major role in urging, and sometimes requiring, IUD use. In Egypt, the Islamic objection to sterilisation contributes to relatively greater use of IUDs. A negative attitude towards oral contraceptives, deemed unsafe during Soviet times, has carried over in several former Soviet republics in Central Asia and has resulted in high IUD use, despite efforts by the government to promote other methods (Sullivan et al. 2006). Similarly, in Vietnam, misconceptions about other products preclude their uptake and favour use of IUDs (Do Trong et al. 1995).

Health care provider support and training: Studies in low-use countries, including Ghana, Guatemala and Kenya (Osei et al. 2005; Population Council 2004; Stanback and Omondi-Odhiambo 1995), show that health care providers are often biased against the IUD, lack adequate training in insertion techniques, and may provide IUD patients with poor care and inadequate counselling about side-effects. In Egypt, on the other hand, the availability of a large pool of physicians trained in performing IUD insertions contributed to greater use of the method. In general, while programme managers tend to like the IUD for its cost-effectiveness, overworked providers often see it as cumbersome due to the relatively time-consuming gynaecological procedure required.

Popularity of competing products: In much of Africa, injectable hormonal contraception (primarily Depo-Provera) has supplanted the IUD as the long-acting method of choice. In Kenya, for example, IUD use among married women dropped from 3.7 percent in 1989 to 2.4 percent in 2003, while injectable use increased over the same period from 3.3 percent to 14.3 percent (Ross, Stover and Adelaja 2005).

From the history of IUD introduction, the following lessons can be learned:

- Cost matters. The cost-effectiveness of the IUD drove its substantial early support, particularly among programme managers and donors, and led to the institutionalisation and continued popularity of the method among many of the family planning programmes established in the 1960s.

- Strong, sustained stakeholder support is needed at many levels. While programme managers and donors like the IUD, a lack of commitment or inadequate training among health care providers has limited its use in many settings.

- Real and perceived method side-effects can limit uptake of a method for many years, and may have ripple effects, as in the case of the Dalkon Shield.

- Every country and cultural setting is different and methods may need to be positioned differently in different contexts.

- Second-generation products, like Mirena, may have benefits appealing to new users, but can also present new barriers (such as cost).

- Expect the unexpected and be quick to respond. The Dalkon Shield experience continues to taint user perceptions of all IUDs, even 30 years later.

IMPLANT CONTRACEPTION

Norplant, the first hormonal implant contraceptive, consists of six plastic capsules filled with levonorgestrel, a progestin commonly used in oral contraceptives. The capsules are inserted under the skin on the inside of the upper arm in a simple clinical procedure using local anaesthesia. The device is highly effective for up to seven years, and can be removed at any time by trained personnel. Side-effects include spotting, bleeding and amenorrhea. While more expensive than the IUD (US$23 per set in the public sector), Norplant is another highly effective, long-acting and reversible contraceptive method (see Appendix 1).

Although enthusiastically introduced internationally in the late 1980s and 1990s, Norplant currently accounts for less than one percent of overall contraceptive use in most parts of the developing world, with the exception of Indonesia, where the method is used by almost five percent of married women (ORC Macro 2006).

History of Introduction

The concept of a long-acting contraceptive implant was first proposed in 1966. After 17 years of development by the Population Council, Norplant was approved in Finland, the country of manufacture, in 1983. Programme managers, international agencies, donors and clinicians were enthusiastic about Norplant because it is highly effective, requires only a single clinic visit and demands no repeated action by the user. Unlike inserting an IUD, inserting Norplant requires no gynaecological procedure, and early acceptability studies indicated that women were generally positive about the method. For all these reasons, it was widely thought that Norplant would make a major contribution to family planning programmes in developing countries.

Extensive international clinical trials and acceptability studies were followed by a vigorous international access programme, led by the Population Council, Family Health International, other international nongovernmental organisations (NGOs) and the World Health Organization (WHO). Beginning in 1984, a series of thirty "pre-introduction studies" were conducted in all regions of the developing world, with countries selected on the basis of their interest, viable clinic capacity, potential to serve as models within their region and provision of a range of contraceptive choices. These novel studies, lasting several years, tested the product under local conditions and measured acceptance, continued use, safety and efficacy. The transfer of clinical and counselling skills was a key component, and prototype training materials were developed (Population Council 2007; Grubb, Moore and Anderson 1995; Harrison and Rosenfield 1998).

User acceptability studies revealed some country- and cultural-specific concerns. For example, in some Muslim countries, irregular bleeding was a problem for women who were expected to abstain from intercourse during menses. In addition, in some settings health care providers were seen to be overly directive in encouraging women to adopt the new method. Overall, however, these pre-introduction studies were considered to be successful, and in several countries served as the basis for subsequent larger-scale introduction (Grubb, Moore and Anderson 1995).

By 2002, 62 countries had given regulatory approval to Norplant, three international training centres had been established and several countries began expansion of services to the national level. A major post-marketing surveillance survey, undertaken by WHO, was highly positive (Meirik et al. 2001).

However, problems and constraints emerged over time: lack of trained personnel, weak counselling about side-effects, problems with removal, occasional reluctance by some clinicians to remove Norplant at the client's request and user complaints that side-effects were sometimes ignored or minimised by providers. It was also sometimes difficult to track clients to ensure they returned to have their implants removed after five to seven years.

The US Food and Drug Administration (FDA) approved Norplant in 1990, and the method was introduced in the US in 1991 by the US manufacturer, Wyeth-Ayerst. Wyeth adapted elements of the international introduction experience in its marketing efforts, and high levels of enthusiasm and rapid roll-out resulted in the training of many physicians and high initial uptake totalling over one million units in the first year. However, significant negative publicity was generated by isolated instances of legal attempts to require Norplant use as a part of court sentences and proposed mandatory use by several states.[1] Bleeding and removal problems and other real or imagined side-effects were also magnified by the media. Major lawsuits resulted and, although none were successful, Norplant was nonetheless withdrawn from the US market in 2002.[2] Following litigation in the United Kingdom, Norplant was withdrawn from that market as well (Harrison and Rosenfield 1998).

The Population Council began testing a second generation implant, Jadelle, in 1977. Jadelle was approved in Finland and by the FDA in 1996, initially as a three-year method, and then extended to five years in 2001. Consisting of two solid plastic rods impregnated with levonorgestrel, Jadelle is easier to manufacture, insert and remove than Norplant, but has the same effectiveness and duration of use (Population Council 2007). Jadelle's public sector price is similar to that of Norplant. Wyeth

[1] A few judges and legislators seized upon the opportunity presented by Norplant to employ the product coercively by requiring that certain individuals have Norplant inserted in lieu of jail sentences.

[2] Bleeding problems and difficulty in removal of improperly inserted capsules were picked up in the media. Lawyers seized on these issues, as well as imagined auto-immune problems linked to the silicone in the capsules. (The launch of Norplant followed soon after major legal action against companies manufacturing silicone breast implants, and the same group of lawyers led the litigation against Norplant.) Thousands of lawsuits resulted and negative media accounts played up the controversy. While none of the lawsuits were successful in court, the burden on the company in defending them, and the damage done to the reputation of Norplant were devastating.

has declined thus far to introduce Jadelle into the US market, but the product has been approved in Europe and has significant levels of acceptance in several European countries. A new programme to introduce Jadelle at no cost into developing countries has been initiated by the provider, through a new entity, the ICA Foundation.

Another second-generation implant, Implanon, was approved by the FDA in 2006. It is a single rod device containing another progestin, etonogestrel, and is effective for three years. As a single implant pre-loaded in its inserter, it is easier to use. A Chinese implant, Sinoplant, which is similar to Jadelle has also been developed. It is available in China and Indonesia. Side-effects of all three types of implant are similar.

From 1984 to 2002 an estimated 10.5 million Norplant sets had been used. Jadelle has now largely displaced Norplant in developed countries. Limited efforts are ongoing to expand Jadelle, Implanon and Sinoplant use in developing countries. It is possible that these three improved implants could renew interest in implant contraception and expand use in some developing countries, but this remains to be seen.

Factors Hampering the Uptake of Implants

Most of the problems and constraints inherent in the application of implant technology in developing countries were identified before wide-scale use. However, overall enthusiasm for the method was so strong that positive momentum was maintained for many years. The major constraints were:

Cost: The cost of Norplant was a major issue from the outset, but donor enthusiasm and financial support for introduction activities enabled the work to go forward, and minimised initial governmental concerns about the high cost of Norplant and the substantial programmatic costs for training. Over five to seven years, it was argued, the cost of Norplant would approach that of oral contraceptives over a similar period. In practice, however, average duration of use ranged from 2.5 to 3.5 years.

Health care provider support and training: Like the IUD, implants must be inserted by a health professional. Many countries have had difficulty training sufficient numbers of providers. In addition to insertion techniques, providers need training in good counselling skills and positive provider-client relations.

Side-effects: While side-effects were well-known and carefully measured, they were not considered to be major problems in the early phase of research and initial introduction, as long as women were thoroughly counselled before accepting the method. This proved to be difficult in many settings, and side-effects – while generally mild – still remain limiting factors in some countries.

Directive and coercive behaviour: While the sponsoring agencies made every effort to ensure voluntary acceptance and informed choice, isolated instances of coercive use resulted in much negative publicity. In developing countries, the sponsoring agencies insisted that implants be offered by well-trained providers in a voluntary fashion as one of several available contraceptive options. However, high levels of

enthusiasm by health providers occasionally resulted in overly directive actions.

Failure to manage expectations: This novel contraceptive technology attracted a great deal of media attention, and initial efforts were made to ensure that careful, balanced information was provided to the media. As Norplant began to be made available, however, overly enthusiastic publicity quickly emerged, some of it dramatically overselling the method. This was followed by highly negative media coverage as the problems described above surfaced.

From the history of Norplant introduction, the following lessons can be learned:

- Beware the "magic bullet syndrome." Norplant was heralded at the outset as a major breakthrough, which heightened expectations and thus magnified disappointments as the method ran into difficulties.

- Cost matters. Despite initial enthusiasm and willingness to pay on the part of donors and programme managers, the relatively high initial cost of Norplant remains a significant hurdle.

- Choice matters. Concerns that health care providers and legal authorities were pressuring women to choose Norplant have resulted in negative publicity and resistance to the method.

- Real and perceived method side-effects should be taken seriously, and health care providers must be well-trained in counselling women in what to expect when using a method (not simply in insertion and removal).

- Second-generation products, such as Jadelle and Implanon, may provide opportunities to attract new users.

- Expect the unexpected and be quick to respond. Despite careful pre-introduction studies, new and magnified concerns arose as Norplant services were expanded.

FEMALE CONDOM

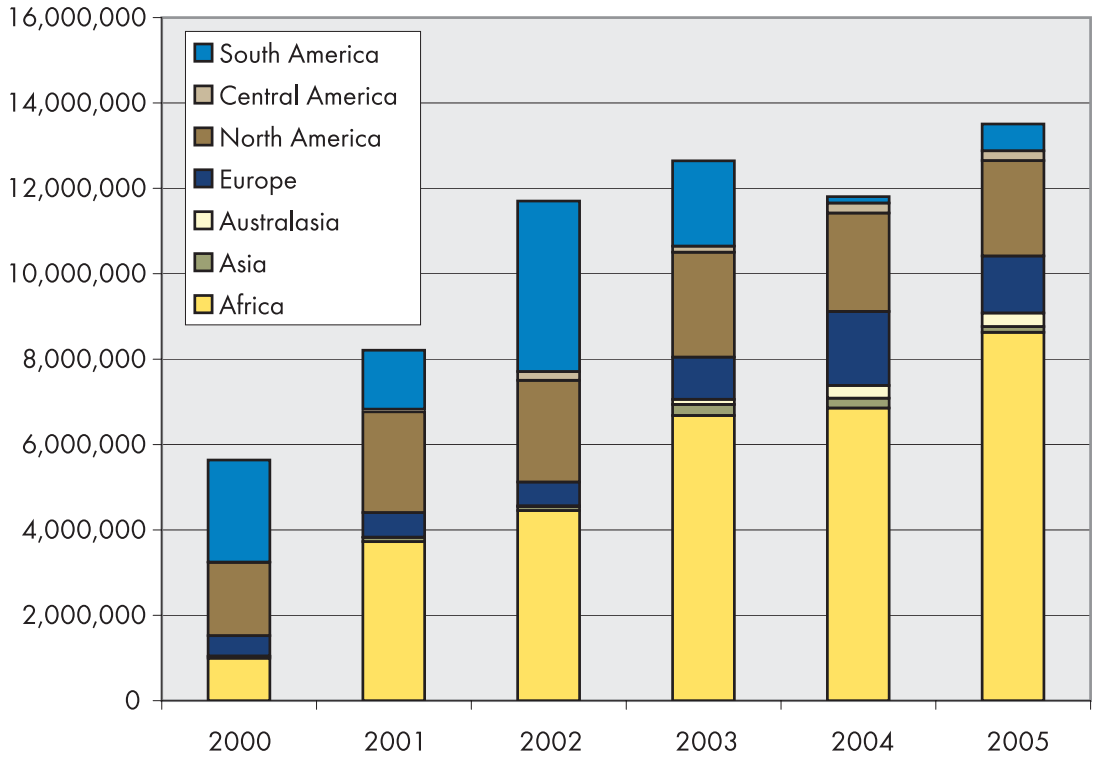
The female condom is the first HIV-prevention technology developed since the onset of the AIDS epidemic. It provides the only female-initiated means to prevent both sexually transmitted infections (STIs) and pregnancy. The most widely available type[3], FC, is a thin polyurethane sac with a flexible internal ring inserted into the vagina, and an outer ring used to hold it in place outside the vagina. When properly and consistently used, it is highly effective in preventing HIV and STI transmission, and is also an effective contraceptive (see Appendix 1). It has virtually no side-effects. FC has a public sector price of approximately US$0.68 per unit (PATH 2006).

History of Introduction

The FC female condom was approved as a contraceptive by the FDA in 1993. Since the mid-1990s, FC has been marketed in 90

[3] Two other female condoms, the V'Amour Female Condom and the Natural Sensation Panty Condom are in limited distribution but have not been approved by the FDA and are not procured by major donors.

Figure 2: Number of female condoms in public and private sectors by region, 2000-2005 (Source: UNFPA 2006)



developing countries by its manufacturer, the Female Health Company; by social marketing organisations; and by national health and AIDS programmes, with the support of UNAIDS and several donor institutions. More than 100 million female condoms have been distributed, of which approximately 12 million were distributed annually in developing countries in recent years (see Figure 2). In contrast, six to nine billion male condoms are distributed each year.

Research has demonstrated high initial acceptability in a number of different cultures and social groups (Cecil et al. 1998; Van Devanter et al. 2002; Choi et al. 2003). Evidence on longer-term acceptability is less clear. Various studies have also shown an increase in protected sex acts when female condoms are added to the method mix (Musaba et al. 1998; Fontanet et al. 1998; Hatzell Hoke 2005). Commercial sex workers have successfully used female condoms, often as an alternative to male condoms. Gender power relations are a critical aspect of negotiating female condom use, and require special attention in each cultural setting (Mantell et al. 2001). Limited acceptability studies of female condom use among men have also been generally encouraging.

By far the most successful programmes are in Brazil, South Africa and Zimbabwe (Warren and Philpott 2003; PATH 2006). Modest social marketing efforts continue in Venezuela, Zambia and Tanzania. In other countries, lack of sustained programme support and funding has

resulted in very poor access and low levels of use. Donor support has been uneven and rarely sustained over several years.
Efforts have been made to lower the per-use cost of the female condom by bulk purchase, reuse or new product design. Reuse of the female condom by washing with a detergent has been successfully tested (Beksinska et al. 2001). Whether reuse could be successfully implemented on a large scale is unclear, but it would certainly bring down the cost per coital act. WHO does not recommend reuse but says the final decision should be made locally and has issued guidelines for safe and effective reuse.

A second-generation product, FC2, made of synthetic latex, is easier to mass produce. With very large bulk orders (200 million units), the price of the FC2 could drop to US$0.31 per unit, although such large orders seem unrealistic at this time (PATH and UNFPA 2006).

Other female condoms under development include the Woman's Condom, a new V'Amour condom, the Silk Parasol Female Panty Condom and the Belgian Female Condom (PATH 2006). However, all depend on funding for several more years of research. It is not clear whether these alternative female condoms will be significantly cheaper than the currently available model (though the product design may potentially be more acceptable to some users).

Periodic international and national advocacy efforts in support of female condoms have been undertaken over the past decade, with the Joint United Nations Programme on HIV/AIDS (UNAIDS), WHO, European Union and other international and national groups calling for increased availability of female condoms. In 2005, the United Nations Population Fund (UNFPA) launched the Global Female Condom Initiative which aims to scale-up female condom programming in 28 countries (PATH and UNFPA 2006). NGOs and grassroots campaigns have also contributed, as in the case of Zimbabwe where women's groups organised a petition with 30,000 signatures to pressure the government into introducing female condoms in the country. A recent international meeting on female condoms called for another round of advocacy and led to the development of a document, "Female Condom: A Powerful Tool for Protection," to promote the method (PATH 2006). Despite these substantial efforts, thus far there has not been sustained acceptance of female condoms as an important component of international HIV-prevention efforts.

Factors Hampering the Uptake of the Female Condom

Despite the great promise of the female condom as a female-initiated way to prevent both STIs and unwanted pregnancies, in most settings, the method has not taken hold. Some of the problems have been:

Cost: The public sector unit price of female condoms is many times that of a male condom. However, cost-effectiveness analyses have demonstrated that female condoms offer substantial health care savings. A South African modelling analysis showed that a relatively modest investment in distributing female condoms to sex workers would be less than half the otherwise resulting cost of treatment of HIV and other STIs. The comparison of the

unit costs of female and male condoms is very large, but when full programme costs are included the difference between the two is dramatically reduced (PATH and UNFPA 2006).

Usability factors: The physical appearance of female condoms sometimes evokes an initial negative reaction, as it is perceived to be cumbersome and difficult to insert, and some users complain about noise during coitus. Female condoms also face the stigma attached to any barrier method for HIV prevention or any vaginal product. Although the female condom is a female-initiated method, it is visible and therefore requires partner concurrence. This can be a negative feature, but also presents an opportunity for male involvement. As with all barrier methods, the need for insertion before intercourse is a significant challenge, although, unlike the male condom, the female condom is not coitally dependent and can be inserted several hours prior to intercourse.

Provider reactions: The 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.

Comparison with male condoms: Negative views of male condoms are often similarly levelled at female condoms. While male and female condoms do share many characteristics, the female condom is nonetheless the only female-initiated product available for HIV prevention. Yet, with a few country exceptions, female condoms have not benefited from sustained introduction, marketing and financing programmes.

Lack of strategic programme introduction: In the few countries that have seen sustained uptake, the governments have made long-term commitments to providing female condoms. Grassroots and women's groups also gave support, strong social marketing programmes were established and donors – as well as the governments themselves – provided sustained financial support. The most successful programmes have been sensitive to local attitudes and conditions. Marketing strategies, in some cases, have emphasised enhanced sexual pleasure with female condoms, an approach that has also been used successfully with male condoms and vaginal spermicides.

From the introduction history of the female condom, the following lessons can be learned:

- Cost matters. The expense of the female condom relative to male condoms has been a significant barrier to uptake. In addition to ongoing efforts to reduce costs, cost-effectiveness analyses showing the longer-term potential for savings should be used to inform policy and programming decisions.

- Choice matters. Even though billions more male than female condoms are distributed each year, adding the female condom to the method mix has successfully increased the proportion of sex acts that are protected, suggesting that offering another option attracts users who would otherwise not be using any method of protection.

- Strong, sustained stakeholder support is needed at many levels. A lack of enthusiasm among donors, programme managers and providers, despite positive acceptability

studies, has been a significant problem for the female condom.

- Perseverance is essential. The countries that have seen the greatest success with the female condom have made long-term commitments to providing the method. It is hoped that ongoing efforts among advocates and NGOs to promote the method will, over time, broaden access and funding.

4. CONTRACEPTIVE PROVISION

A critical element in the introduction and ongoing success of any product is having adequate capacity to get relevant and high quality information, supplies and services to users. In the case of family planning, four main sectors – civil society, government, social marketing and private – have responded to the information and service needs of different populations. Reviewing the roles these different sectors have played in contraceptive service provision offers some useful lessons for potential roles in developing access for microbicides.

CIVIL SOCIETY

Advocacy and Demonstration of Demand and Quality

The idea that contraceptives should be made widely available for women's use emerged in the US and Europe in the first half of the twentieth century, through the work of pioneers like Margaret Sanger, whose efforts led to the creation of the International Planned Parenthood Federation (IPPF). The growth of family planning in the developing world was initially driven by the advocacy and consensus-building initiatives of civil society organisations such as IPPF, the Ford and Rockefeller Foundations and the Population Council (Seltzer 2002). These initial efforts were crucial in demonstrating the need for family planning (in terms of women's expressed desires to limit family size or space pregnancies) and building demand among women in many countries.

Overcoming stigma, government inertia and religious opposition to family planning have been enormous and ongoing struggles in many countries, with civil society groups always in the forefront. Civil society groups have also been important in directly providing high-quality services. In Colombia, for example, Profamilia, the local IPPF affiliate (with tacit support from the government), established an effective national family planning programme and became the primary provider of reproductive health services throughout the country because the government was unwilling to take on religious opposition and initiate a programme itself.

However, in most cases, civil society groups have not been able to provide high-quality services on a large scale. And cultural and religious beliefs can make the provision of family planning services sensitive for some civil society organisations. For example, in Tanzania, where faith-based groups provide around 40 percent of healthcare services, condoms are not provided in faith-based hospitals and clinics (Strategies for Enhancing Access to Medicines 2001).

Similarly, many civil society groups have been established to advocate for greater political attention to AIDS, and to provide healthcare and support. Treatment advocacy groups, organisations of people living with HIV, women's groups and faith-based organisations have been key actors. The early advocacy work of ACT/UP in the US was extremely effective, and has led to the creation of many similar advocacy groups, including the Treatment Action Campaign in South Africa, The AIDS Support Organisation (TASO) of Uganda, the International HIV/AIDS Alliance, the International Council on AIDS Service Organizations (ICASO) and the Society for Women and AIDS in Africa (SWAA).

To date, there has been limited integration of civil society provision of family planning and broader sexual and reproductive health (SRH) services with HIV/AIDS advocacy and services. The existence of different funding streams, an initial focus among HIV/AIDS organisations on care for people living with HIV and, in some instances, a focus on work with marginalised communities who are not always well-served by SRH-focused organisations all helped institutionalise a new, separate set of organisations and activities to address HIV/AIDS in some countries. Donor conditionalities on funding (e.g., the US "Mexico City policy," which denies funding to organisations providing abortion counselling or services) may have also encouraged the separation of SRH and HIV/AIDS services. However, despite some operational challenges and different emphases between the two fields, links between SRH and HIV/AIDS are now being made (Interact Worldwide 2006; IPPF 2006).

Microbicides will be used by reproductive-age women, who are often already served by family planning and reproductive health organisations. Microbicide introduction will require community mobilisation and support, and would benefit from improved civil society coordination on SRH and HIV/AIDS.

GOVERNMENT PROGRAMMES

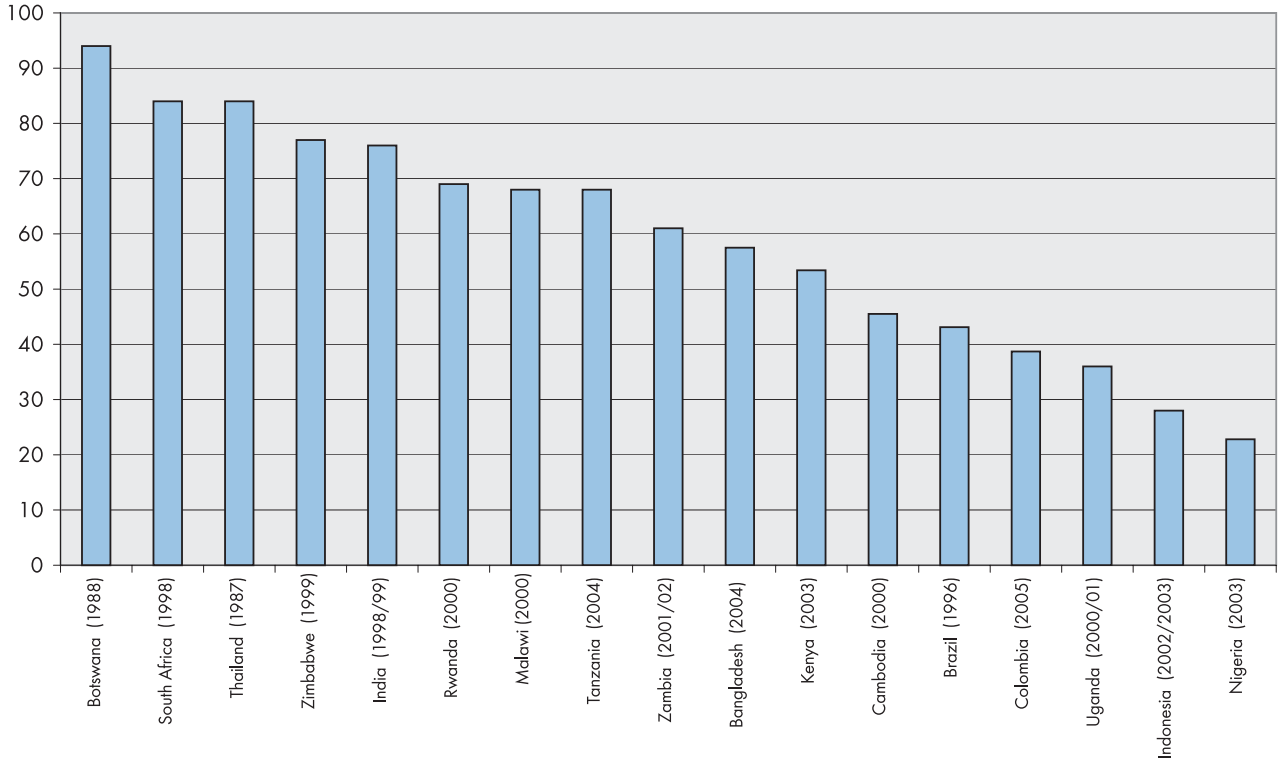
Providing Access to Services for the Poor

Government health services play an important role in providing family planning services (see Figure 3). The first government-led national family planning programme was launched in India in 1959, followed by other countries in the 1960s and 1970s. By 1976, seven in ten developing country governments (109 countries) provided some form of support for contraception. By 2001, this number had increased to 184 countries (UN 2003).

In addition to establishing programmes to directly provide services, governmental support has facilitated access to contraceptives by publicly legitimising family planning, educating the public, addressing cultural or professional opposition and supporting a range of national policy initiatives, such as increasing the minimum age-at-marriage, allowing tax-free importation of supplies and removing laws that might inhibit programme implementation (e.g., regarding provision of family planning information to key populations).

Historically, the majority of international donor support for reproductive health and family planning has gone to governments. Initially, donors supported independent vertical

Figure 3: Source of supply of modern contraceptive methods in select countries, % public sector (survey year) (Source: ORC MACRO 2006)



government family planning programmes because Ministries of Health were often slow to accept family planning and governments struggled to include it in existing health service structures. A prominent example is the Indonesian National Family Planning Board, which was created as a cabinet-level entity with a successful national programme operating independently from the Ministry of Health. While the vertical approach permitted the rapid development of dedicated national programmes and made it easier to measure family planning efforts, it often failed to integrate family planning into broader health programmes and infrastructure, and made projects vulnerable to changes in donor priorities. Over time, maternal and child health services incorporated family planning into their larger programmes and, following the Cairo Conference in 1994, integration of reproductive health/family planning into national health systems became the norm.

However, public health systems and government programmes, particularly in sub-Saharan African and South Asia, are often highly constrained by inadequate funding (compounded by unreliable donor support), weak infrastructure and severe staff shortages. These constraints result in low service coverage (especially in rural areas), stock-outs and poor quality of care. Low expectations of public sector services often lead to low service utilisation rates, with many people resorting to faith-based and other civil society organisations or private sector providers for

health commodities or services (Mendis et al. 2007; Ewen and Dey 2005).

In the government sector, just as within civil society, much HIV funding and programming is being delivered vertically and in parallel to other health financing and funding. While this has supported rapid increases in HIV services, concerns have been raised regarding the sustainability of these new structures, and about the risk of diverting resources away from existing broader and already strained systems. In recognition, more emphasis is now being placed on approaches to scale up HIV-prevention and treatment services in ways that can strengthen health systems (WHO 2003), including greater linkages with SRH services (WHO/UNFPA/IPPF 2005). The outcome of these approaches will be important for decisions on the initial introduction, scale-up and long-term sustainability of microbicide access.

SOCIAL MARKETING

Niche between Public and Private Sectors

Social marketing occupies a niche between the public and private sectors, using private sector marketing methodologies and distribution channels to promote public health. Social marketing programmes focus on creating demand for services, brands or health in general, and behaviour change. By providing easy and reliable access to low-cost, quality-assured products, social marketing programmes have increased coverage and consistency of service use or behaviour change in its target populations.

Social marketing for family planning began in the 1960s to promote wider condom use. It spread throughout South Asia in the 1970s and in other regions during the 1980s. Social marketing organisations – both national and international – proliferated following the advent of the HIV/AIDS epidemic. Today, the focus on family planning and HIV and STI prevention remain, but the social marketing field has broadened to include products for malaria prevention, nutrition, water treatment and other health issues (Population Services International 2006).

Social marketing product and programme costs are usually subsidised by international donors, who invest approximately US$350 million annually in social marketing programmes (Institute for Health Sector Development 2004). In 2005, social marketing provided approximately five percent of all couple years of contraceptive protection in developing countries excluding China (DKT International 2006). However, social marketing's share of the contraceptive market varies widely from country to country, from 86 percent in Nigeria to just 2.5 percent in South Africa (Meadley 2003).

Social marketing has been most successful at delivering over-the-counter products, like condoms, but innovative methods have been developed to provide prescription products. For instance, in Sri Lanka, where pills were to be provided only with a prescription, "prescriptions" were printed in newspapers with all the necessary information that women could take to their doctors for signature (Harvey 1997).

Social marketing organisations have begun to develop franchising initiatives to expand access to provider-dependent methods that must be distributed in a clinic. In social franchising, the central organisation provides training, marketing support and branding to retail outlets and clinics, and the outlets (franchisees) agree to provide quality products and services at low prices. For example, in Pakistan the "Green Star" network of family planning clinics and retail outlets provide IUD services to the urban poor. Voucher schemes are also often used to encourage vulnerable clients to visit a clinic for specific services (such as providing subsidy vouchers for insecticide treated nets for malaria prevention to new mothers at antenatal clinics). A prescription-only microbicide may benefit from social marketing innovations such as these.

Social marketing programmes can be less effective at reaching people in rural areas, where low population densities and poor infrastructure increase costs. Some commentators have argued that co-payments usually required by social marketing programmes can provide a barrier to access for the very poor (Sachs 2006), although evidence on the equity of social marketing programmes for different commodities is mixed (Chapman and Astatke 2003). Even with co-payments, however, social marketing programmes require long-term investment by governments and/or donors.

Social marketing excels at identifying and developing market segments, skilful product positioning, market research and demand-generation, all of which are critical components for introducing a new category of product and making such approaches particularly attractive for microbicides. In addition, social marketing organisations already work in the areas of SRH and HIV prevention, two important entry points for microbicides.

PRIVATE SECTOR

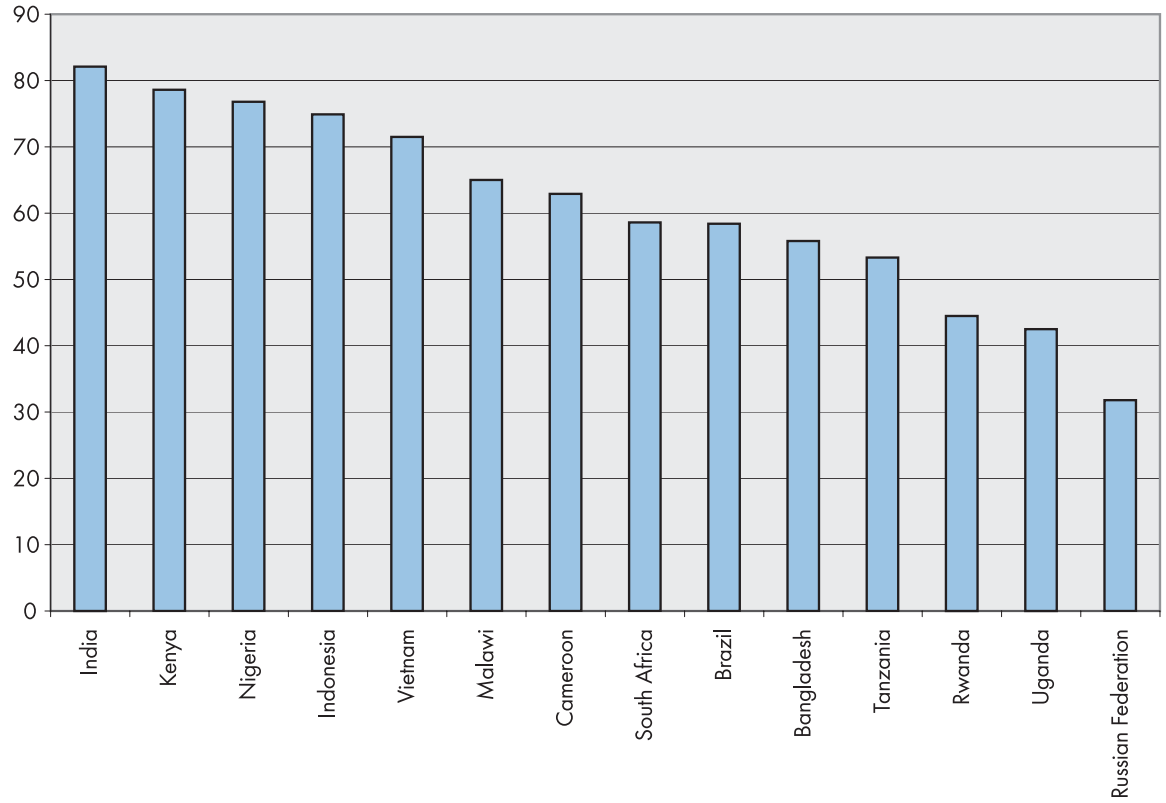
Key to Sustainability?

In many medium- and low-income countries, private expenditure significantly exceeds public spending on health (see Figure 4). Most private spending is for acute treatment rather than preventive services, and as much as 90 percent of out-of-pocket expenditure is for pharmaceuticals (Institute for Health Sector Development 2004).

The private sector could be an attractive delivery channel in certain instances. One study shows that the private sector is preferred to the public sector by young women and adolescents for family planning services in several African countries (Murray et al. 2005). However, it is important to note that more generally, poor women are less likely to use private healthcare services compared to poor men, especially if they do not earn an income (Rakodi 2002).

A country's income is not necessarily a predicator of a vigorous private sector, as evidenced by the robust private sector health activity in poor countries like India and Bangladesh. More important determinants are potential market size, the availability of distribution and promotion channels, and a favourable regulatory and business climate. The concentration of population in urban areas also facilitates commercial sector activity because it reduces distribution and promotion

Figure 4: Private expenditure on health as % of total health expenditure in 2001 (Source: WHO 2004a)



costs (Bulatao 2002). Many development agencies, especially US Agency for International Development, have made efforts to expand the role of the commercial sector in providing contraceptives in order to promote sustainability.

However, the private sector is not a panacea. Regulatory capacity, quality assurance and enforcement are weak in most developing countries (Institute for Health Sector Development 2004). Low quality of drugs and poor prescribing and dispensing are pervasive problems in the private sector (WHO 2004a). This is particularly true in rural and peri-urban areas, where medicines are primarily sold by chemical sellers and general stores that are often unlicensed and have staff with little or no training. Counterfeit drugs also pose a problem: 70 percent of antimalarials in South East Asia and over 50 percent of all drugs tested in Nigeria were found to be counterfeit (Institute for Health Sector Development 2004) and contained little, no or the wrong active ingredients. In addition, high price mark-ups are common and can present a serious affordability barrier to the poor (Ewen and Dey 2005).

The private sector already plays a major role in the delivery of health commodities and provides important distribution outlets for

eventual microbicide access, but improved regulation, quality control and enforcement are needed. Strategies are also needed to better align public health goals and commercial incentives, particularly to improve affordability and rural accessibility.

5. LESSONS FROM CONTRACEPTIVE UPTAKE EXPERIENCES

Encouragingly, substantial new resources are flowing to the health field, much of it spurred by the HIV/AIDS epidemic. Funding for HIV and AIDS efforts in developing countries increased 28 fold between 1996 and 2005, reaching an estimated total of US$8.3 billion last year (Piot 2006). Innovative health financing mechanisms – such as the Global Fund for AIDS, Tuberculosis and Malaria, the US President's Emergency Plan for AIDS Relief, and the Global Alliance for Vaccines and Immunization – that can commit large sums over longer periods than traditional bilateral funding, could greatly benefit microbicide introduction and scale-up through a variety of distribution channels.

The experiences of family planning programmes suggest that civil society, government, social marketing and private sectors could have mutually supporting roles for microbicide access. Further, it is important to keep in mind that an eventual microbicide will be introduced into settings where some mix of contraceptive products, as well as existing HIV-prevention tools, are already being successfully distributed. Thus, whatever the mix of delivery channels mobilised, joint planning for microbicide introduction and scale-up as part of broader HIV and SRH programmes will be essential.

The experiences of family planning and reproductive health programmes also suggest that the most effective mix of distribution channels will differ from country to country. And new channels and approaches will also be needed in some countries – particularly to reach populations that are currently poorly served, including the many women in sub-Saharan Africa, who lack access to family planning and SRH services.

HIV/AIDS has transformed what is perceived to be achievable in delivering health services in developing countries. Although at an early stage, attention is now being paid to the potential of these HIV resources to build broader health system capacity, and to better integrate HIV and SRH services. The long-term sustainability of microbicide access will depend on supporting existing health structures and capitalising on what is already in place.

LEARNING FROM THE PAST, LOOKING TO THE FUTURE: LESSONS FOR MICROBICIDES

Many lessons for microbicide access can be drawn from the international family planning/sexual and reproductive health movement and its successes and difficulties in reducing fertility rates throughout the world:

1. **Beware the "Magic Bullet Syndrome."** The frequent tendency of sponsoring agencies, researchers and providers to become highly enthusiastic about their newly developed technology can result in great optimism, overselling of the product and insufficient attention given to limitations and constraints. This can lead to disappointment, negative reactions and even abandonment of the method. It is essential to proceed cautiously, recognise product limitations early and examine the potential market in light of existing methods.

2. **Cost Matters.** The unit price of a reproductive health commodity greatly influences consumer and donor decision making. Product price is, however, only one element of total cost: the programmatic costs required to get the product to users are usually several times greater. Cost-effectiveness studies will be essential to determine the true value of microbicides in different settings. Strong and sustained donor and government support, akin to support for male condoms, will be needed if microbicides are to be made widely accessible. Recent interest in international financing mechanisms for new health products may help to offset the apparent burdensome costs of procurement.

3. **Choice Matters.** The family planning field has shown the importance of providing choice to meet individuals' changing needs and preferences. A variety of contraceptive technologies are now available, although local preferences and provider biases have contributed to substantial variations in uptake patterns in different countries. As HIV-prevention options expand, they, too, must respond to different country contexts and changing personal needs. Unlike the gradual growth of contraceptive technologies, the HIV-prevention field faces the prospect of an expansion of options over the next few years, with the potential advent of approaches as diverse as male circumcision, pre-exposure prophylaxis (PrEP) and microbicides. Managing simultaneous introductions of new technologies into existing HIV-prevention and SRH services will require considerable strategic planning and coordination.

4. **Secure Strong, Sustained Stakeholder Support.** The history of the family planning movement emphasises the fundamental importance of building and sustaining support among multiple constituencies and stakeholders, from donors and developing country policy makers to civil society organisations and community leaders. Full understanding of the importance of microbicides by key opinion leaders is essential to long-term success.

The strong and ongoing support of international agency leaders and donors is crucial, as microbicides will require substantial long-term subsidisation. Developing products that women and their partners will want to use, building sustained, broad-based support among policy makers and health providers, and generating demand for an eventual product are all crucial to success.

5. **Perseverance Is Essential.** New technologies can take years, even decades, before they are fully accepted. After more than 30 years, the IUD is still not commonly accepted in sub-Saharan Africa, although it is widely used elsewhere. Widespread demand generation, especially for a new category of product like microbicides, takes time. Inevitably, setbacks will occur. Long-term planning for full access is essential from the outset, and all stakeholders must understand that overnight success is highly unlikely.

6. **Pay Close Attention to Real and Perceived Side-Effects and Media Response.** Side-effects perceived to be minor or manageable in the development stage can become major problems in full-scale access efforts. Rare events that were not detected in the development phase can emerge later, and need close and immediate attention. Media can quickly highlight real or perceived problems – even in other countries. Legal challenges can emerge and these attacks can be costly, effectively destroying markets and forcing manufacturers to withdraw products.

7. **International Procurement and Logistics Systems Are Essential.** Donors need to develop procurement systems, or include microbicides in existing ones, to assure value in bulk purchasing, predict current and future needs, and ensure timely, efficient and sustained distribution to countries. Effective national logistics and supply systems are needed to ensure effective, low-cost distribution of microbicides and avoid stock-outs.

8. **Every Country and Cultural Setting Is Different.** Market research is essential to appropriately position and price microbicides in each market segment. Special attention needs to be given to gender power relations in different cultural settings. A positive message (e.g., improving family life, sexual pleasure and lubrication) is more effective than a negative one focusing on disease and death. Stigmatising a product by associating it with a particular group, such as sex workers and their customers, may limit more widespread use.

9. **Build on Existing Health Structures.** While introduction strategies will require some level of specificity to establish microbicides and deliver them quickly to key populations, integration with existing HIV and SRH programmes and use of many of the same delivery channels will be crucial to securing widespread use. Public, private and non-profit sectors can all play a role in reaching different populations and in ensuring reliable, affordable, accessible and acceptable microbicide programmes. All possible mechanisms for providing access to microbicides should be exploited, including government health systems, local NGOs, faith-based groups,

community organisations, industry, the police and military, commercial sales through pharmacies and social marketing. The variety of delivery approaches is important, but they require strengthening of regulatory and accountability systems.

10. **Plan for Scale-Up.** The history of contraceptive introduction emphasises the importance of planning for both introduction and scale-up. Funding and support for pilot programmes does not necessarily translate into longer-term, widespread adoption and use. Success in first-adopter communities and countries plays an important role in supporting subsequent uptake. For microbicides, initial introduction should be planned to maximise uptake and demonstrate impact. As importantly, defining what counts as "successful introduction" will be essential to maintaining momentum for scale-up.

11. **Second-Generation Products Offer New Access Opportunities.** Improved, second-generation products offer important opportunities to expand the initial programme. This is particularly important because the first microbicides to be introduced will likely be superseded relatively quickly, both by more effective products and increased variety in presentation and delivery method (e.g., both coitally and non-coitally dependent products). If the second-generation product is more expensive than the original the advantages of the new product must be marketed effectively to offset the price differential.

12. **Expect the Unexpected: the Roller-Coaster.** Despite the most carefully planned microbicide access strategy, unanticipated events are likely to occur. These could include known side-effects being misrepresented in the media, rare or unanticipated side-effects, religious opposition, false rumours, legal actions, ethical questions, donor fatigue and change in policies, financial mismanagement and changes in government leadership, among others. As with the introduction of contraceptives, these problems can lead to loss of confidence in the method, negative media reports, lawsuits and loss of stakeholder support. Quick response to unexpected events is crucial.

APPENDIX 1

Comparative data on the IUD, implant and female condom contraceptive methods

Product	Replacement Frequency		% of women experiencing an unintended pregnancy within the first year of use[4]		Public Sector Cost per unit[4]	Illustrative Cost per Couple-Year of Protection (product and programming costs)[5]					Public Procurement -# of units (in 000s)[6]				
	Typical Use	FDA Approved	Typical Use	Perfect Use		Kenya	Ghana	Uganda	South Africa	India	2000	2001	2002	2003	2004
TCu380A IUD	3.5 years[1]	10 years[3]	0.8	0.6	$1.55	$0.72	$0.54	$0.77	$0.93	$0.66	3328	7087	5945	6304	6642
Norplant	3.5 years[1]	5 years[3]	0.05	0.05	$23.80	$7.76	$7.58	$7.81	$7.98	$7.70	260	272	232	155	175
Female Condom	There is evidence that FCs are re-used but not enough research to ascertain the extent of the practice[2]	each sex act	21	5	$0.59	$119.00	$118.55	$119.12	$119.53	$118.85	~	3950	6770	4729	8971

[1] Janowitz et al 1999
[2] Francis-Chizororo and Natshalaga 2003
[3] USAID 2006
[4] Trussel 2004
[5] UN Millennium Project 2003. Does not include follow-up programming costs for implant and IUD beyond initial insertion. For implants, this estimate does not include removal costs.
[6] UNFPA 2005

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IPM MISSION:

The mission of IPM is to prevent HIV transmission by accelerating the development and availability of safe and effective microbicides for use by women in developing countries.

HEADQUARTERS:
8401 Colesville Road
Suite 200
Silver Spring, MD 20910
USA

IPM BELGIUM:
Rue du Trône, 98, 7th floor
1050 Brussels
Belgium

IPM SOUTH AFRICA:
Zomerlust Estate
PricewaterhouseCoopers Building
Bergriver Boulevard, Paarl, 7646
P.O. Box 3460, Paarl, 7620
South Africa

www.ipm-microbicides.org