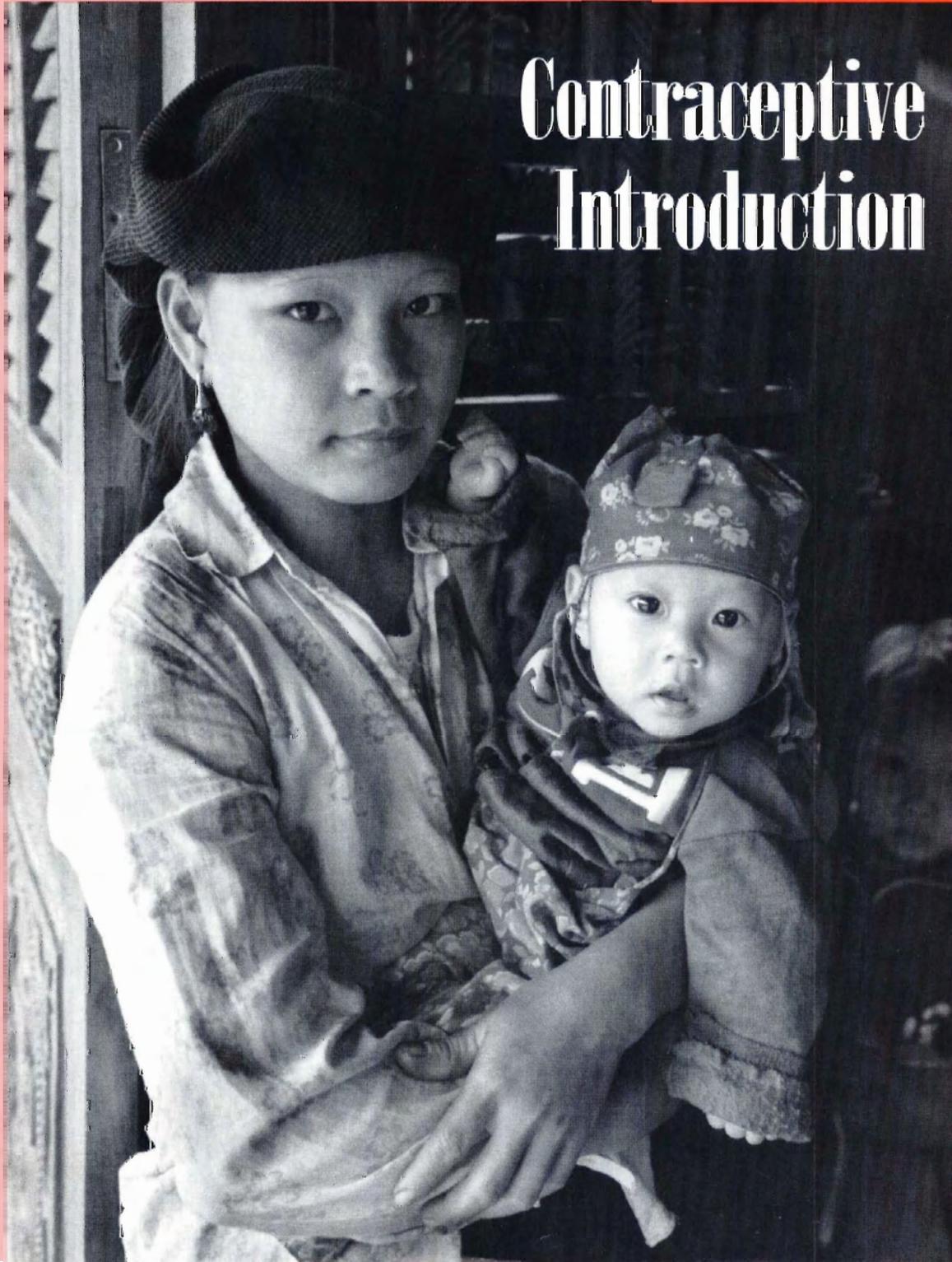


# Network

FAMILY HEALTH INTERNATIONAL, VOL. 16 NO. 1, SEPTEMBER 1995

## Contraceptive Introduction



# News Briefs

## HPV CAUSES CERVICAL CANCER

Genital human papillomavirus (HPV), a common sexually transmitted disease, is responsible for the majority of the world's 500,000 new cervical cancer cases reported each year, according to a recent study.

The study suggests that preventing the sexual transmission of HPV could curtail the number of cervical cancers, which is the second-most common cancer among women.

"HPV is now widely considered as the cause of more than 90 percent of the cases," says Dr. Keerti V. Shah of Johns Hopkins University School of Public Health in Baltimore, MD, USA, one of several researchers who conducted the study. "It shows that if you can prevent the infection, you can prevent cervical cancer."

Laboratory analysis of specimens from 932 women with invasive cervical cancer showed that HPV was present in 866 women (93 percent). The field study was conducted in 32 hospitals in 22 countries between 1989 and 1992. There are more than 35 distinct types of HPV, 20 of which are known to be cancer-causing.

The study, conducted by researchers from Johns Hopkins, the National Cancer Institute in the United States, L'Hospitalet del Llobregat in Spain, and the International Agency for

Research on Cancer in France, was published in the June 7 issue of the *Journal of the National Cancer Institute*.

## ONE-ROD IMPLANT EASY TO INSERT

Early clinical trial results on an experimental subdermal implant called Implanon indicate that insertion and removal of the one-rod device are relatively easy.

"It's easy to insert, like giving an injection," says Dr. Samuel Pasquale, professor of obstetrics and gynecology at Robert Wood Johnson Medical School in New Brunswick, NJ, USA, one of several sites across the United States involved in a two-year study among 232 women using the experimental implant. At the medical school, 22 women volunteered to use Implanon during the first year of the study.

Removals, Dr. Pasquale says, take about one minute to perform. Three of the 22 volunteers have had the implant removed — one due to mood swings, another due to bleeding problems and a third because she moved out of state.

Implanon is similar to Norplant, which is widely used throughout the world. Norplant uses six rods inserted in the arm and typically takes about 10 minutes to insert and 20 minutes to remove. Unlike Norplant, Implanon does not require an incision to be made for insertion. Rather, it is inserted under

the skin in the arm using a large needle, a process that takes about 20 seconds.

Both implants are progestin-only methods, but use different synthetic hormones. Implanon contains etonogestrel (3-keto-desogestrel) while Norplant uses levonorgestrel (LNG). Norplant, developed by the Population Council, is approved for five years of use. Implanon is being developed by Organon Inc. as a three-year implant. Dr. Pasquale reported the preliminary results for his site at the 1995 annual meeting of the American College of Obstetricians and Gynecologists in San Francisco.

## PROTEIN MAY LEAD TO CONTRACEPTIVE

Researchers at Duke University in the United States have isolated a protein in sperm that is critical to fertilization of the ovum, a discovery that could lead to the development of a contraceptive vaccine or new barrier methods.

Dr. Pat Saling and her colleagues identified the protein responsible for signaling to the sperm that it has reached the egg. This chemical signal prompts the sperm to release enzymes and proteins that dissolve the egg's outer surface (the

zona pellucida), which is necessary for fertilization to take place.

Scientists speculate that a contraceptive could be developed that would target the signaling protein, called the zona receptor kinase protein (ZRK), and cause a premature release of enzymes and proteins. Hence, sperm would no longer be capable of penetrating the egg's wall once they reached the egg. The contraceptive might be administered in foams or creams and inserted vaginally. In addition, a vaccine might be developed to immunize women against the ZRK protein.

"The portion of the protein that is exposed on the surface of the sperm appears to be unique, suggesting that a contraceptive ... could be designed that would not upset other biological functions," says Dr. Saling, associate professor of obstetrics and gynecology at Duke in Durham, NC, USA.

Development of a contraceptive would take at least a decade, scientists say. The findings were reported in the July 7, 1995 issue of *Science*. Research, conducted in collaboration with the University of Sheffield in England, was supported by the U.S. National Institutes of Health.

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*Cover photo by Sean Sprague/Impact Visuals of a Vietnamese woman and child in Na Lang village, near Lao Cai. Vietnam recently initiated a carefully planned introduction of DMPA, an injectable contraceptive.*





# Introduction Strategies Raise Key Questions

**B**efore a new contraceptive is introduced into a country or community, or use of an existing method is greatly expanded, fundamental issues should be raised.

These issues focus on three aspects: the method itself, the service delivery system, and the potential users. The many characteristics of a method's technology, such as whether it requires a trained provider to begin or discontinue, are important to understand and evaluate. The method's side effects and duration are factors. How the new option fits in with the users' needs and preferences, as well as the community's culture, should be considered. Service delivery concerns, such as additional training or staff requirements, are also essential considerations.

When contraceptive methods move into large-scale use without careful evaluation of these basic concerns, problems can arise. Providers may not be adequately informed or trained, and users may not receive essential counseling and information. The method's characteristics may not be well understood, including side effects and how to manage them. Misunderstandings and false rumors can circulate, damaging the method's credibility.

Logistical and economic issues must also be anticipated. A dependable way of supplying commodities must be organized, and additional services needed for the method ought to be planned, such as removal of implants or IUDs. Adding a method may affect how previously available methods are used. The cost of providing the method, and what users are willing to pay, may be decisive.

Several organizations, including FHI, have developed strategies for introducing or expanding use of a contraceptive method. FHI has two decades of experience with contraceptive introduction. Introduction strate-

gies have continued to evolve as more is learned about how methods, users and service delivery systems interact.

In 1993, FHI's work in this area was synthesized in a written strategy for DMPA. While it focuses on the three-month injectable as a case study, it is designed for use with any method. It involves a needs assessment and addresses regulatory issues, service delivery policies and procedures, information and training, evaluation and other concerns.<sup>1</sup>

A similar approach, developed by a World Health Organization task force, seeks to identify the method mix that is most desirable for local circumstances. Whether a new option should be introduced at all is a key decision. "What would an ideal method mix look like?" asks Martha Brady of the Population Council, which is collaborating with WHO to test its model. "We need to look at who can provide which methods, where, and to whom. All of these levels have to fit. It would not be practical or necessarily desirable to offer every method in all settings."

Good contraceptive introduction strategies seek to improve the overall quality of family planning programs rather than simply expanding choices. They also recognize that even a very good contraceptive technology requires careful planning before it is widely used. "Scientists have continued to seek longer-acting, more effective methods that are easy to use, easy to deliver and have fewer side effects," a report by the WHO task force says. Introducing an attractive new method without careful planning, however, may only magnify existing problems. "Every method has a different side effect pattern, and places a different potential burden on the service delivery setting."<sup>2</sup>

Most strategies tend to plan and evaluate in steps, beginning with the use of existing data and selective interviews with policy-makers, providers, users, women's health advocates and others. More thorough research may be done at a later stage, before a method is introduced throughout a country. The new method may be offered on a limited basis at a small number of clinics, for example, to evaluate service delivery concerns and user perspectives.

All of the many concerns regarding service delivery, user perspectives and method technology are closely intertwined and are shaped by local circumstances, including rates of sexually transmitted diseases.

The following articles describe recent contraceptive introduction efforts involving Norplant, DMPA and barrier methods and provide lessons on approaches that have worked well. They show the importance of proper planning and a careful evaluation of how users, service delivery systems and the technology of the method itself interact with each other.

## Norplant: The Need for Training and Counseling

Norplant introductory programs have emphasized the need for provider training, adequate counseling and informed consent for users, and ready access to removal. These needs require a well-prepared service delivery infrastructure.

If counseling is not always available, then some users may not be informed adequately about a method's side effects or how to manage them. The need to return for follow-up services may not be clear to users, and providers may not have prepared adequately to give follow-up services. For example, a study of Norplant users in Bangladesh found that some women attempted to remove the implants themselves or to enlist the help of untrained people because some of the original providers did not offer adequate removal services, says FHI's Dr. Karen Hardee, who coordinated the study.<sup>3</sup>

Lack of planning in introducing intrauterine devices (IUDs) during the 1960s resulted in problems with supply management, infection control, access to removal, and fears among a poorly informed public. "People tried to learn from the mistakes of the 1960s," says Dr. Hardee, who has studied quality of care issues extensively. "The result

was that a lot more planning went into the introduction of Norplant" when the implant was first introduced in developing countries during the 1980s.

Norplant provides up to five years of pregnancy prevention with little user or provider action needed after insertion. However, it needs to be removed after five years when its effectiveness begins to decline, or earlier if women wish. Also, Norplant's tendency to cause menstrual irregularities (as do all progestin-only methods) makes good counseling essential for high continuation rates.

The Population Council, which developed Norplant, and other agencies, including FHI, worked with the U.S. Agency for International Development (USAID) on its worldwide introduction strategy. The strategy sought to establish a consistent channel of supply between manufacturer and distributors, obtain national regulatory approvals, build local capacity to use Norplant by training providers and setting up pre-introductory studies, develop information and training materials, and ensure that it was offered as part of a range of choices to clients.

The pre-introductory studies were particularly important. They helped country officials assess the method's acceptance and programmatic implications, allowing potential difficulties to be addressed before Norplant

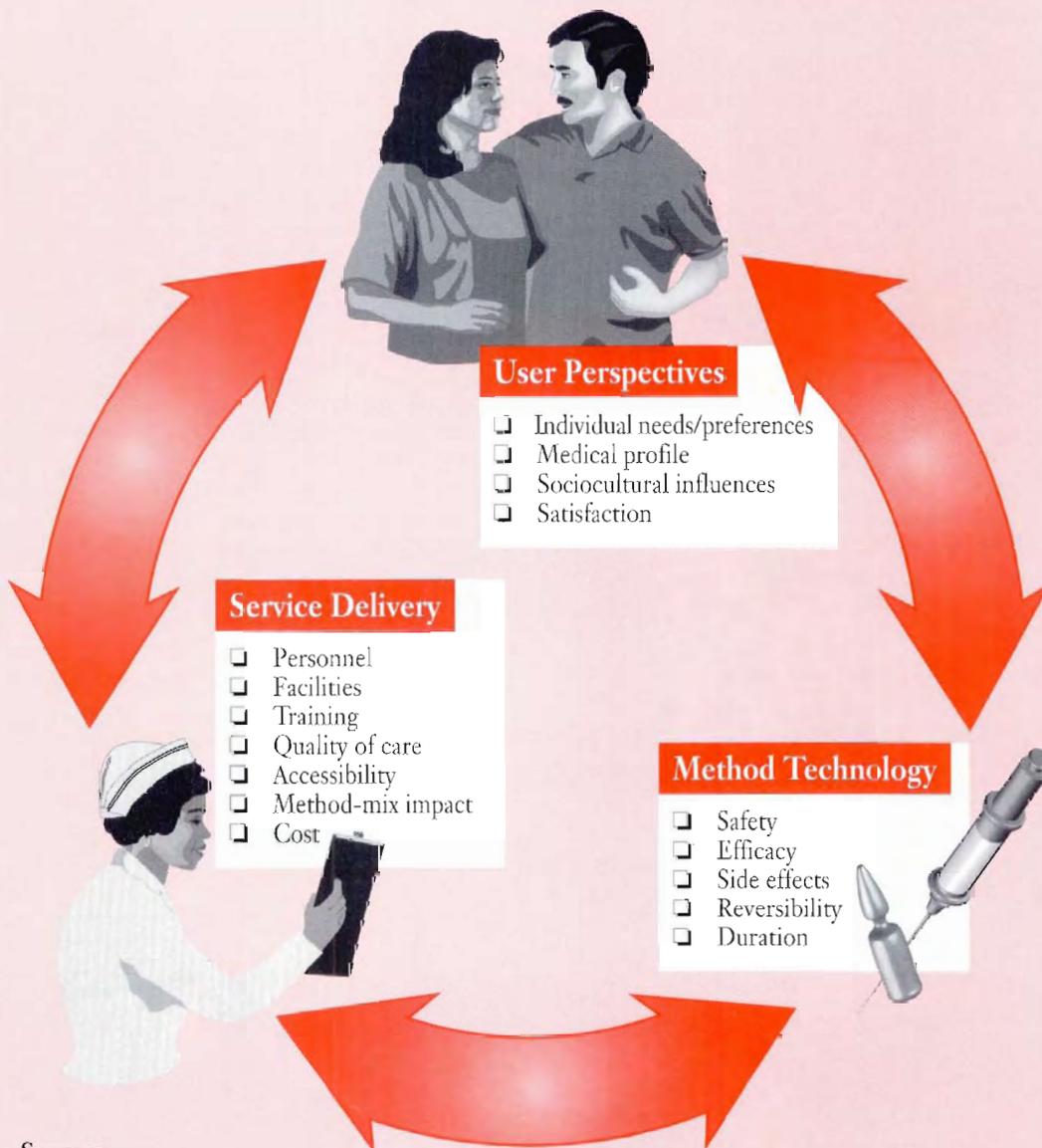
DAYA ABEYWICKREMA/FPA SRI LANKA



DR. SRIANI BASNAYAKE,  
FAMILY PLANNING ASSOCIATION OF  
SRI LANKA, INSERTS NORPLANT.

## CONTRACEPTIVE INTRODUCTION

Introducing a contraceptive method should include a careful evaluation of how the method works, how it would fit in with the existing service delivery system and what users think of it.



### Sources:

Spicehandler J, Simmons R. *Contraceptive Introduction Reconsidered: A Review and Conceptual Framework*. Geneva: World Health Organization, 1994.

Family Health International. *A Proposed Approach for Contraceptive Introduction: Depo-Provera*. Unpublished paper. Durham: Family Health International, 1993.

was integrated into a family planning program.<sup>4</sup> As contraceptive introduction models typically recommend, these studies examined how the method would actually work in a specific country or culture. A pre-introductions study among 694 women in Haiti, for example, found that 99 percent of them liked the method and 96 percent would recommend it to a friend.<sup>5</sup> Consequently, expansion moved forward quickly, and by 1992, Haitian providers were inserting Norplant

into nearly 10,000 women a year. The viewpoints of users, carefully evaluated ahead of time, indicated such acceptance would occur.

Greater demand, however, requires a corresponding increase in trained personnel to insert and remove the implant. To address this concern, a Haitian hospital has trained nurse auxiliaries to do insertions in rural clinics, and FHI is assessing whether insertions and removals by nurse assistants are as successful as those performed by physicians. The study could lead to a change in service

delivery regulations. Preliminary findings indicate the nurse assistants perform as well as the doctors, says FHI's Betsy Tolley, who is coordinating the study. "The clients seem to be well-informed, while infections or complications from the insertions by nurse assistants are as rare as they have been when doctors made the insertions," says Tolley.

### VIETNAMESE ASSESSMENT

An important question is whether a new method should be introduced at all. In Vietnam, a needs assessment suggested that Norplant should not be introduced.

In 1994, the Vietnam Ministry of Health, Vietnam Women's Union, United Nations Population Fund (UNFPA) and WHO gathered information on provider skill levels, program needs, cultural and political restrictions, and women's concerns regarding all contraceptive methods in the Asian country. The team analyzed contraceptive prevalence surveys, interviewed 100 actual and potential family planning users, and talked to providers in 12 community health centers and two large clinics.

Following this needs assessment, the government changed its strategy on Norplant, explains Dr. Ruth Simmons, a member of the

team and co-chair of a WHO task force on contraceptive introduction. Due to Norplant's heavy service demands, the team recommended delaying the introduction of Norplant until the service delivery system is stronger. A systematic introduction of DMPA, the three-month injectable, was initiated instead.

"Previous efforts have assumed that service delivery capabilities would be adequate to provide the new technology or could be improved where necessary," stated the team's report. "It is increasingly recognized that introducing new contraceptive methods adds burdens and complexities to the service delivery, training and administrative/operational systems which may act to reduce rather than improve quality of care."<sup>6</sup>

## DMPA: Gradual Expansion, Continuing Evaluation

In 1993, the Philippines Department of Health decided to introduce DMPA nationwide. An FHI and Pathfinder International team working with the health department developed a draft strategy covering pricing, information, training, commodities, logistics, evaluation, suggested service delivery guidelines, and other elements.<sup>7</sup>

DMPA (depot-medroxyprogesterone acetate) is an easy to use, highly effective three-month injectable suitable for most women, but may cause menstrual irregularities and may result in a delayed return to fertility. Good counseling can prepare women for these side effects and improves user acceptance and continuation rates. "We knew that a staged introduction in selected areas was very important, so that any problems with supplies or training could be addressed before the program got over-extended," says Susan McIntyre of FHI, who worked on the strategy.

The introduction strategy involved the government's nationwide network of public clinics, a social marketing campaign coordinated by The Futures Group's SOMARC project, and private providers, which worked directly with the manufacturer. In the clinics, the first phase involved 10 pilot areas where logistics, trained personnel, information and education, and local support were strong. "It gave us time to get all the pieces of the puzzle into place," says Patrick Coleman, senior resident adviser of Johns Hopkins University/Population Communication Services (JHU/PCS) and coordinator for information materials in the introduction.

In the next phase, the project expanded into more districts. Getting enough people trained and having sufficient information materials in a timely fashion were important concerns. DMPA stocks had to be readily

available, and an information packet went to each clinic, including a book for record keeping and materials for clients.

The Philippines experience offers valuable lessons. "Any country planning to introduce or expand DMPA use should consider having a DMPA task force to ensure availability of most, if not all, of the things that are needed to have a successful campaign," says Dr. Rebecca Infantado, head of the Philippine Family Planning Service.

An important but often overlooked part of an introduction strategy is research on how the effort is working. About 35,000 women started using DMPA between April 1994 and February 1995, and continuation rates have been very high. An expansion that will offer DMPA nationwide began this summer. "DMPA might equal pill acceptance," says Dr. Infantado. "We believe the biggest challenges ahead include managing of perceived and real side effects and supply and distribution of the contraceptive."

## Barrier Methods: The Role of STDs

The AIDS pandemic has focused attention on providing barrier contraceptive methods, which can reduce risk of sexually transmitted diseases (STDs). "Decisions about contraceptives should reflect both the need to prevent STDs and the need to prevent unplanned pregnancies," says Dr. Ward Cates, FHI's corporate director of medical affairs. "So far, most family planning programs have appropriately focused on pregnancy at the expense of STDs. However, the importance of preventing reproductive tract infections is being increasingly recognized as essential to good reproductive health care."

Consequently, a needs assessment for contraceptive expansion should address STD/HIV issues. This includes STD/HIV prevalence rates in program areas and the ability of programs to address STD prevention and management. Prevention includes information, counseling and condom distribution. STD management covers diagnosis of STDs, treatment with antibiotics, partner tracing and attempts to keep infected persons from spreading the disease.

"Until recently, condoms have not been favored by most family planning providers due to concerns about condom effectiveness, acceptability, consistent and correct use, breakage, logistics and cost," explains Dr. Nancy Williamson of FHI, who has studied the integration of STD services with family planning programs. "Promoting condoms aggressively requires a major reorientation for many family planning programs."

Most funding and interest in condom promotion has been through AIDS prevention programs that are usually quite distinct from family planning agencies. Combining these two networks of agencies, staff expertise and funding sources creates substantial administrative challenges.

The methods most effective at preventing STDs, barrier methods, are usually not the most effective contraceptives. Thus, providers have an added responsibility to give clients clear information, counseling and access to the methods most desired.

At the same time, many family planning programs should consider providing information and counseling on STD/HIV prevention, including condom distribution, says Dr. Williamson.

"The emphasis should not be on what the programs should promote, but how to provide information clearly enough so that a woman or man can make a really educated choice," says Laurie Fox, who directs FHI's family planning/STD integration research. "It is not up to the programs to choose a method. It is up to each individual."

Successful AIDS prevention programs suggest that people will use barrier methods for family planning when they are available. Population Services International (PSI) and the SOMARC project, both supported by USAID, have developed condom distribution campaigns throughout the world. From 1987 to 1991, annual condom sales increased from 300,000 to 18.3 million in Zaire, where PSI launched its first AIDS prevention campaign with the Zaire National AIDS Committee. Three of every four persons reported that they bought the condoms for family planning as well as for AIDS prevention.<sup>8</sup>

## FEMALE CONDOM

The need for female-controlled methods to protect against STD/HIV has encouraged USAID to evaluate whether to provide the female condom to family planning programs. USAID recently made a one-time purchase of 250,000 female condoms for use

in 22 countries. FHI has prepared information packets for family planning managers and a survey instrument to gather users' opinions (see related article on page 23). This approach is consistent with introduction strategies that suggest a new method could be made available on a limited basis and carefully evaluated before large-scale distribution.

Whether USAID will add the female condom to the methods it routinely supplies overseas involves many complex issues, especially overall budget constraints, says Mark Rilling of USAID's commodities office. "The degree of interest among programs and the price they are willing to pay will help us determine whether to purchase the female condom on a longer-term basis," he says.

For the female condom to be used widely in developing countries, service delivery systems must identify the most likely users, determine how to help women continue using the device even when men resist, and overcome the relatively high cost of the condom, says Carol Joanis of FHI, who has led several acceptability studies on the female condom. "Often a woman cannot persuade a man to use a male condom," she says. "In our previous studies, the women most interested in using the method were those at high risk of STD/HIV exposure. The female condom provides another option for pregnancy and disease control for women."

One possible way to lower the cost is to determine if the female condom can be used more than once without losing effectiveness or compromising safety. In a re-use study being conducted by FHI, preliminary results show that cleaning of the device after one use does not harm it structurally. If final results are encouraging, FHI will request permission from the U.S. Food and Drug Administration (FDA) to begin a study in which women would use a female condom multiple times. The female condoms would be tested against manufacturers' specifications after varying numbers of uses. If they continued to meet safety and efficacy specifications after multiple use, FDA may be asked to approve the device for more than one use. The FDA has approved the Reality and Femidom female condom brands for one-time use only.

Working with women's advocacy organizations in Kenya and Brazil, FHI is conducting a study of about 100 women from each country to determine what kind of support a woman needs to use a female condom, even when men initially resist. "Such efforts may help women's organizations get more involved in STD prevention and get the female condom to a larger population of women," says Dr. Maxine Ankrah, senior adviser on women's issues for FHI's AIDS Control and Prevention Project (AIDSCAP). "Then we might be able to introduce it more widely through a social marketing or a community-based distribution approach."

— William R. Finger and Sarah Keller

## FOOTNOTES

1. Family Health International. A proposed approach for contraceptive introduction: Depo-Provera. Unpublished paper. Durham: Family Health International, 1993.

2. Spicehandler J, Simmons R. *Contraceptive Introduction Reconsidered: A Review and Conceptual Framework*. Geneva: World Health Organization, 1994.

3. Hardee K, Khuda BF, Kamal GM, et al. Contraceptive implant users and their access to removal services in Bangladesh. *Int Fam Plann Perspect* 1994; 20(2):59-65.

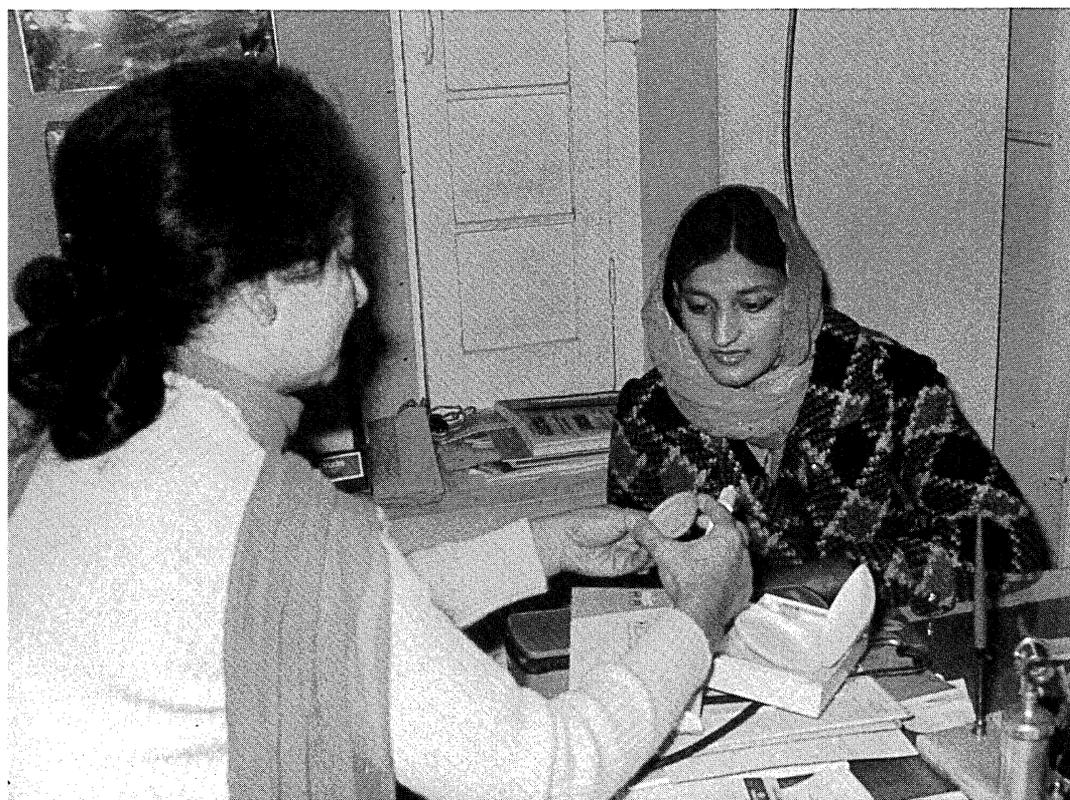
4. Beattie KJ, Brown GF. Expanding contraceptive choice: The Norplant experience. Eds, Van Look P, Perez-Palacios G. *Contraceptive Research and Development 1984 to 1994*. (Geneva: World Health Organization, 1994) 263-76.

5. Balogh S. Haiti private sector family planning project: Norplant strategy. Unpublished paper. Durham: Family Health International, 1992.

6. Vietnam Ministry of Health. Assessment of the need for contraceptive introduction in Vietnam. Unpublished paper. Dec. 19, 1994.

7. Hardee K, Huber D, McIntyre S, et al. Proposed strategy for the introduction of DMPA into the Philippine family planning program: Prepared for the Department of Health and The USAID/Manila. Unpublished paper. Durham: Family Health International, 1993.

8. Convisser J. *The Zaire Mass Media Project*. (Washington: Population Services International, 1992) 16.



SEAN SPRAGUE/IMPACT VISUALS

A WOMAN IN LAHORE, PAKISTAN  
LEARNS ABOUT BARRIER METHODS,  
SUCH AS THE DIAPHRAGM, AT A  
FAMILY PLANNING CLINIC.

# Cost Analysis Plays Vital Role

Evaluating costs helps managers make better informed decisions about expanding or adding methods, services.

Limited resources require family planning programs to choose among competing priorities, such as adding a contraceptive method, improving counseling, expanding community-based delivery systems into hard-to-reach rural areas, expanding clinical programs and broadening services to include sexually transmitted diseases. Program managers need information on costs and benefits of services to make better informed decisions about these services.

“What do you get and what does it cost?” asks Dr. Barbara Janowitz, who directs FHI’s Service Delivery Research Division. “These are the two questions to ask when introducing a new contraceptive method or expanding the availability of a method. The same two questions hold when a program considers adding a new service in the reproductive health field. To make logical choices, managers need to know what various services cost as well as what impact a specific change in program function will have.”

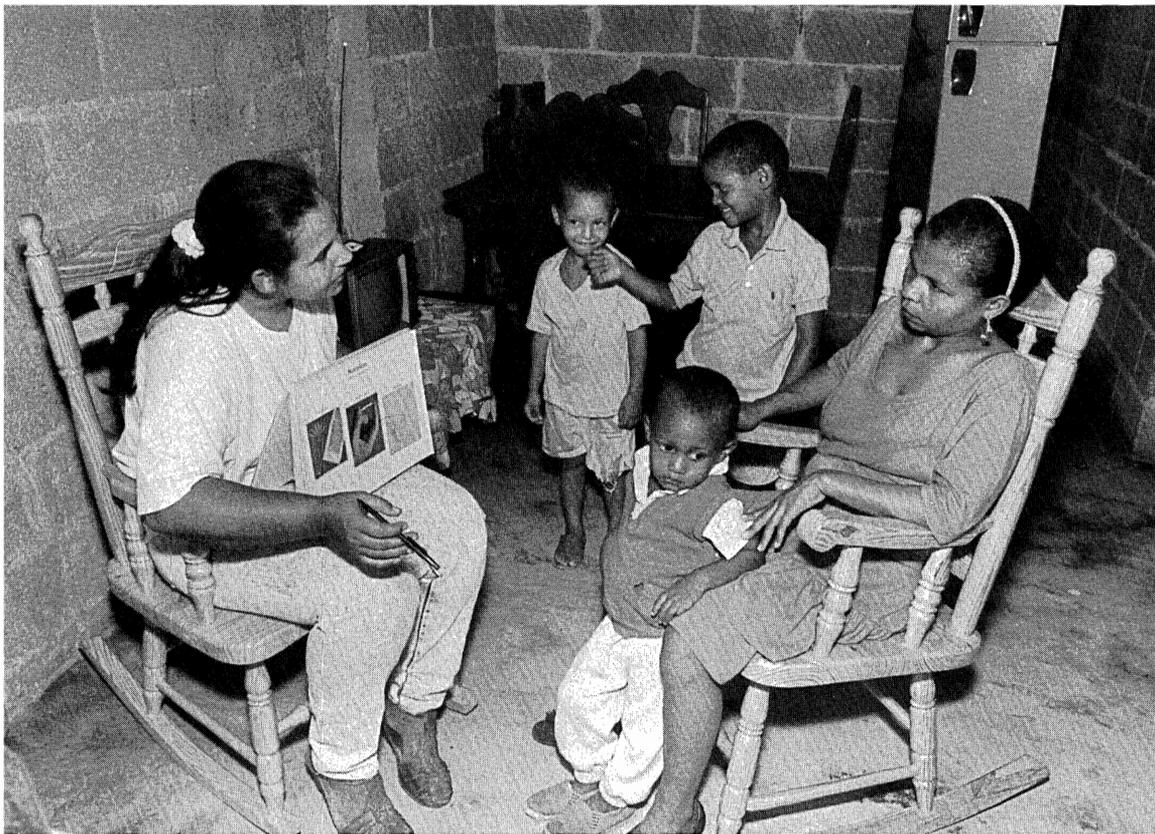
She and her colleagues have developed a manual to assist program managers to undertake such studies. It describes the way a program can calculate the costs of its services and then use that information to evaluate whether to add or expand contraceptive choices and make other types of changes in service delivery. Governments and nongovernmental organizations (NGOs) in Bangladesh, the Dominican Republic, Ecuador, Mexico and other countries have worked with FHI using this approach.<sup>1</sup>

“The manual considers only the fertility reduction outcomes of family planning programs,” says Dr. Janowitz, “but the approach can be expanded to include impacts on other aspects of women’s lives or those of their families. For example, outcomes could also include reductions in high-risk pregnancies and fewer sexually transmitted infections because of increased condom use.”

Most cost studies rely on the cost of providing a couple-year of protection (CYP) — the level of contraceptive use equal to one year of contraceptive protection. CYP, however, does not take into account failure rates during normal use nor does it consider the broader ways that contraception might affect a person, including protection from sexually transmitted diseases.<sup>2</sup>

Other organizations have begun to develop cost analysis methodologies. For example, Management Sciences for Health, a U.S.-based organization, suggests a simple, step-by-step process that can determine the costs of each type of visit to a clinic using only personnel and commodities costs. These are usually two of the largest cost items. Expenses for training, maintenance, information and other items are not included in this model.<sup>3</sup>

Among the cost issues that the FHI manual and other similar methodologies can help managers address are: the cost of adding a contraceptive method or expanding its use; how to assess the cost effectiveness of various service delivery systems; and how to increase contraceptive access by reallocating limited resources through changes in unnecessary practices or regulations.



BERYL GOLDBERG

A CLIENT VISITED BY A COMMUNITY-BASED FAMILY PLANNING WORKER DOES NOT INCUR TRANSPORTATION COSTS TO A CLINIC, BUT THE OUTREACH PROGRAM DOES HAVE THE ADDITIONAL COST OF TRANSPORTATION. THIS COMMUNITY-BASED WORKER VISITS A HOME IN SANTO DOMINGO, DOMINICAN REPUBLIC.

## METHOD CHOICES

When a family planning program considers changes in the kinds of contraceptives it provides, many factors, including cost, play a role. For example, a new technology that may attract new clients could become available, such as the hormonal implant Norplant. The increase in HIV/STDs may prompt more interest in promoting condoms and other barrier methods at family planning clinics. Interest in involving men could lead to campaigns to inform them about vasectomy, as has been done in Kenya, Brazil and other countries.

If a method attracts new users or meets an identifiable need, such as STD prevention or involvement of men, then program managers might consider reducing or eliminating one service to provide another.

A study in Thailand, coordinated by the National Family Planning Program (NFPP) and FHI, compared the incremental cost of Norplant with IUDs and injectables. It also examined how adding Norplant might increase overall contraceptive use. Providing three years of protection with Norplant cost

U.S. \$9.40 per year, compared with about U.S. \$5 for injectables and U.S. \$1.40 for the IUD. Of the 550 new Norplant acceptors interviewed, 96 percent of the women said they would have used another modern method if the implant had not been available. "Thus introducing the implant or significantly expanding its use in Thailand will cost more than expanding the use of the IUD or injectables," concluded Dr. Janowitz and her colleagues in the study.<sup>4</sup>

The study included only additional or marginal costs related to the specific methods (commodities, supplies and labor providing the services). Since the expansion was implemented within the existing hospital structure, no infrastructure costs were included. Also, costs to the client such as travel and lost wages were not included, although these can be important considerations from the users' point of view.

The NFPP in principle wants to offer Norplant as an additional method in its national network of community hospitals, where it traditionally has provided contraceptives at subsidized prices. The study identified three choices the NFPP can make: spend limited resources to subsidize this method, charge users higher prices, or limit its use to women who have completed their families and do not want to be sterilized.

In Ecuador, a study examined the cost of adding the injectable DMPA in the clinics of a nongovernmental organization. The study found that when injected by a nurse, DMPA cost about half as much to deliver as the pill, U.S. \$6.68 a year compared to U.S. \$12.88 for the pill. The calculation included only marginal costs specific to the method — commodities, supplies and labor providing the services. (The DMPA cost was higher when injected by

doctors, whose salaries are higher than those of nurses.) The difference in cost to the clinic was mainly due to the cost of the commodities to the program.

The clinic charged the same for DMPA and the pill, U.S. \$22 per year. The part of the fee not needed for method-specific costs went toward the overall program expenses, such as the clinic facility and administrative costs. Thus, a DMPA user contributed U.S. \$15.32 per year toward these other clinic costs, compared with U.S. \$9.12 for the pill user. In the case of this Ecuador NGO, DMPA was a good source of revenue.

Circumstances in a country often make it misleading to compare costs from one country to another.<sup>5</sup> The situation in Ecuador, for example, differed substantially from that in Thailand described earlier, so the numbers in these two studies should not be compared.

In Nyeri, Kenya, the Provincial General Hospital began a postpartum IUD program in the early 1990s but did not know whether to continue it. An FHI study compared the cost of immediate post-placental insertion (IPPI), which is performed within 10 minutes after the placenta is expelled, and insertion at a maternal and child health clinic, which is done at least six weeks after the birth.

The study compared incremental costs for the two types of insertions and found that for one year of protection, costs were 41 percent higher when the IUD was inserted at the clinic (U.S. \$4.75), compared with insertion done in the delivery room (U.S. \$3.37). The major additional cost was the time spent on preparation for sterile conditions at the clinic, conditions that were already present in the delivery room. This study contributed to the hospital's decision to continue its postpartum IUD program.<sup>6</sup>

#### IMPROVING DELIVERY SYSTEMS

Many programs must decide how to divide limited resources among clinical and community-based services, while also making each system as efficient and high-quality as possible.

Working with the National Family Planning Program in Bangladesh, FHI is conducting a nationwide cost study, examining clinical and outreach

programs administered by the government and by NGOs. In the last seven years, the government has nearly doubled the number of outreach workers, from 13,000 to 23,000, and now spends U.S. \$22 million a year on salaries alone, including the services of 4,500 supervisors.

This commitment to a community-based distribution system has contributed to a sharp increase in contraceptive use, particularly among pill users. Over the last decade in Bangladesh, the proportion of married women of reproductive age using contraception has more than doubled, from 19 percent to 45 percent, and pill use has jumped six-fold, from 3 percent to 17 percent. The portion of users getting their pills from outreach workers has gone from 45 percent to 70 percent.

Preliminary results from the FHI studies indicate that while the existing systems have been successful, they can serve even more users without major cost increases. The studies have gathered data by accompanying workers on home visits, analyzing records, monitoring when supervisors and outreach workers went to work, calculating time spent with a client, and other approaches.

"The community-based workers could meet a lot of increased demand without any additional costs," says Dr. Janowitz, who is coordinating the Bangladesh studies. "Some outreach workers work shorter hours than

they are supposed to work." Regarding the clinics, preliminary results indicate that many are under-utilized, and hence many more people could also be served at the clinics without major cost increases.

A study in Nigeria, Tanzania and Zimbabwe also showed the importance of using a clinical system efficiently. In each country, about one-fourth of the clinics served approximately 80 percent of the new clients, concluded a research team led by the Population Council. Considerable room exists "for expanding services in the large number of facilities that have relatively few clients," the study found. "Alternatively, resources could be concentrated in the most heavily used service-delivery points."<sup>7</sup>

Contraceptive cost studies generally do not include costs to the user. If a woman has to visit a clinic for a resupply of a method, such as pills or injectables, she incurs the cost of transportation. A woman visited by a community-based worker does not have transportation costs, but the outreach program does have that additional cost.

"The program costs of a clinic-based and an outreach program may appear to be the same but the costs to the user may be different," explains Dr. Janowitz. "You have to consider both the cost of programs in providing a method and the cost to the user in getting the method. Cost to the user may affect demand for contraception and cannot be ignored."

SEAN SPRAGUE/IMPACT VISUALS



A MOTHER AND HER CHILDREN VISIT A CLINIC IN DHAKA, BANGLADESH. AN FHI MANUAL FOR ANALYZING COSTS OF FAMILY PLANNING SERVICES HAS BEEN USED IN BANGLADESH AND OTHER COUNTRIES.

Different service delivery systems often use information campaigns when attempting to expand contraceptive services. Few data show how much it costs to change a person's behavior through such an effort, but studies have compared the value of different promotion approaches. An analysis of a male motivation campaign in Zimbabwe, for example, found that "radio was by far the most cost-effective in reaching people and encouraging them to use family planning." The study found the cost of using radio was U.S. \$2.41 per new family planning user, while the cost of pamphlets was U.S. \$28.06 per new user, although the radio program had been available longer than the pamphlets. While the radio campaign cost almost twice as much as the pamphlets (U.S. \$93,000 compared to U.S. \$50,000), it resulted in more than 20 times more new users.<sup>8</sup>

#### UNNECESSARY REGULATIONS

Some requirements for using contraceptives add unnecessary costs, which can limit access to potential users. Examples include the number of follow-up visits recommended for IUD users and mandatory laboratory tests prior to receiving oral contraceptives.

Some programs recommend up to three or four follow-up visits for IUD users. To determine whether so many visits are needed for women with no or mild symptoms, FHI researchers analyzed records from clinical trials of IUDs involving 11,000 women in nine countries. The study found that less than 1 percent of follow-up visits by women with no or mild symptoms had a health risk that would not have been detected without the follow-up visits.<sup>9</sup> "It makes sense not to have so many visits and let the staff do something more useful," says Dr. Janowitz, who led the study.

In Ecuador, Centros Medicos de Orientación y Planificación Familiar (CEMOPLAF) wanted to know if it could reduce its norm of four return visits for IUD acceptors without endangering a woman's health. A study by FHI and the Population Council compared four return visits to one visit, interviewing some 5,000 women. It concluded that one follow-up visit would detect 66 percent of the health problems, and four visits would uncover 73 percent. But by changing to a one-visit norm, CEMOPLAF would save about U.S. \$33,000 per year.<sup>10</sup>

"We implemented the one-visit follow-up norm at 15 days after insertion, the time when most problems occur with an IUD," says Teresa de Vargas, executive director of CEMOPLAF. Following this change, from 1992 to 1993, the number of revisits declined by a third. "We have used the increased staff time to provide expanded gynecological and prenatal services."

Another expensive practice followed by some countries, particularly in francophone Africa, is to require a set of laboratory tests before providing oral contraceptives. Commonly required lab tests are used to detect cervical cancer, diabetes, high cholesterol, anemia and liver function problems. In a prospective study of 410 women in an urban area of Senegal, such tests indicated possible contraindications for pill use in only 20 women, nine of whom returned for a second test. Of those nine, only one had a confirmed contraindication. The cost of such mandatory tests in Senegal ranges from U.S. \$55 to \$216, depending on the type of lab a woman chooses, as much as five times the monthly per capita income in Senegal.<sup>11</sup>

The study led to a new national policy to eliminate the tests. "Even though the government of Senegal no longer requires these tests, many doctors and midwives still do,"

SOME CLINICS ATTRACT MORE CLIENTS THAN OTHERS, SUGGESTING HOW RESOURCES SHOULD BE ALLOCATED. MOTHERS WAIT WITH THEIR CHILDREN AT A FAMILY PLANNING CLINIC IN THE DOMINICAN REPUBLIC.



BERYL GOLDBERG

## \$17 BILLION NEEDED BY YEAR 2000

says John Stanback of FHI, who led the study. "Because of the expense, the tests have the potential for keeping thousands of women in urban areas from using the pill."

When unnecessary regulations limit access to contraceptive methods for some users, women in particular may suffer. Unwanted pregnancies can result in maternal mortalities and chronic maternal morbidities. Other problems include the issues of stress and time lost from work because of poor health that may be linked to lack of access to good quality family planning services.

Providing adequate access to contraception can also reduce health-care costs for unwanted pregnancies. A recent study in the United States compared the costs of 15 different contraceptive methods to the health costs of not using any contraception. Based on U.S. data, including insurance costs for the health care associated with unwanted pregnancies, it found that all 15 methods were less costly when compared with using no method. While the study applies to the health-care system used in the United States, it has implications for all countries. "The message is simple: regardless of payment mechanism or contraceptive method, contraception saves money," the study concluded.<sup>12</sup>

In many countries, governments essentially pay the health-care costs that the insurance system supports in the United States. "An important question for all governments to consider is, 'What does it cost not to use a method?'" says Dr. Janowitz.

— William R. Finger

### FOOTNOTES

1. Janowitz B, Bratt JH. *Methods for Costing Family Planning Services*. Durham: FHI and UNFPA, 1994.

2. Shelton JD. What's wrong with CYP? *Stud Fam Plann* 1991; 22(5): 332-35.

3. Analyzing costs for management decisions. *The Family Planning Manager* 1993; 2(2).

4. Janowitz B, Kanchanasinith K, Auamkul N, et al. Introducing the contraceptive implant in Thailand: Impact on method use and cost. *Int Fam Plann Perspect* 1994; 20(4): 131-36.

5. Janowitz B, Bratt JH. Costs of family planning services: A critique of literature. *Int Fam Plann Perspect* 1992; 18(4): 137-44.

6. Hubacher D, Janowitz B, Mate EM, et al. Comparing the Costs of Two IUD Programs in a Kenyan Hospital. Paper delivered at APHA Annual Meeting, 1992.

7. Mensch B, Fisher A, Askie I, et al. Using situation analysis data to assess the functioning of family planning clinics in Nigeria, Tanzania and Zimbabwe. *Stud Fam Plann* 1994; 25(1): 18-31.

The United Nations Population Fund (UNFPA) estimates that U.S. \$17 billion will be needed to fund reproductive health care in developing countries by the year 2000, about U.S. \$10 billion of it for family planning.<sup>1</sup> Currently, about half of the estimated funds needed for family planning is being spent, less than U.S. \$5 billion.

Because of limited resources, major donors are focusing on fewer countries. The U.S. Agency for International Development (USAID) is planning to phase out support for family planning in such countries as Jamaica and Brazil because these countries' programs have advanced sufficiently. USAID may shift resources to other countries with more pressing needs.

The UNFPA also makes decisions based on country needs. "Working with national program managers, we allocate resources at the macro level — how much resources go for commodities, for training and for other areas," says Dr. Richard Osborn, senior technical officer at UNFPA.

The developing country governments themselves are hard-pressed to fill the gap. Currently, about two-thirds of family planning funds spent worldwide come from developing country governments, although most of this is accounted for by seven countries (China, India, Indonesia, Mexico, South Africa, Turkey and Bangladesh).<sup>2</sup>

Programs in many countries are now grappling with how to sustain existing programs, much less add new services. Programs are considering various types of user fees and public-private partnerships. Worldwide, consumers currently provide about 14 percent of family planning funds, but the portion is higher in most Latin American countries. In a few countries, insurance, social security and other public-private arrangements contribute.

8. Piotrow PT, Treiman KA, Rimon JG, et al. *Strategies for Family Planning Promotion — World Bank Technical Paper Number 223*. Washington: The World Bank, 1994.

9. Janowitz B, Hubacher D, Petrick T, et al. Should the recommended number of IUD revisits be reduced? *Stud Fam Plann* 1994; 25(6): 362-67.

10. Foreit F, Bratt J, Foreit K, et al. Cost control, access and quality of care: The impact of IUD revisit norms in Ecuador. Unpublished paper. 1994.

Among the types of new approaches being considered are expanding social marketing programs, making retail sales easier by removing constraints on prescriptions and prices, and improving the quality of services so that clients may be more willing to pay for contraceptives.<sup>3</sup>

Governments are also attempting to understand how family planning funds fit into their overall health-care budgets. But currently, planners at the national level cannot easily estimate how much they are spending on family planning or reproductive health services.

"Standard rules of thumb are needed so that expenditure estimates can be made quickly and at low cost," says Dr. Barbara Janowitz of FHI. FHI is attempting to develop guidelines that can be used to compare spending for family planning and reproductive health in different countries. Studies in Bangladesh, Ecuador, Ghana, Mexico and the Philippines seek to determine how much of a country's resources are being spent on family planning services and for what type of function, such as training, administration, service delivery and information. The Evaluation Project at the Population Center at the University of North Carolina and in-country organizations are assisting with this research.

— William R. Finger

### FOOTNOTES

1. United Nations Population Fund. Background note on the resource requirements for population programmes in the years 2000-2015, July 1994. Unpublished paper.

2. Population Action International. *Financing the future: Meeting the demand for family planning*, 1994.

3. Lande RE, Geller JA. Paying for family planning. *Population Reports* 1991; Series J, No. 39.

11. Stanback J, Smith JB, Janowitz B, et al. Safe provision of oral contraceptives: The effectiveness of systematic laboratory testing in Senegal. *Int Fam Plann Perspect* 1994; 20(4): 147-49.

12. Trussell J, Leveque JA, Koenig JD, et al. The economic value of contraception: A comparison of 15 methods. *Am J Public Health* 1995; 85(4):494-503.



# Women's Views Influence Use

Introduction strategies should consider user perceptions about effectiveness, side effects and convenience.

The attitudes and views of women, the primary users of family planning methods, are important to consider when introducing any new contraceptive method.

Women's decisions about use, non-use or discontinuation can be affected by their perceptions of contraceptive risks and benefits, concerns about how side effects may influence their daily lives, and assessments of how particular methods may affect relationships with partners or other family members. Incorporating women's perspectives into contraceptive introduction strategies can help local family planning programs increase user satisfaction, improve continuation rates, and expand method use, experts suggest.

Several international and national organizations are conducting research to learn more about women's perspectives. One multicountry study found that contraceptive effectiveness was extremely important to women, and many cited effectiveness as the primary reason for choosing a contraceptive method, according to Dr. Rachel Snow, principal investigator. Approximately 550 contraceptive users and non-users took part in focus group discussions as part of the study, which involved women who lived in poor urban and suburban areas in Cambodia, India, Mexico, Pakistan, Peru, South Africa and the United States.

For example, women in Udaipur, India said effectiveness was a major concern and must be balanced with method side effects. Women in Lima, Peru listed effectiveness as the first attribute of an ideal contraceptive.

The ideal duration of effectiveness for a long-term reversible method was three to five years, study participants said, and some suggested three months to a year as the ideal length of effectiveness for injectable contraceptives.

Women were questioned about side effects, particularly their tolerance for menstrual bleeding disturbances. Tolerance for amenorrhea varied, but most women said they would not accept heavy or more frequent bleeding.

The study also questioned women about their knowledge of barrier methods. Researchers found that women knew very little about these methods, other than the male condom. In Karachi, Pakistan, study participants said the idea of using barrier methods would be "terrifying" or "difficult" due to inability to negotiate method use with their partners.

"Most of the studies that have been done do not offer much information on non-users," says Dr. Snow, an assistant professor at the Harvard University School of Public Health in Boston. "That has weakened our ability to take a scientific approach to understanding what women want in contraception."

While Dr. Snow cautions that the results should not be construed to apply to all women in a particular country, findings do offer insights that may help scientists involved in development or refinement of contraceptives and can offer information that may help family planning program managers in introduction and service delivery.

## FEMALE-CONTROLLED

In recent years, women's health advocates have asked scientists to intensify their research on female-controlled barrier method contraceptives. Barrier methods offer the advantage of protection against pregnancy and some types of sexually transmitted diseases.

In response, FHI, the Population Council and WHO recently began a study on introducing the diaphragm into family planning programs. The two-year prospective study will explore women's views on acceptability, as well as method effectiveness, says Carol Joanis of FHI, a technical monitor for the study. In addition, researchers will try to determine the demands placed on service delivery systems when the diaphragm is added to the mix of existing contraceptives, and researchers will examine the impact of training regarding the diaphragm on health providers' knowledge, attitudes and practices.

"We want to introduce the diaphragm using good standards of care, where women have access to several methods and individual counseling," says Susan Palmore, director of FHI's Policy and Research Utilization Division, who has worked with WHO and the Population Council to coordinate the study. "Women who come into a clinic will be given information about all contraceptive methods. Then we want to see which women will choose the diaphragm and how they use the diaphragm in a real-life setting."

Women are typically instructed that prior to sexual intercourse they should put spermicide on the diaphragm, insert the device into the vagina to cover the cervix, and leave the diaphragm in place for at least six hours after intercourse. For repeated acts of intercourse, additional spermicide should be added.

The diaphragm study will explore whether women modify those instructions to suit their lifestyles and what impact those modifications might have on satisfaction and effectiveness. For example, some women might use the diaphragm only during the fertile periods of their menstrual cycles, some may use the diaphragm without spermicide, others may ask their partners to use condoms for additional protection against pregnancy or sexually transmitted diseases (STDs).

The study is under way in Colombia, Turkey and the Philippines — countries where the diaphragm is not widely used. Up to 2,100 diaphragm users in at least 14 health clinics will participate.

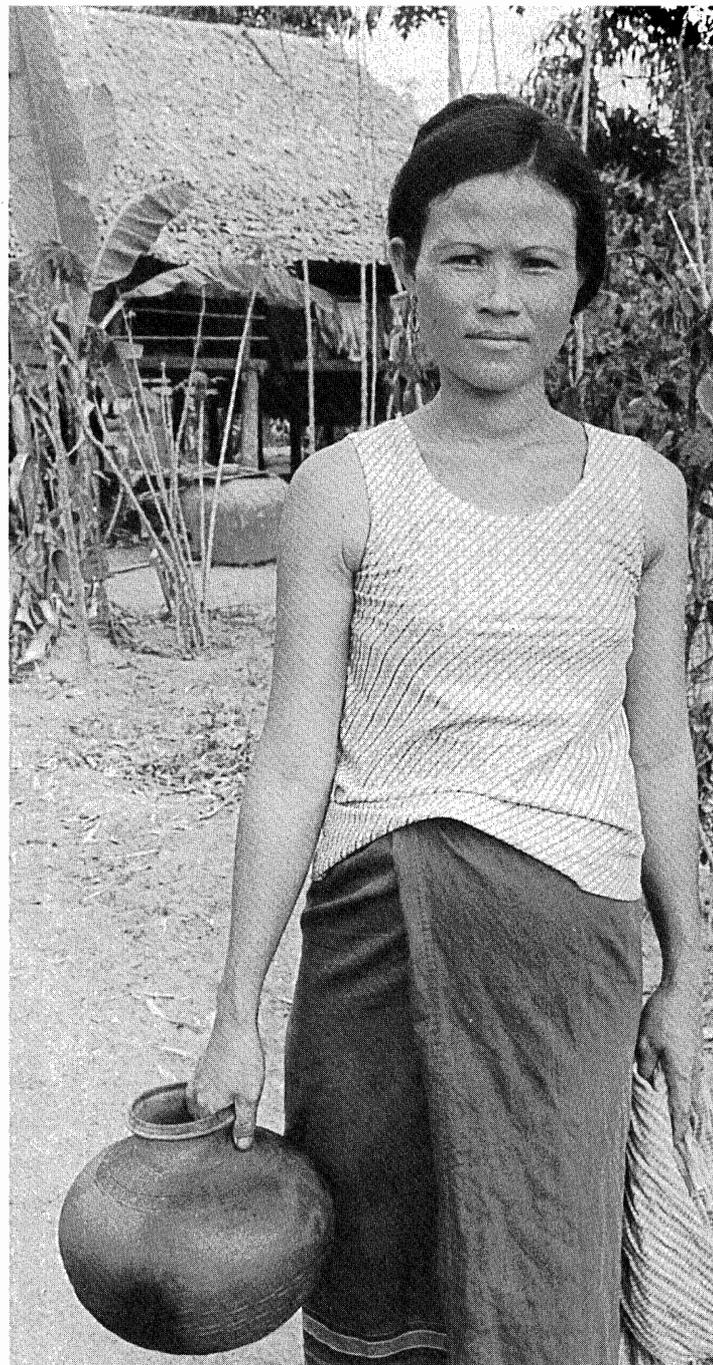
Clients will be monitored for six to 12 months to determine patterns of diaphragm use, satisfaction with the method, perceived advantages and disadvantages, partner satisfaction, and reasons for discontinuation. Clients will be questioned about whether convenience, cost or user-control were factors in their choice of the diaphragm. They will be asked about problems, such as difficulties with insertion or irritation from spermicide. Also, they will be asked about their partners' views on the diaphragm, whether their partner influenced their choice of methods, and the woman's ability to determine family size and spacing of births.

Similar data will be collected from 600 women who have chosen other reversible contraceptive methods.

As part of the study, participating counselors and clinicians attend a training program, which offers information on all contraceptive methods, but focuses on diaphragm fitting, counseling and the study protocol.

By using client interviews, focus groups, observations in clinics, and surveys of providers, researchers will measure the rates of diaphragm acceptance when women are given the opportunity to choose it from an array of methods; learn women's reasons for discontinuation or continuation; and identify characteristics of clients who are likely to accept and use the diaphragm effectively.

Results will help health ministries, donor agencies, policy-makers and family planning program managers if they plan future introduction or reintroduction strategies for the diaphragm. Also, the study could be replicated in other countries to learn about variations in use and satisfaction among clients and providers in other cultures.



LEAH MELNICK/IMPACT VISUALS

A STUDY AMONG WOMEN IN CAMBODIA AND OTHER COUNTRIES FOUND THAT CONTRACEPTIVE EFFECTIVENESS WAS EXTREMELY IMPORTANT TO THEM. THIS WOMAN LIVES IN THE KANDAL PROVINCE OF CAMBODIA.

## VILLAGE PERSPECTIVES

In Bangladesh, a nongovernmental organization has made efforts to include women's perspectives when contraceptives are introduced in local villages. The Bangladesh Rural Advancement Committee (BRAC) works to improve the quality of life for the country's poor through economic, educational and health programs. The organization began a distribution program for oral contraceptives

and condoms in 1972, and two years later found the pill continuation rate was 20 percent — higher than expected.

To improve continuation rates, BRAC organized “village committees,” in which local residents talked to health workers about their contraceptive needs.

“We talk about continuation — what are the pros and cons of the methods,” says Dr. Sadia Afroze Chowdhury, director of BRAC’s health and population program. “The village committees are primarily made up of women, and they tell us what they feel would be most appropriate for the women living there.”

The committees have offered valuable information for health providers, Dr. Chowdhury says. For example, one meeting revealed that women did not want to use intrauterine devices (IUDs) because they feared the side effect of heavier bleeding.

“We know what contraceptive methods are available in Bangladesh, so we know what we can offer, but we have to know what the family planning consumer wants,” says Dr. Chowdhury. “If the community is not interested, they won’t come in for services. The village committees have helped us sharpen our focus. It has been a mutual learning experience and we change our programs according to women’s needs.”

Farther south in Asia, the Vietnam Women’s Union, an 11-million member group that works to improve the legal rights of women and children, has made family planning one of its priorities.

Union members work closely with the Vietnamese Ministry of Health and the National Committee on Family Planning, providing information and education on contraception to community members. The union trains local residents to encourage neighbors in their villages to consider family planning. In 1991-92, the Women’s Union held 371 workshops to train 20,000 people.

The Women’s Union has conducted a pilot program in which trained volunteers provided education, information and counseling about user-controlled contraceptives, such as the condom and oral contraceptives, which are available in pharmacies and do not require a visit to a health clinic.

“In each pilot commune, there are 10 trained volunteers taking care of 70 to 100 women of reproductive age,” writes Mrs. Vo Thi Thang, vice chairperson of the Women’s Union. “One year after the model program was implemented, contraceptive use, particularly use of pills and condoms, ranged from 30 to 60 percent in different communes.”<sup>1</sup>

In Vietnam, the use of modern contraception is 37 percent among married couples, with IUDs as the primary means of family

planning. Several organizations, including WHO, are working with the Women’s Union to expand women’s choice of methods through the introduction of other contraceptives.

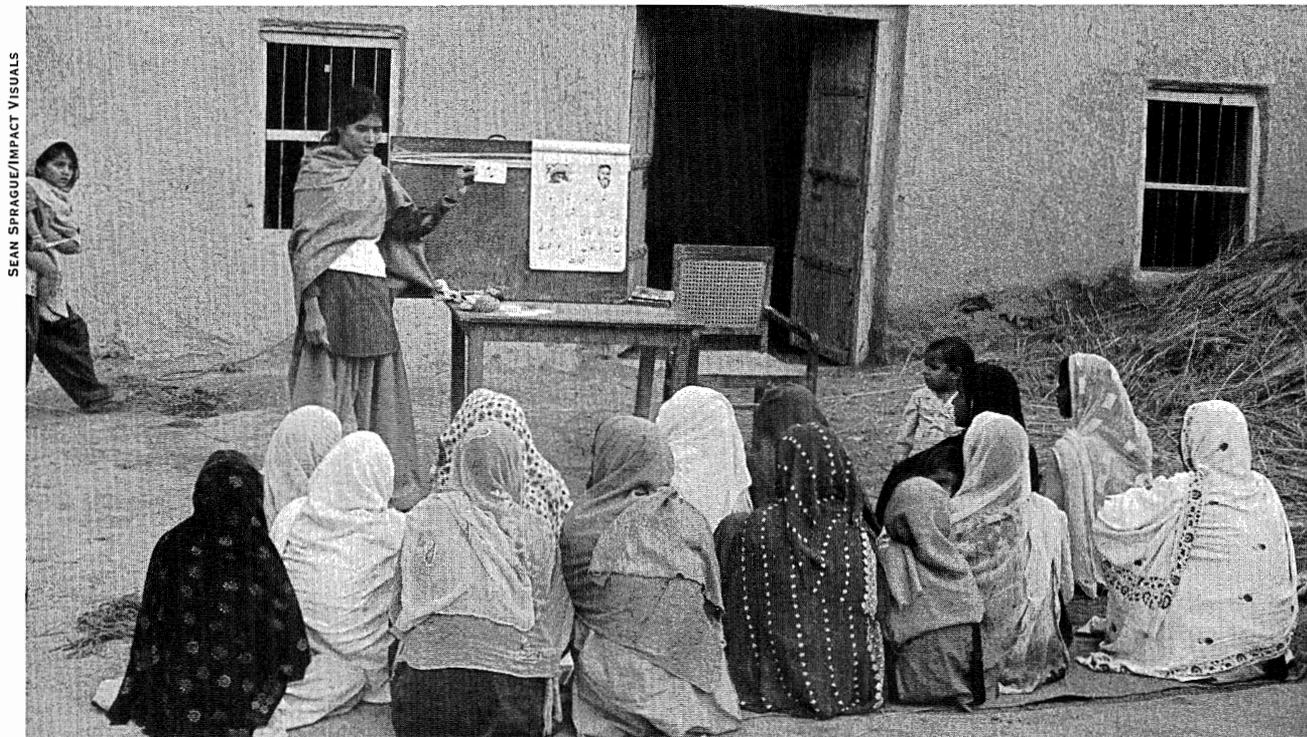
Currently, the Women’s Union is working with a WHO task force to develop a proposal to introduce the three-month injectable method, depot-medroxyprogesterone acetate or DMPA.

“Having members of the Women’s Union participate in the process adds a different set of perspectives,” says Dr. Peter Fajans of WHO. “The Women’s Union members are more likely to have an insight into women’s perspectives on the problems experienced by women living in rural villages, the problems with service delivery and women’s ability to have the contraceptives of their choice.”

The effort to include women’s perspectives in contraceptive introduction has grown, in part, out of the international movement for women’s rights. Many women’s groups have called for improvements in health care, including increased access to family planning and reproductive health services, as a way to improve the overall status of women.

To foster a dialogue between women’s health advocates and scientists on family planning issues, WHO sponsored “Creating

WOMEN ATTEND AN ADULT LITERACY CLASS IN PUNJAB, PAKISTAN.



SEAN SPRAGUE/IMPACT VISUALS

## MICROBICIDES RESEARCH AND THE WOMAN'S PERSPECTIVE

Common Ground" meetings in Europe, Asia and Latin America. Participants have strongly urged the inclusion of women's perspectives on the research and introduction of contraception.

At the Common Ground meetings, women and scientists have discussed their differences in perspectives on family planning. For example, scientists have traditionally measured contraceptive safety through clinical studies on toxicology and carcinogenicity. Women's health advocates say they are also concerned about the effect of a particular method on overall health and about side effects, such as menstrual bleeding disturbances. Scientists measure acceptability through continuation and discontinuation rates. Women's health advocates suggest that indicators of acceptability include measurements of informed choice and user satisfaction as well.<sup>2</sup>

A precise understanding of the users' perspectives is not easy to obtain. "It is fashionable these days to say we must find out from 'real women' what they want," says Adrienne Germain of the International Women's Health Coalition. "Those who seek to do this must take into account whether the women they are asking are free to say what they want, and whether their circumstances — their knowledge, information, experience in making choices about anything, access to well-trained providers — actually allow them to imagine what they might want in a contraceptive.... Women often do not have the technical information to fully perceive whether a method is good for them or not."

### USER SATISFACTION

In the West African country of Mali, where only 1 percent of married women use modern contraception, FHI is studying women's views on the introduction of Norplant, the subdermal implant that protects against pregnancy for five years. FHI surveyed 325 Norplant users and 300 users of other methods to ask about satisfaction with method choice and with service delivery after six months.

The survey found that the majority of women were satisfied with Norplant, but some suggested improvements in the service delivery system.

"The aspect of the method women like most is that it is easy to use, and to a lesser extent, that it lasts five years," says Karen Katz of FHI, who worked on the Norplant introduction study. "The majority of women

Researchers working to develop microbicides, which could give women a means of protecting themselves against sexually transmitted diseases, are soliciting women's views to help ensure that the new technology will meet their needs.

Women will be involved in many aspects of microbicide development, including the implementation of clinical trials, and introduction of the method into family planning and reproductive health programs. Researchers estimate it will be seven to 10 years before a microbicide product is approved for widespread use.

Microbicides may offer a non-contraceptive female-controlled barrier method to protect against AIDS and HIV infection by blocking STD bacteria or viruses. It might be contained in a gel or film that is inserted into the vagina, much like available spermicides. A modified formulation might offer contraceptive protection as well.

"Traditionally contraceptive development has been biomedically driven — driven by scientific discoveries," says Christa Coggins, staff associate with the Population Council. The microbicides research, however, is seeking women's perspectives to guide research, before discoveries are made. The Population Council is working collaboratively with the U.S.-based International Women's Health Coalition (IWHC) and The Pacific Institute for Women's Health.

A meeting of women's health advocates and scientists was held in 1994, and women's groups will be involved in later stages. "Involving women's health advocates in clinical trials benefits both the study participants and the scientists," says Amparo Claro, coordinator of the Latin American and Caribbean Women's Health Network in Chile, and one of the health advocates working with the Population Council. By working with scientists in clinical trial sites, "women's health advocates can establish open and meaningful communication with the study participants, which would provide, for the scientists, more accurate and complete reactions to the product."<sup>1</sup>

The Population Council plans Phase I clinical trials of a noncontraceptive microbicide in the United States, Finland, Chile, Australia, and the Dominican Republic, says Coggins. A second study, which will use focus groups and interviews to determine women's preferences for microbicide formulation — in film, vaginal inserts or gel — will be conducted in Côte d'Ivoire, Zimbabwe, Thailand and the United States, she says.

— Barbara Barnett

### FOOTNOTE:

1. *Partnership for Prevention: A Report of a Meeting Between Women's Health Advocates, Program Planners and Scientists*. New York: The Population Council, 1994.

had already recommended Norplant to another person. What they like least is the side effect of bleeding disturbances.

"The principal reasons why users of other methods did not choose Norplant were that they did not know enough about it or preferred the method they were currently using."

Most women were satisfied with the counseling they received, but 15 percent said they wish they had received more information, particularly about disruption of menstrual cycles, a common Norplant side effect. Women suggested the best ways to improve Norplant services were to provide more information and education on the method, find a solution to bleeding problems and reduce clinic waiting times.

"Satisfaction is a difficult concept to measure because clients are often reluctant to be critical," says Katz. "Therefore, we asked a number of related questions to get at different aspects of satisfaction. That way, we can further ascertain what women liked and what needs improvement."

Mali's Division of Family and Community Health, part of the Ministry of Health, Solidarity and the Elderly, will include the survey results in its evaluation of Norplant introduction. Information gained from the survey will be used to evaluate whether or not to expand Norplant provision in Mali.

In Southeast Asia, at the request of the Vietnamese Ministry of Health, FHI conducted a study on user satisfaction of two contraceptive methods — IUDs and quinacrine nonsurgical sterilization. The retrospective study involved more than 3,000 women who had used IUDs or quinacrine and was conducted to assist the government in its evaluation of whether quinacrine should be considered for widespread introduction. Due to concerns from women's health advocates, donors and international health organizations about quinacrine safety, the Vietnamese government has discontinued quinacrine sterilizations until further evaluations are done.

Women were questioned about their perceptions of how IUD use or quinacrine sterilization affected their health and other aspects of their lives, including relationships with their husbands, ability to work, and ability to care for children. Also, the survey measured satisfaction by asking women about fear of pregnancy and method failure. And the survey questioned women about their access to services, waiting times in health clinics, counseling from providers, and informed consent.<sup>3</sup>

Eighty-six percent of the quinacrine acceptors said the method was a good choice for them, and 80 percent of IUD acceptors were happy with their method. The majority of women in both groups reported that contraceptive use had not affected their sex lives, but some women in both groups noted that method use did affect other aspects of their lives, including their ability to do farm work and housework. Some reported such side effects as dizziness, fatigue or headaches.

Most women were satisfied with waiting times at clinics and said the clinics were close to their homes, so travel was not a problem. More than 80 percent of women in both groups said they received counseling about possible side effects and where to get help for problems before they received their method.

"What we learned in the study is that effectiveness is important to women," says Dr. Cindy Waszak. "Satisfaction with a method is often determined by the woman's perception of how well the method does or does not prevent pregnancy. In Vietnam, where there is a country-wide effort to expand women's access to affordable, safe contraception, this type of information can be used in developing future introduction or reintroduction strategies."

To learn more about women's satisfaction with family planning, FHI is conducting the Women's Studies Project. The five-year project, funded through a cooperative agreement with the U.S. Agency for International Development, is examining women's perceptions of how family planning has positively or negatively affected numerous aspects of their lives, such as work, education, relationships with spouses, and community participation.

"Local women's health advocates have been involved in this project from the outset," says project director Dr. Nancy Williamson. "Women's health advocates were interviewed, along with scientists, government officials and health providers, to help determine areas of interest for research. Women's health advocates serve on in-country advisory committees that monitor research, and they will be instrumental in disseminating research results to local communities."

Results from the Women's Studies Project, which will be conducted in the Philippines, Indonesia, Brazil, Bolivia, Egypt and Zimbabwe, are being used to improve family planning programs and policies, to ensure they reflect women's needs.

#### NEW METHODS, NEW OPTIONS?

As national and international organizations develop contraceptive introduction strategies that take into account women's perspectives, they should consider the impact of introduction of a new method on women's overall health and welfare. Some scientists and women's health advocates have suggested that introduction of a new method will do little to enhance women's health if the current health-care system is ill-equipped to perform procedures, to give counseling, or to manage side effects.

In Indonesia, family planning policymakers decided not to introduce Cyclofem, a monthly injectable, when researchers concluded it would do little to expand women's contraceptive options.

Introductory trials in six public health centers found that Cyclofem gave women a contraceptive choice that did not interrupt menstrual bleeding patterns, was highly effective, and allowed for rapid return to fertility.

However, when other factors were considered, the addition of Cyclofem meant only "relatively modest" increases in women's access to quality care, researchers said. Two other types of injectable contraceptives were already available in Indonesia, and because women had to return to the clinic more often for repeat injections, costs to clients would be higher than with injectables that lasted two or three months. In addition, Norplant had recently been introduced for women seeking a long-term contraceptive method.<sup>4</sup>

"In addition to user perspective, you must look at logistics, service delivery systems, training needs. Does the service delivery system have the capability to provide the new method with an appropriate level of quality of care?" says Dr. Ruth Simmons, co-chair of a WHO steering committee on contraceptive introduction and technology transfer and a professor at the University of Michigan in the United States.

"You must ask these questions within the broader context of women's reproductive health."

— Barbara Barnett

#### FOOTNOTES

1. *Interagency Meeting on Vietnam: Final Report*. Research Triangle Park: Family Health International, 1994.

2. *Creating Common Ground: Women's Perspectives on the Selection and Introduction of Fertility Regulation Technologies*. Geneva: World Health Organization, 1991. *Creating Common Ground in Asia: Women's Perspectives on the Selection and Introduction of Fertility Regulation Technologies*. Geneva: World Health Organization, 1994.

3. Hieu DT, Vinh DQ, Tong NK, et al. *A Retrospective Study of Quinacrine Sterilization in Vietnam*. Unpublished paper. Durham: Family Health International, 1995.

4. Simmons R, Fajans P, Lubis F. *Contraceptive introduction and the management of choice: the role of Cyclofem in Indonesia*. *Contraception* 1994; 49(5):509-25.



# Good Reproductive Health Involves Many Services

Combining family planning with other reproductive health services may improve care, but raises questions.

**R**eproductive health is life-long, beginning even before women and men attain sexual maturity and continuing beyond a woman's child-bearing years.

Family planning has traditionally focused on only one aspect of reproductive health care that is needed during a particular time of life—providing safe, effective and affordable contraception. In addition to family planning, reproductive health care includes pregnancy and postpartum care, prevention and treatment of sexually transmitted diseases, pregnancy termination, cancer screening and infertility counseling, among other services. Related health concerns are numerous, including counseling about domestic violence or gender inequality.

Different stages in a person's life require different reproductive health services. Adolescents and unmarried women may not have access to effective contraceptive methods. Pregnant women need dependable emergency care that is quickly available. Women with reproductive tract infections and women who have terminated unwanted pregnancies may need special counseling.

Poor reproductive health accounts for a substantial portion of all deaths among women ages 15 to 49 worldwide.<sup>1</sup> These deaths arise from complications during pregnancy or childbirth, from reproductive tract infections, and unsafe abortion. Domestic violence and sexual abuse contribute to these deaths, as well as to many injuries and illnesses.

"We continue to get more data showing women's reproductive health problems are far more prevalent than we previously thought," says Dr. Karen Hardee, a senior research associate at FHI. Some of these conditions can be improved by expanding family planning services into other areas of reproductive health care, she says, although careful planning and evaluation are necessary to determine which additional services would be feasible and worthwhile.

## LIMITED RESOURCES

Expanding reproductive health services can be effective but also raises questions about how limited resources should be spent. Some experts maintain that many reproductive illnesses and deaths could be prevented or treated using technology currently available in most countries.<sup>2</sup> In some countries, maternal health investments of US \$1.50 a year per person of the total population can reduce maternal mortality by as much as 65 percent, according to Anne Tinker at the World Bank.<sup>3</sup>

A substantial number of family planning programs have already implemented services that go beyond contraceptive services. In 1993, the U.S. Agency for International Development surveyed 50 countries on reproductive health activities either ongoing or planned to begin by 1995. The survey divided reproductive health into four categories: family planning or safe regulation of fertility; maternal health and nutrition; protection from STDs; and reproductive rights. More than half of the agencies surveyed had already integrated some



FRAN ANTMANN/IMPACT VISUALS

COMBINING POSTPARTUM SERVICES WITH FAMILY PLANNING IN A PERUVIAN STUDY ACHIEVED HIGHER CONTRACEPTIVE PREVALENCE AND COST SAVINGS. THESE PERUVIAN WOMEN WORK IN A REMOTE VILLAGE.

form of STD services with family planning, and one-fourth were providing services from all four categories.<sup>4</sup>

Combining services may improve efficiency by reducing duplication and minimizing the number of workers and facilities needed.<sup>5</sup> In an evaluation by the Population Council, programs in Tegucigalpa, Honduras and Lima, Peru that combined postpartum services with family planning achieved a higher contraceptive prevalence and cost savings. In an experimental study in Lima, women offered contraception before hospital discharge were substantially more likely to be using contraception six months postpartum, compared to women who did not receive any family planning after childbirth. Because in-patient IUD insertion in Lima cost \$9.38 per woman compared to \$24.16 for out-patient insertion, implementing postpartum family planning at Peruvian Social Security Institute (IPSS) hospitals is expected to save about 5 percent of IPSS's annual family planning costs.<sup>6</sup>

However, integrating new health services into a family planning program may enhance one component of health care at the expense of another. Primary health care clinics in many countries already have many tasks to meet, says FHI's Dr. Nancy Williamson, who has written extensively on the integration of family planning and STD services.

"A lot of people have good will and want to cover a larger reproductive health need, but from a family planning perspective the question is, 'How can we find compatible activities without diluting family planning?'" asks Dr. Williamson, who directed the evaluation of a large maternal and child health and family planning integration project in the Philippines. "More thought needs to be given on how to integrate the activities for a worker or a client."

There are many reproductive health services that could be added to family planning services. Two of the most widely studied service categories include maternal health care and STD prevention or treatment.

#### STD PREVENTION

Family planning programs may be an appropriate place to provide STD prevention and treatment because many of the functions overlap. Counseling on sexual activity (including abstinence) and providing barrier contraceptives, which help protect against STDs, are examples of related services, says Dr. Ward Cates, FHI's corporate director of medical affairs.

Having an STD increases a person's risk for HIV infection and transmission. STDs also contribute to reproductive tract problems in women, can harm unborn fetuses, and increase a woman's chances of developing cervical cancer.<sup>7</sup> Most STDs, including syphilis, genital

herpes, chancroid, genital warts, bacterial vaginosis, trichomoniasis, chlamydia and gonorrhea, increase a woman's risk for illness and death during pregnancy and childbirth. Swelling and infection in the upper reproductive tract can cause ectopic pregnancy, resulting in hemorrhage.

Family planning providers can prevent some of these infections through screening, condom distribution, couples counseling, maintaining hygienic facilities, and being sure that contraceptive services or procedures do not spread or aggravate infections.

Combining basic STD screening and some of the more inexpensive treatments with family planning may be easy to do and worthwhile, says Dr. Williamson. "There's fairly wide agreement among scientists that if a family planning program's clientele has an STD problem, the program should try to do something about it." Health providers should consider developing a simple way to evaluate their clients' STD risk in order to determine how much to spend on screening for a particular disease.<sup>8</sup> Because STDs are frequently asymptomatic in women, inexpensive screening may not be completely successful. Dependable diagnostic procedures are often costly and may require laboratories or expensive equipment.

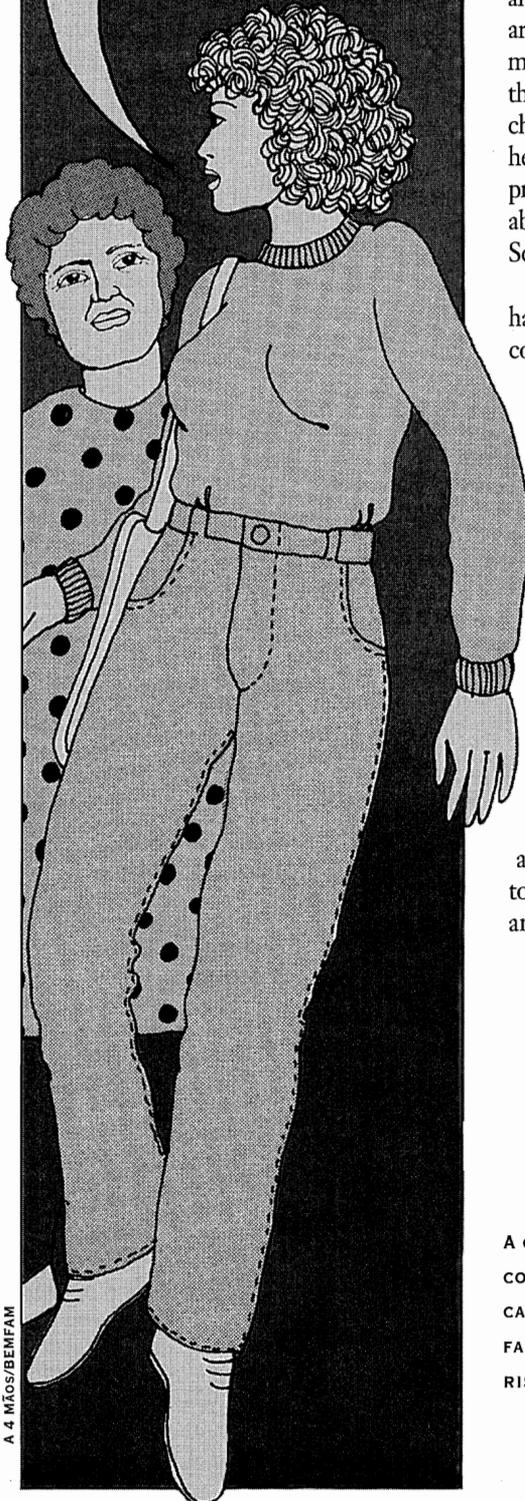
One inexpensive method for assessing risk is interviewing clients about their symptoms, also called a "syndrome-based approach." However, in addition to a lack of symptoms in some clients, cultural values may discourage talking openly about intimate relationships and risk behaviors. In Rio de Janeiro, Brazil, FHI researchers were able to encourage frank discussions of STD risk and sexual relations at family planning clinics by using a cartoon soap opera with clients who met in small groups. In private counseling later, the number of clients who were willing to discuss their partners' infidelity and to identify themselves as being at risk for HIV infection increased dramatically compared with their willingness prior to the group sessions, says Dr. Patsy Bailey, public health specialist at FHI's Maternal and Neonatal Health Center. "By talking about it in a group, they allowed themselves to admit it," says Dr. Bailey. "There may have been less denial."

Another question concerning the efficacy of combining STD services with family planning involves the type of clients family planners typically serve. To be most effective in the fight against STDs, health workers may have to target high-risk populations, such as prostitutes and other people with multiple partners. Treating an STD in one high-risk person may avoid transmissions to many others. Family planning clients, however, typically are married women with only one partner. "Nevertheless, family planning providers should not assume their traditional clients do not have a problem," says Dr. Bailey. "The number of women infected with HIV has been increasing, even among groups you wouldn't normally think would be at risk. It seems to justify an intervention."

FHI's Dr. Williamson urges family planning providers to assess the STD risk of clients, even if it is only to ask clients about their risk of infection. "I don't see how you can recommend a contraceptive method if you don't know a client's STD risk," she says. "Yet it isn't being done often enough. It isn't going to be perfect, you have to tailor the questions to each setting, but it doesn't cost anything to do."

Clients should consider their risk of STDs when choosing a method. Family planning programs tend to encourage contraceptives that will be the most effective at preventing pregnancy. Preventing STDs, however, may require the use of latex condoms, which are typically less effective at preventing pregnancy than longer-acting

AH! ENTÃO DEVE SER POR ISSO QUE A SÔNIA QUER REUNIR A MULHERADA HOJE A NOITE. DISSE QUE É COISA GRAVE, DEVE SER ISSO... MAS DEIXA EU IR EMBORA, SE NÃO, PERCO O MEU EMPREGO! ATÉ LOGO MAIS.



A 4 MÃOS/BEMFAM

methods since some people do not use barrier methods consistently and correctly. One option is use of "dual methods," using a barrier method to guard against STDs and another method as a contraceptive, such as injectables, the pill, or Norplant.

## MATERNAL HEALTH

Family planning plays a major role in preventing maternal mortality and morbidity. "The biggest dent you can make in maternal morbidity is not getting pregnant," says Dr. Judith Fortney, director of FHI's Maternal and Neonatal Health Center. Although there are risks associated with any contraceptive method, these risks are substantially lower than the health risks associated with pregnancy and childbirth. Family planning can also reduce health risks associated with closely spaced pregnancies, high-risk births, and unsafe abortion, concluded a National Academy of Sciences (NAS) panel.<sup>9</sup>

Maternal mortality declines when women have better access to safe contraception, according to Dr. Fortney. For example, maternal mortality fell by one-third in a rural area of Bangladesh following a community project that increased contraceptive prevalence to 50 percent, compared with 23 percent in a control area.<sup>10</sup> Family planning programs may also be appropriate places to counsel women on prenatal care and to encourage breastfeeding.

Although family planning providers rarely see women when they are pregnant or in the midst of childbirth, they could easily give information about prenatal care, pregnancy complications and encourage breastfeeding. They could also provide basic prenatal services, such as iron and iodine supplements, and tetanus toxoid and malaria prophylaxis in infested areas, says Dr. Fortney.

A CHARACTER IN A CARTOON BOOK TALKS ABOUT A COMMUNITY MEETING TO DISCUSS AIDS. THE CARTOONS ENCOURAGE CLIENTS AT BRAZILIAN FAMILY PLANNING CLINICS TO DISCUSS THEIR STD RISKS.

A MotherCare program in Cochabamba, Bolivia increased women's awareness of danger signs in pregnancy by providing such basic information — a relatively inexpensive service.<sup>11</sup> "Forget about weighing patients, forget about nutrition. Every woman knows she should eat more, and she would if she could," says Dr. Fortney. "But if you tell clients symptoms to look out for — indicators of pregnancy complications, when you really have to go to a hospital, where to go, how to get transportation — then you'll really be doing something to reduce maternal mortality."

Family planning providers may be able to help pregnant patients plan hospital transportation in advance, she says. A woman's ability to reach obstetric care often depends on help from the community. Since most life-threatening complications occur during labor and delivery, every pregnant woman needs rapid access to emergency obstetric care. The majority of maternal deaths and much of chronic morbidity resulting from childbirth are due to lack of timely medical help for pregnancy complications.<sup>12</sup>

After a woman has given birth, family planning providers can play an important role in counseling about birth spacing and contraceptives. For example, many breastfeeding mothers may not know about the natural contraceptive benefits from breastfeeding, also called the Lactational Amenorrhea Method (LAM). LAM is highly effective during the first six months postpartum as long as a woman has not resumed menstruation and is fully or nearly fully breastfeeding.

## PRIORITIES

There are many ways to define reproductive health. Different definitions and priorities are being proposed by women's health advocates and family planning organizations around the globe.

One approach, articulated by FHI's Dr. Hardee and Kathryn Yount of Johns Hopkins University School of Hygiene and Public Health, uses the consensus statement from the United Nation's 1994 International Conference on Population and Development to identify possible services. Good reproductive health, according to the statement, should include freedom from the risk of sexual diseases; the right to regulate one's own fertility with full knowledge of contraceptive choices; and the ability to control sexuality without being discriminated against because of age, marital status, income, or similar considerations.<sup>13</sup>

Achieving these goals will require a wise use of resources, which may include ways to integrate different reproductive services. For example, family planning programs and other reproductive health projects may be able to share certain services, such as maintaining a central file of patient records. The policies and administrative structure of each country will play a role in determining how different health services are combined.

Client needs and the culture of each community and country should be considered. "To look at reproductive health means looking at all aspects of people's lives," says Dr. Hardee. "Certainly, you need to prioritize. But we think that's something you have to do at a country level."

Another effort to define reproductive health and prioritize goals is being made by NAS, a U.S.-based scientific society. "We don't think we're going to come up with in-

structions, or a recipe for action," says John Haaga, director of the NAS Committee on Population. "But a lot can be done to clarify priorities that should bring us closer to some answers." In 1996, a NAS study panel may recommend a priority list of reproductive health care services that could be used in many settings, he says.

— Sarah Keller

## FOOTNOTES

1. Starrs A. *Preventing the Tragedy of Maternal Deaths: A Report on the International Safe Motherhood Conference*. Nairobi: World Health Organization, 1987. Jacobson JL. *Worldwatch Paper 102: Women's Reproductive Health: The Silent Emergency*. (Washington: Worldwatch Institute, 1991) 5.

2. Jacobson.

3. Tinker A. Safe motherhood: How much does it cost? Unpublished paper. World Bank, 1990.

4. Pillsbury B, Maynard-Tucker G. *USAID Reproductive Health Baseline Survey: A Survey of Projects and Activities Implemented and Planned by USAID Missions and Cooperating Agencies*. Washington: USAID, 1994.

5. Hardee K, Yount K. *From Rhetoric to Reality: Delivering Reproductive Health Promises through Integrated Services. Women's Studies Project Working Paper No. 2*. Durham: Family Health International, 1995.

6. Foreit J, Lagos G. Effectiveness and cost-effectiveness of post-partum IUD insertion in Lima, Peru. *Int Fam Plann Persp* 1993; 19(1): 19.

7. Family Health International. *Proceedings of Understanding STDs and the Public Health Approaches to Their Control: The Appropriate Role of Family Planning Programs*. (Durham: FHI, 1994) 2.

8. FHI, 4.

9. DeVanzo J, Parnell A, Foege W. Health consequences of contraceptive use and reproductive patterns. *Journ Amer Med Assn* 1991; 265(20): 2692-96.

10. Fauveau V. Matlab maternity care program. Unpublished paper. World Bank, 1991. 29.

11. Pillsbury, D-1.

12. World Health Organization Maternal Health and Safe Motherhood Programme Division of Family Health. *Care of Mother and Baby at the Health Centre: A Practical Guide*. (Geneva: WHO, 1994) 9.

13. International Conference on Population and Development. *Programme of Action of the International Conference on Population and Development*. New York: United Nations, 1994.

# The Female Condom: Controlled by Women

The U.S. Agency for International Development (USAID) recently provided a limited supply of female condoms to family planning programs in 22 countries. USAID will evaluate whether to continue supplying them. As part of the introduction of this method, FHI prepared an information packet for family planning managers. The following is a concise overview statement and a question and answer sheet that were included in the packet.

The female condom is a barrier method of contraception that is highly effective in preventing pregnancy, provided it is used correctly and consistently. Research on how well this relatively new method protects against sexually transmitted diseases (STDs) remains to be done. Its ability to protect against STDs, including HIV, is speculative but promising.

This female-controlled barrier method may be especially useful for women at risk of STDs who have difficulty convincing their male partners to use latex condoms. The female condom is marketed as Reality in North America and Femidom in Europe. The U.S. Food and Drug Administration (FDA) approved it for marketing in the United States in 1993.

## STRONGER THAN LATEX

Female condoms are made of a polyurethane plastic that is sturdier than male latex condoms, potentially offering less frequent breakage, improved comfort, and longer shelf life, even under unfavorable storage conditions.

This device consists of a soft, loose-fitting sheath and two flexible polyurethane rings at each end. One ring is at the closed end of the sheath and serves as an insertion mechanism and anchor inside the vagina. The outer ring forms the external edge of

the device and remains outside the vagina after insertion, thus providing protection to the labia and the base of the penis during intercourse. This design may reduce the potential for transfer of infectious organisms between sex partners, particularly genital ulcer diseases.

Unlike latex male condoms, which are weakened by using oil-based lubricants, the female condom may be used with any type of lubricant without compromising its strength. It is prelubricated, but more lubricant may be added by users.

## ONE SIZE, ONE-TIME USE

While this device is currently approved for a single use only, studies are under way to determine if the female condom can be cleaned and used more than once without lowering efficacy or compromising safety. Fitting by a health professional is not required as the device does not have to be precisely placed over the cervix.

## CONTRACEPTIVE EFFECTIVENESS

In its ability to prevent pregnancy, the female condom is similar to other barrier methods, such as the diaphragm and male latex condom. To determine contraceptive effectiveness, Family Health International (FHI) and the Contraceptive Research and

# THE FEMALE CONDOM: FREQUENTLY ASKED QUESTIONS

## I. Safety and efficacy

**Question: How effective is the female condom as a contraceptive?**

**Answer:** Its ability to prevent pregnancy is similar to other barrier methods, such as the diaphragm and latex male condom (88 percent contraceptive effectiveness over six months for the female condom in the United States). If used correctly and consistently every time, the female condom is 95 percent effective.

As a group, the barrier methods are less effective than sterilization, injectables such as DMPA, and the subdermal implant Norplant, all of which are close to perfect in terms of preventing pregnancy. Oral contraceptives (the pill) also provide more effective contraception than the female condom.

**Question: How effective is the female condom at preventing sexually transmitted diseases, including HIV?**

**Answer:** The ability of the female condom to prevent the transmission of HIV and other sexual diseases is speculative, but promising. Laboratory studies have found that the female condom is impermeable to various STD organisms, including HIV.

Only one study involving human use has been done to evaluate its STD prevention properties. Among 20 women with recurrent vaginal trichomoniasis, none of them experienced reinfections while using the device consistently and correctly.

**Question: Is it safe to use?**

**Answer:** Like most barrier methods of contraception, the female condom is safe to use. According to the manufacturer, no allergic reactions have been reported. The female condom is a good option for the small number of people who are allergic to latex, the material used in most male condoms.

**Questions: What are the contraindications for use?**

**Answer:** The female condom should not be used by people who are sensitive to polyurethane or silicone.

## II. The materials involved

**Question: What is the female condom made of?**

**Answer:** The device is made of a thin, soft polyurethane sheath and two flexible polyurethane rings. The inner ring is closed and

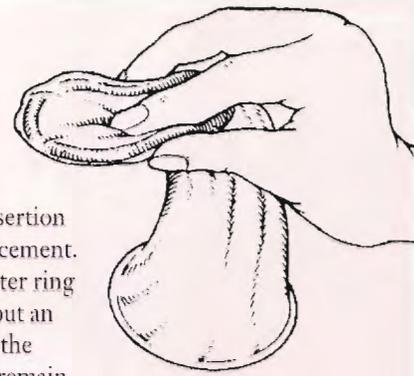
helps with insertion and placement. The outer ring and about an inch of the sheath remain outside the vagina during use. Each condom is prelubricated with silicone, and a container of water-based lubricant is supplied for those who prefer more lubrication.

**Question: Does the female condom come in different sizes? Does a woman need to be "fitted"?**

**Answer:** There is one size only, no fitting is required. The female condom is designed to fit most women.

**Question: How long can this device be stored and still be used effectively?**

**Answer:** In the United States, the female condom called Reality is dated to expire two years after manufacturing. However, its "shelf life" (how long it can be stored and still be safe and effective during use) is be-



Development Program (CONRAD) conducted a clinical trial of the female condom in nine centers — six in the United States and three in Latin America. For the 377 women entered in the trial, the six-month life-table pregnancy rate was 15.1 per 100 women (12.4 per 100 in the United States and 22.2 per 100 in Latin American centers). This typical failure rate in the U.S. centers was similar to six-month failure rates for the diaphragm, vaginal sponge and the cervical cap during typical use.

What if the device is used correctly for every act of intercourse? In the FHI/CONRAD collaborative study, the six-month failure rate during perfect use of the female condom was 4.3 per 100 women. Comparison of the U.S. data with data from other studies indicates that the probability of failure during perfect use for the female con-

dom is similar to the male condom and the diaphragm, and slightly lower than that for the cervical cap and the sponge.

## PREVENTION OF STDs AND AIDS

Laboratory studies have found that the female condom is impermeable to various STD organisms, including HIV and other viruses. Only one study involving human use has been done to evaluate the prophylactic properties of the female condom. In it, 104 women who had been previously diagnosed and treated

WOMEN AT A FAMILY PLANNING CLINIC IN CAMEROON EXAMINE A FEMALE CONDOM.



TOM TURK/FHI

lieved to be longer. The two-year expiration date may be extended if studies indicate a longer shelf life is warranted.

**Question: Is the female condom affected by heat, cold, air pressure or humidity?**

**Answer:** No. Unlike latex male condoms, the female condom is generally unaffected by atmospheric conditions, including altitude, humidity or the normal temperature ranges found in storage. However, the device should not be exposed to extreme heat or cold.

**Question: Can this device rip or tear during use?**

**Answer:** Any sharp object, including fingernails, rings or other jewelry, can rip or tear the female condom. The rip and tear rate in one study, however, was less than 1 percent of the female condoms used.

### III. Programmatic concerns

**Question: Can the female condom be used simultaneously with other contraceptives?**

**Answer:** It may be used with any nonbarrier contraceptive (such as oral contraceptives) and with spermicidal cream or gel. However,

it is not recommended for use with a male latex condom, since friction between the two devices may displace them or cause breakage.

**Question: Can the female condom be used by women who have recently given birth or undergone a pregnancy termination?**

**Answer:** Yes, it may be used when contraception or STD protection is needed any time following delivery.

**Question: Can this device be used if a woman has a tampon inserted?**

**Answer:** No.

**Question: Can it be used by pregnant or menstruating women?**

**Answer:** Yes.

**Question: Is this an appropriate method for young women (under 20 years old)?**

**Answer:** This method is safe and effective for any woman of any age, provided she understands how to insert it correctly and how to avoid tearing or ripping the device.

**Question: Can the female condom be inserted hours before use?**

**Answer:** Yes, although it may not be very comfortable to do so. It may be worn under clothing for several hours prior to use. If this is done, re-lubrication will be necessary for correct and comfortable use.

**Question: Do people like to use the female condom?**

**Answer:** In studies over six years among diverse populations, many women reported that they liked the device and would recommend it to others. There were few complaints about insertion, although some women said it took more than one attempt to get used to inserting the condom. The most frequent complaints were not liking the inner ring and movement of the device during use.

for recurrent vaginal trichomoniasis were assigned to a group using the female condom or to a control group (volunteers who indicated they would not use the condom). Each group was followed for a 45-day period of their usual sexual activity. Reinfection with trichomonas occurred in seven of the 50 controls (14 percent) and five of the 34 non-perfect users (14.7 percent), but none of the 20 perfect users of the female condom. FHI and the World Health Organization will conduct at least one study of female condom use and cervical infection. Until then, the efficacy of using female condoms for STD prevention remains speculative, but promising.

The U.S. FDA recommends using the male latex condom as a highly effective preventive measure against STDs, but using the female condom as an alternative when the male partner will not use a condom.

### ADVANTAGES AND DISADVANTAGES

This unique device offers several advantages:

- The female condom does not constrict the penis, as do latex male condoms. As a result, sensitivity for males may be better. Similarly, females have reported minimal loss of sensation while using the product. Unlike latex, the polyurethane material in the female condom allows the transfer of body heat, which may improve sensation.
- Since the female condom covers much of the external female genitalia, it provides a more extensive barrier and may offer somewhat greater protection than male condoms against genital ulcer diseases, such as herpes and chancroid.

- The device is female-controlled. For a woman at risk of STD, the female condom provides a prophylactic option should her partner refuse to use a male condom.

- Preferences for lubrication vary. The female condom can be used with any type of lubricant without compromising the integrity of the device, which is an advantage in countries where water-based lubricants are hard to obtain.

- Some women find the female condom is more convenient to use than other female barrier methods. It can be used without a



THE FEMIDOM FEMALE CONDOM, MARKETED PRIMARILY IN EUROPE, IS SIMILAR TO THE REALITY BRAND RECENTLY PURCHASED BY USAID FOR 22 COUNTRIES.

spermicide. Like the diaphragm, cervical cap and sponge, it can be inserted well before intercourse, although it may not be comfortable to do so.

As with any contraceptive method, the female condom has disadvantages:

- The female condom is relatively expensive. The average price in the United States is about \$2.50 each, about five times the price of a male latex condom. (If the device can be used safely and effectively more than once, its cost to a user would be lower.)

- It covers the external female genitalia. While that feature may offer better STD protection, many couples find this unappealing. It is a commonly cited reason for discontinuing use of the device.

- Some users complain that it is noisy during use. During vigorous use, it may be pushed into the vagina.

- Though very rare, female condom breakage was reported in about 1 percent of devices used in one clinical trial. (This is lower than the expected breakage rate for latex condoms, between 2 and 5 percent of devices used.)

#### WHAT PEOPLE LIKE OR DO NOT LIKE

Over six years, FHI has evaluated the acceptability of the female condom among diverse populations. The most frequent complaints were not liking the inner ring and movement of the device during use. There were few insertion-related complaints, although some women said that it took more than one attempt to get used to inserting the condom. Many women reported that they liked using the device and would recommend it to others.

The appearance and even the concept of this first generation of female condoms is unfamiliar to most people. Perceptions may change with time as people become more accustomed to the device.

#### SOURCES:

1. Bounds W, Guillebaud J, Newman GB. Female condom (Femidom). A clinical study of its use-effectiveness and patient acceptability. *Br J Fam Plann* 1992; 18:36-41.
2. Farr G, Gabelnick H, Sturgen K, et al. Contraceptive efficacy and acceptability of the female condom. *Am J Pub Health* 1994; 84:1960-64.
3. Feldblum P, Joanis C. *Modern Barrier Methods: Effective Contraception and Disease Prevention*. Durham: Family Health International, 1994.
4. The Female Health Company, Division of Wisconsin Pharmacal. *Reality Female Condom: An Alternative for Women*. Chicago: Wisconsin Pharmacal, 1994.
5. Ford N, Mathie E. The acceptability and experience of the female condom, Femidom among family planning clinic attenders. *Br J Fam Plann* 1993; 19:187-92.
6. Soper DC, Shoupe D, Shangold GA, et al. Prevention of vaginal trichomoniasis by compliant use of the female condom. *Sex Transm Dis* 1993; 20:137-39.
7. Trussell J, Sturgen K, Stricker J, et al. Comparative contraceptive efficacy of the female condom and other barrier methods. *Fam Plann Perspect* 1994; 26:66-72.

# FHI Quinacrine Studies

Family Health International will not proceed with new animal studies on the safety of quinacrine, a drug that has been used in nonsurgical female sterilizations. Lack of long-term funding for this project prompted the decision. It is estimated that the work could take eight years and \$8 million to complete.

Currently, FHI is involved in follow-up of two clinical studies, one in Chile funded by the U.S. Agency for International Development and the Mellon Foundation, and one in Vietnam financed by a grant from the Buffett Foundation. These studies of women who had previously undergone quinacrine sterilization will continue.

Quinacrine pellets, placed in the uterus with a modified IUD inserter, dissolve rapidly and result in the chemically-induced closure of the fallopian tubes. Quinacrine sterilization can be performed without anesthesia and by trained non-physicians in an outpatient setting, making it a potentially useful option in areas where medical facilities are scarce or for women who do not want surgery.

FHI, which has studied quinacrine since the 1970s, had planned to conduct new animal research on quinacrine's potential toxicity, including a lifetime carcinogenicity study in rodents. Previous FHI-sponsored toxicology studies were conducted more than 10 years ago, when government requirements in the United States for evaluating toxicity were significantly different. The decision to begin new toxicology studies was made in 1994 after an expert panel, organized by FHI, met to evaluate quinacrine research. Following that meeting, FHI sponsored short-term tests on genetic

toxicity, which confirmed that quinacrine can cause genetic damage in the in-vitro (test tube) systems used. FHI has forwarded these results to the World Health Organization and the U.S. Food and Drug Administration.

FHI will continue monitoring the health of 1,492 women in Chile who underwent quinacrine sterilizations from 1977 through 1989. This study was prompted by the observation of a small cancer cluster, which included a single case of uterine leiomyosarcoma, a relatively rare uterine cancer. Results from data up to 1991 found no evidence that quinacrine increased the risk of cancer among the women, but the study is too small to prove quinacrine's safety in this regard. These results were published in the August 1995 issue of *Fertility and Sterility*.

In Vietnam, FHI has begun a long-term follow-up study of more than 2,000 quinacrine users and a control group of about 1,500 women. The study was initiated at the request of the Vietnamese government, after the women had already received quinacrine sterilizations performed by Vietnam Ministry of Health providers. Quinacrine sterilizations were suspended in Vietnam in 1993 at WHO's suggestion, pending further toxicologic evaluation of quinacrine.

# Resources

## FHI WORKING PAPER ON INTEGRATED SERVICES

Family Health International's Women's Studies Project has published a working paper on integration of family planning and reproductive health services. *From Rhetoric to Reality: Delivering Reproductive Health Promises through Integrated Services* explores the benefits of integrated services and reviews lessons learned from past experiences with integration.

The 44-page paper was written by Dr. Karen Hardee, a principal research scientist at FHI, and by Kathryn M. Yount of Johns Hopkins University. To receive a free copy, contact Debbie Crumpler, publications coordinator, FHI, PO Box 13950, Research Triangle Park, NC 27709 USA, or telephone (919) 544-7040, or fax (919) 544-7261.



## REPORT ON CHANGING FAMILY STRUCTURE

The changing structure of families worldwide and the social and economic implications of these changes are described in *Families in Focus: New Perspectives on Mothers, Fathers, and Children*, a new report from the Population Council. The authors address the increase in number of households headed by women, the high global levels of marital dissolution, and the difficulties that children of single-parent households face. The book suggests new directions for research, programs and policies. The cost of the book to individuals and organizations in developed countries is U.S. \$12.50; for those in developing countries, there is no charge. Con-

tact Don Bucher, The Population Council, One Dag Hammerskjold Plaza, New York, NY 10017, USA, or call (212) 339-0514, or fax, (212) 755-6052.

## FAMILY PLANNING GUIDE FOR PROVIDERS

Information about contraceptive methods is available in JHPIEGO's *Pocket Guide for Family Planning Service Providers*.

The guide, intended for use by clinicians when they need immediate answers to questions about a client's condition or a contraceptive method, contains sections on providing services, specific contraceptive methods, and contraception for clients with special needs. The guide costs U.S. \$6 and can be obtained by contacting JHPIEGO Corp., Materials Management, 1615 Thames St., Baltimore, MD 21231-3447, USA, or by calling (410) 614-0585, or by faxing (410) 955-6199.

## BOOKLET FOR MOTHERS DISCUSSES BREASTFEEDING

An 88-page booklet, *Breastfeeding, the Best Option*, discusses breastfeeding in simple, straightforward language.

Aimed at mothers and organizations that promote breastfeeding, the booklet answers commonly asked questions about breastfeeding, including its advantages to mother and child, how to handle problems and special situations, and how



to manage supplements and weaning. Write: Survival for Women and Children Foundation, 636, Sector 16-D, Chandigarh-160 015, India, or call 91-172-770231, or fax, 91-172-704533.

## AIDS PREVENTION BOOKLET IN ASIAN LANGUAGES

A 16-page illustrated booklet on AIDS prevention is available from the BBC World Service in Chinese (Mandarin), Indonesian, Thai, Vietnamese and Burmese. A cassette recording of AIDS education messages broadcast on local

radio also is available in Chinese, Indonesian, Thai, Vietnamese and English. To obtain the booklet or cassette, contact Sue Martin, Publicity and Marketing Manager for Asia, BBC World Service, Bush House, PO Box 76, Strand, London WC2R 4PH, or call 44-171-257-2878, or fax, 44-171-240-1833.



## COUNSELING FAMILY PLANNING CLIENTS ABOUT STDs

Because of the cost and difficulty of treating sexually transmitted diseases (STDs), family planning programs should focus on counseling and other activities aimed at preventing infection, says a new report from Population Action International (PAI). The report, *Preventing AIDS and STDs: Priorities for Family Planning Programs*, is part of PAI's policy information series. The publication is free to people in the developing world and is available to others for U.S. \$3. Contact Carolyn Ross at Population Action International, 1120 19th St., NW, Suite 550, Washington, DC 20036, USA, telephone (202) 659-1833.